Inspection report on compliance with HTA licensing standards
Inspection date: **26 and 30 November 2021**

Darent Valley Hospital

HTA licensing number 12226

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
Darent Valley Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	-	-
A&E	-	-	-

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 Darent Valley Hospital ('the establishment') had met the majority of the HTA's standards, one major and four minor shortfalls were found against standards for Consent, 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 shortfall

Standards	**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	*Perinatal PM examinations:* Consent training for clinicians who seek consent for PM examinations does not address the requirements of the HTA Act and HTA's Codes of Practice.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	*Perinatal PM examinations:* No consent training records were available 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 perinatal PM examination is not assessed.	

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	During the traceability audit of bodies in the fridges some minor inconsistencies were identified by the inspection team. These included spelling errors and different identifying information of the deceased detailed on the whiteboard and mortuary register. However, full traceability was maintained through other identifiers.	**Minor**
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	The procedure for viewing of the deceased does not include a check of a minimum of three points of identification with the family prior to entering the viewing room. However, the establishment ask for three identifiers from the family when they initially call to arrange the viewing. This information is used to check against the identification tags on the body when preparing the body for viewing. *Prior to the issue of the draft report the establishment provided evidence that this has been addressed.*	**Minor**
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	Relevant material is sent off-site for analysis. The establishment was unable to provide assurance that they receive confirmation once this has arrived at its intended destination.	**Minor**

Minor shortfalls

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	Some areas of the mortuary are showing minor signs of wear and require maintenance to ensure decontamination procedures are effective: • There is some peeling of the floor in the body store and PM room • The sealant in the PM room is peeling away from the wall	**Minor**

	• There is rust on the fridges and trays	

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(d)	The DI is advised to liaise with the referral centre providing the consent forms for perinatal PM examination as the forms do not adequately reflect the requirements of the HT Act. The form only gives the options for tissue taken at PM to be retained or returned at a later date and relies on consent seekers to provide other options such as disposal of the material. The consent form also refers to outdated HTA Codes of Practice.
2.	GQ2 (b)	The DI is advised to ensure that repetitive non-conformances are adequately investigated and to ensure that effective corrective actions are put in place.
3.	GQ4 (b)	The DI is advised to review how errors in written records are managed within the mortuary to ensure correction is in line with the record management SOP.
4.	PFE2 (c)	The DI is advised to record the condition checks of bodies. This should include the date of the check, the condition of the body and include sufficient detail of actions taken in relation to expediting release from the mortuary and/or actions taken to prevent deterioration to the body.
5.	PFE2 (e)	Whilst fridge alarm tests are undertaken, the DI is advised to implement regular unannounced fridge alarm tests for the mortuary to test that the out of hours call out procedures are working. This will provide robust challenge of procedures that are in place to respond to alarms, to ensure they work as expected in the event of a unit failure.

Background

The establishment has been licensed by the HTA since June 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in February 2017.

The establishment is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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 assessment 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 for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records

Audits were conducted for four bodies in refrigerated storage and one body in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. Discrepancies were found in three cases between information on fridge doors and paper records.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention and repatriation of these tissues.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists, portering staff, and a consent seeker for perinatal PM examinations.

Report sent to DI for factual accuracy: 29 December 2021

Report returned from DI: 14 January 2022

Final report issued: 04 February 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: 22 May 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.