Inspection report on compliance with HTA licensing standards
Inspection date: **24-25 July 2024**

Grange University Hospital

HTA licensing number 12036

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 **Grange University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Satellite site **Nevill Hall Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Satellite site **Royal Gwent Hospital**	Licensed	Licensed	Licensed

Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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.

The targeted unannounced site visit of Grange University Hospital found one minor shortfall out of the 15 HTA postmortem standards assessed. This was regarding access to risk assessments.

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.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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 have suitable mitigations to reduce the risk of incidents. However, mortuary staff interviewed had not had oversight of the risk assessment documents and could not easily access them when requested. *The establishment took immediate action to address this shortfall before the final report was finalised.*	**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 (f)	The DI is advised to review the mortuary specific staff induction framework to ensure it includes the importance of traceability and identification checks within the mortuary.
2.	T1 (a)	The DI is advised to review, and monitor, the use of paper forms of identification. Paper or stickers used as identification tags poses the risk of writing becoming illegible. Bodies are currently accompanied by paperwork attached to the outer sheets. The DI is advised to review alternative methods, to mitigate against the risk of this paperwork being checked instead of identification bands.
3.	T1(b)	The DI is advised to review the different processes used across sites to record traceability, this will further mitigate the risk of transcription errors and improve efficiency.

Background

Grange University Hospital has been licensed by the HTA since October 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2022

Since the previous inspection, there has been a change to the Designated Individual and Corporate Licence Holder Contact.

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 08 April 2024. This followed two HTA reportable incidents within the classification '*Release of the Wrong body*' since the last regulatory assessment. Accordingly, this inspection focused on the following standards: GQ1 (a), GQ1 (c), GQ1 (e) GQ3 (a), GQ3 (b), GQ3 (c), GQ3 (f), GQ6 (a), T1 (a), T1 (b), T1 (c), T1(d), T1 (e), T1 (f), and PFE2 (a).

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:

Review of governance documentation

A review of staff training, competency assessments, Risk assessment and standard operating procedures was undertaken. A full review of the remaining governance documentation will be undertaken at the next routine inspection to be scheduled.

Visual inspection

The inspection team undertook a visual inspection of the body storage areas across all three sites. This included discussing and observing the process of checking three points of identification when transferring bodies to funeral services.

Audit of records

Audits were conducted for eleven bodies across all three licensed sites. Identification details were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified. Advice was given on site regarding the use of stickers and paper tags on the body identification labels. *See advice T1(a) and T1 (c).*

Body audits were completed for

Meetings with establishment staff

The inspection team met with staff carrying out processes on each licensed site. This included the Mortuary Lead, Anatomical Pathology Technologists, Care After Death Technicians, Quality lead, and Pathology lead. Feedback was discussed on 01 August 2024 with the Designated Individual, Deputy Divisional Director, General Manager, Mortuary Lead, and Care After Death Lead.

Report sent to DI for factual accuracy: 12 August 2024

Report returned from DI: 30 August 2024

Final report issued: 2 September 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.