Site visit inspection report on compliance with HTA licensing standards
Inspection date: **27/28 February 2020**

Frimley Park Hospital

HTA licensing number 30014

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
Frimley Park Hospital	Licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Pathology laboratory	-	-	-
Maternity department	-	*Carried out*	-
A&E department	-	*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 Frimley Park Hospital (the 'establishment') had met the majority of the HTA's standards, eight major and five minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

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		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	There is no training for those seeking consent for adult hospital PM examinations.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	*Adult PM examinations:* Staff seeking consent do not have up-to-date training records. Staff are not required to undergo refresher training. *Perinatal/Paediatric PM examinations:* No records were provided to demonstrate staff have up-to-date training. No accessible records are held for staff to determine who is appropriately trained to seek consent.	
d) Competency is assessed and maintained	Staff competency in seeking consent for PM examination is not assessed. A review of historical adult PM examination consent forms by the inspection team revealed consent had not been obtained in line with the HT Act or the HTA's codes of practice.	

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 include sufficient details of procedures. • The SOPs for viewings and release of bodies from the mortuary do not include sufficient details of what identifiers could be used to identify the deceased and how identification checks should be performed. • The SOP 'disposal of clinical waste, human organs and tissues' use the term 'next of kin' to describe those determining the route of disposal of human tissue retained during the PM examination. This SOP does not reflect the requirements of the HT Act or HTA's codes of practice. • The SOP 'receipt and release of patients' does not detail the disposal options being offered by the establishment for pregnancy loss remains. • The policy for 'the storage of deceased below 0^{o}C' does not detail the procedure for initiating transfer of bodies to alternative establishments for long term storage. This SOP does not state the requirement to condition check bodies on a regular basis, whilst in storage, to ensure dignity is maintained. • Not all SOPs for mortuary activities reflect current local procedures; for example, the practice for identifying bodies with the same or similar name is not aligned with the SOP.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The deceased are stored for in excess of three weeks before transfer to another licensed establishment for coronial PM examination. The condition of bodies is not routinely checked after they have been received into the mortuary. The inspection team observed a number of bodies stored in shrouding that was contaminated with body fluids, leading to a deterioration in condition. The lack of condition checks disregards the dignity of the deceased and does not enable staff to identify bodies requiring movement into long-term storage	**Major**

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 insufficient supervision and training of staff involved in mortuary activities. Staff were observed to use routine equipment incorrectly; for example, using the hoist to remove bodies from storage without applying of brakes.	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	Staff competency has not been assessed, by a suitably trained person, for the mortuary tasks they perform.	
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	No corrective or preventative actions were identified or recorded as completed for mortuary incidents reviewed by the inspection team.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Refrigerated storage facilities were observed by the inspection team to be above the establishment's defined temperature range. No alarm triggered as expected.	**Major (cumulative)**
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 temperature alarm system did not function as expected during the site visit inspection when the temperature exceeded the upper temperature alarm trigger point. The last recorded manual challenge of the temperature alarm system was in 2017. Recorded incidents identifying the failure of the alarm systems to alert staff to temperature deviations outside of expected range have not been investigated or corrective actions completed. The temporary body storage unit was not alarmed.	
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	There are insufficient refrigerated storage facilities. Contingency storage arrangements and temporary body storage facilities are being used by the establishment on a regular basis.	**Major (cumulative)**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There are no useable long-term storage facilities available at the establishment. There are no long-term storage facilities and insufficient refrigerated storage facilities for bariatric bodies.	
f) Temperatures of fridges and freezers are monitored on a regular basis	Deviations of temperatures of fridges from expected ranges are not investigated by staff. Further corrective or preventative actions have not been identified and completed.	**Major**

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	The SOP for seeking consent for adult post-mortem (PM) examination does not define the frequency of refresher training or the requirement for competency assessment.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	Licensed activities in the maternity department, neonatal unit and accident and emergency (A&E) department are not included in the establishment's governance framework for the licence. There is no nominated Persons Designated to help oversee licensed activities in these departments. The DI does not have regular contact with staff undertaking licensed activities in these departments.	**Minor**

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	Mortuary staff and those undertaking licensed activities in the A&E and maternity departments are not aware of the HTA reportable incident (HTARI) categories or who they should contact in the event of an incident.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	PM examinations are not currently conducted at the establishment. However, there were issues identified with the cleanliness of the PM room. Hair and residual human tissue were found in the drains and grates of the PM room floor.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	Equipment used to remove bodies stored in scoops in the bases of fridges do not lower sufficiently to allow the safe removal of bodies from these storage positions.	**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.	GQ3(d)	The DI is advised to ensure all staff have annual appraisals and that systems are put in place to ensure these are completed if those with normal line management responsibility for staff are absent for extended periods of time.

2.	GQ3(e)	The establishment does not currently perform PM examinations and therefore staff have no experience of licensable activities. The DI is advised to utilise access to other establishments within the pathology network to allow trainee staff to gain experience in a wider range of activities.
3.	GQ6(b)	The DI is advised to review all risk assessments relating to licensable activities to ensure all control measures are stipulated and sufficient details of each required control measure are included; for example, the use of three identifiers for identifying a body does not stipulate what identifiers could be used.
4.	GQ6(c)	In light of the ongoing capacity issues - both at this establishment and those providing contingency storage arrangements - the DI is advised to review the current level of risk of lack of capacity for storage of the deceased
5.	PFE2(i)	The DI is advised to review the current contingency arrangements to assure themselves that sufficient storage for bodies at other establishments would be available if the plan needed to be activated.

Background

Frimley Park Hospital has been licensed by the HTA since January 2008. This was the fourth site visit inspection of the establishment; the last inspection took place in November 2015.

Since the previous inspection, Coronial PM examinations are no longer carried out at this establishment. No adult hospital PM examinations have been conducted since 2018.

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

64 out of the total 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards under T2 and standards GQ1(b), GQ2(c), T1(g) and PFE3(e) were not assessed as the standards were not applicable.

Review of governance documentation

The inspection team reviewed policies and procedural documents relating to licensed activities, cleaning records for the mortuary, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection team carried out a visual inspection of the body storage areas, PM room, viewing rooms and tissue storage area. No visual inspection of the maternity department or A&E department was conducted, as it was reported that no storage of relevant material takes place in these areas.

Audit of records

The inspection team performed traceability audits of five bodies in storage. Identification details were crosschecked between the identification band on the body, information on the wipe-board in the body store area and the mortuary register.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff in the A&E department responsible for Sudden Unexpected Deaths in Infants and Children (SUDIC) sample collection, porters who admit bodies into the mortuary, consent seekers for adult and perinatal PM examinations, bereavement team who organise and conduct viewings and the DI.

Report sent to DI for factual accuracy: 2 April 2020

Report returned from DI: 16 April 2020

Final report issued: 20 April 2020

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 site visit 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 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. 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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

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