Inspection report on compliance with HTA licensing standards
Inspection date: **5 and 6 May 2022**

Pathlinks (Grimsby)

HTA licensing number 12310

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 **Diana Princess of Wales Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Scunthorpe General Hospital**	Not Licensed	Licenced	Licensed
Mortuary	-	*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 Pathlinks (Grimsby) ('the establishment') had met the majority of the HTA's standards, four major and two minor shortfalls were found against standards for Governance and quality systems 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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	There is a procedure for the long term storage of bodies however, during the audit the inspection team observed that this had not been followed. One body had been in the care of the mortuary for over 30 days and was showing signs of decomposition. The body showed signs of decomposition on arrival and had not been placed into frozen storage. Records were unclear on what follow up measures had been taken.	**Major**
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	Flooring to the body store and PM room at the hub site is tiled with porous grouting which cannot be fully cleaned. Metal drainage pipes from the fridges are corroded and cannot be fully cleaned.	**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	There is insufficient capacity for the storage of bodies which means that there are 3 units in place over the two sites, only one of which is permanent, the other two are temporary	**Major**
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 temporary body storage units do not have remote temperature monitoring systems, they only have audible alarms. This is not sufficient to alert staff in the event that the storage temperature deviates from an acceptable range out of hours.	**Major**

Minor shortfalls

Standard	**Inspection findings**	**Level of shortfall**
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.	Lone working is commonplace, however there are no specific lone working procedures in place.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment did not supply records to show that the ventilation system provides the necessary ten air changes per hour.	**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 practices:

1.	PFE3(a)	Paint from one of the trolleys within the body store has begun to flake away, exposing metal which is likely to rust. The DI is advised to have the trolleys serviced to preserve their integrity.
2.	PFE1(e)	There is a door between the viewing room and body store facility at the satellite site that remains locked during viewings. Although families are always accompanied by mortuary staff, the lock has an unkeyed manual latch which could be opened inadvertently by families if left unsupervised. The DI is advised to risk assess this arrangement and strengthen security arrangements if necessary.

3.	GQ1(g)	The DI is advised to nominate HTA representatives (Persons Designated) in all areas that carry out licensable activity including the Accident & Emergency departments and Neonatal and Paediatric wards. The DI is advised to extend the invitation to the HTA governance meetings to these representatives.
4.	GQ1(g)	The establishment is part of a joint Pathology service with other neighbouring hospitals and there is some overarching governance relating to licensable activity. The DI may wish to consider meeting with the DI from the other HTA licence to strengthen this harmonised approach.

Background

Pathlinks (Grimsby) has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent inspection took place in July 2016.

Since the previous inspection, there has been some significant changes to the licence arrangements including the change of Designated Individual (DI) in March 2022.

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 in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs were also

reviewed.

Visual inspection
The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, the PM suite as well as the storage arrangements for relevant material held offsite in Lincoln under licence 12314.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included community and hospital cases. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified.

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 and the DI.

Report sent to DI for factual accuracy: 27 May 2022

Report returned from DI: 6 June 2022

Final report issued: 7 June 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: 3 April 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.