Inspection report on compliance with HTA licensing standards
Inspection date: **18 September 2024**

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 Vally Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Darent Valley Hospital ('the establishment') had met the majority of the HTA's standards, five major and two minor shortfalls were found against standards for consent documentation, transfer of organs, 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
All applicable HTA standards have been assessed as fully met.

Major 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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	Whilst the establishment has a consent policy, it does not govern consent for post mortem examination, the retention of tissue, or reflect the requirements of the HT Act or HTA's Codes of Practice.	**Major (Cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	At the time of the inspection the standard operating procedure (SOP) for taking perinatal post mortem consent was in the process of being drafted and had not been approved or distributed to staff already undertaking the consent process.	
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	The post mortem room floor, whilst recently refurbished, requires maintenance. The inspection team noted: • Pooling of stagnant water. • Perished seals on the floor uprising to the wall and post mortem tables; and • Difficulty in accessing gullies for cleaning and flushing. This poses a risk to ineffective cleaning and decontamination of the post mortem room. *The establishment provided evidence that the post mortem room floor had received approval for another refurbishment, before the inspection team left the site.*	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team noted that an automatic closing mechanism to one external door failed, and the door was left insecure. This increases the risk of unauthorised access to the mortuary. *Establishment staff took immediate action to fix the mechanism before the inspection team left the site.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The mortuary has insufficient capacity for storage of bodies. Four temporary units are erected within the mortuary. The inspection team were informed that these had been in permanent use for over seven years, and two were not in use, awaiting repair. These units are showing major signs of wear, such as insecure door closure and failing to maintain suitable temperatures. This poses a risk to the dignity of the deceased, deterioration of bodies, and major mechanical breakdown.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	Although the main mortuary fridges are subject to regular cleaning, the age and subsequent deterioration to one bank of fridges means there is a risk that they cannot be maintained, cleaned, and decontaminated effectively. The inspection team noted exposed, splinted fridge interiors with debris of crumbling wood on the fridge floors. *The establishment provided evidence that these had received approval for refurbishment, before the inspection team left the site.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

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. *This was identified as a shortfall at the previous inspection. Whilst corrective actions were implemented of obtaining receipts for tissue transfers, this new process does not extend to obtaining receipts for transfer of organs.*	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Whilst the mortuary has demarcation of clean, dirty and transition areas, the inspection team noted that these were not being observed by mortuary staff when entering and exiting the post mortem room.	**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.	GQ1 (c)	Whilst recorded condition checks take place on a regular basis; the DI and mortuary manager are advised to consider adding prompts to the condition checking template. These may include checks on a weekly basis, and on release.

2.	T1 (b)	Recording of mortuary processes is currently paper based. The DI is advised to continue with plans to implement an electronic database to improve traceability and efficiency.
3.	PFE1 (c)	The DI and mortuary manager are advised to review and extend cleaning rotas to include all areas cleaned, such as the internal racking and the post mortem room.
4.	PFE2 (b)	The mortuary currently has two external units, which are not intended for use in their current condition. Whilst the HTA have been informed these are not part of the mortuary capacity, the DI is advised that these are turned off. Further, the DI is advised to have documented acknowledgement that staff are aware that these currently do not meet the HTA standards and should not be used.
5.	PFE2 (e)	Mortuary fridge alarm testing is currently conducted by a third party. The mortuary manager is advised to have oversight of the results of the monthly fridge temperature alarm tests.
6.	PFE3 (d)	The DI is advised to review the PPE available and the internal infection control policy as staff are currently performing regulated activities, such as transfer of bodies, in casual clothing.

Background

Darent Valley Hospital has been licensed by the HTA since 29 November 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2021.

Since the previous inspection, there has been a change to the corporate licence holder contact in September 2023.

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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection
The inspection included a visual assessment of the mortuary access points, mortuary fridge rooms, post mortem room, and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and two from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from three coronial cases, and a removed organ from one coronial case. As post mortem tissue is not stored at Darent Valley Hospital, the audit consisted of crosschecking tissue taken, and that recorded as transported to the laboratory at another licensed premises. No discrepancies were identified; however, no receipt was recorded for the arrival of the organ at the laboratory. *See shortfall T1 (h).*

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the Designated Individual, Mortuary Manager, Mortuary Porter, Pathologist, and Bereavement Midwife.

Feedback was provided on 10 October 2024 to the Designated Individual, Mortuary Manager, Divisional Manager, and Corporate Licence Holder Contact.

Report sent to DI for factual accuracy: 29 October 2024

Report returned from DI: 07 November 2024

Final report issued: 08 November 2024

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.