Virtual regulatory assessment (VRA) report on compliance with HTA licensing standards
Inspection date: **27-28 July 2021**

Luton and Dunstable University Hospital
HTA licensing number 12348

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
Luton and Dunstable University Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	-
A&E	-	*Carried out*	-

Summary of assessment 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 Luton and Dunstable University Hospital (the establishment) had met the majority of the HTA's standards, three major and three minor shortfalls were found against standards for Consent, Governance and Quality and Traceability. These related to consent training, governance documentation, staff competency assessments and viewing procedures.

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
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.	The establishment's consent policy for perinatal post mortem (PM) examination does not fully reflect the requirements of the HT Act 2004 and the HTA's codes of practice. This includes, but is not limited to, the following: • Detail of who should give consent to ensure appropriate consent is obtained. • The timeframe in which consent can be withdrawn and who should be contacted to ensure withdrawal wishes are complied with. • The policy states consent should be sought by someone trained in the consent seeking process. However, it does not provide detail of consent training or how a consent trained individual is identified prior to consent being taken. The establishment's consent policy for adult PM examination does not include detail of who should be contacted in the event that relatives wish to withdraw consent. This policy also references previous HTA codes of practice and requires review against the updated codes introduced in 2017.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process.	There are no documented SOPs which detail the process for seeking consent for paediatric, perinatal, and adult PM examinations.	

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.	Not all staff involved in the consent seeking process have received training which addresses the requirements of the HT Act and the HTA's codes of practice.	**Major (Cumulative)**
b) Records demonstrate up-to-date staff training.	The establishment does not have a process to identify which staff have received consent training and when refresher training is due.	
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.	The establishment's procedures do not make it clear that if untrained staff are involved in seeking consent for PM examination, they should be accompanied by a trained individual.	
d) Competency is assessed and maintained.	Competency in seeking consent has not been assessed and maintained.	

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 reflect current practice and do not include sufficient detail of procedures relating to traceability of bodies, tissue, and organs. In some instances, SOPs have been duplicated and contain conflicting information. These include but are not limited to: • Release of bodies SOP 'MP-MOR-Discharge' does not include sufficient detail of checks of three points of identification of the deceased against information brought by funeral directors. It is a duplicate of SOP of 'MOWI 0013.1 routine release of the deceased' which also does not include sufficient detail. • SOP 'MOWI 0014.2 30+ Day check instructions' suggests condition checking of bodies is only initiated following 30 days in storage. However, 'MOWI 0014.2 Monitoring length of stay of bodies in the mortuary' suggests condition checking of bodies is instigated earlier than 30 days but provides no detail of how condition checking is completed and recorded. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient details of procedures.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOP's are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.	Some SOPs have been written and authorised by the same person or have not been regularly reviewed.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform.	Portering staff and out-of-hours general managers involved in licensed activities have no on-going competency assessments following initial training and sign-off. Competency assessments for staff working in the mortuary are not up to date.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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 final check using a minimum of three points of identification of the deceased prior to visitors entering the viewing 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.	C1(c)	The DI is advised to review the information leaflet provided to families during the seeking of consent for adult PM. The leaflet uses the wording ‘Next of Kin’ which is not a recognised term for those giving consent under the HT Act and should instead refer to the ‘appropriate person’.
2.	GQ2(a)	The DI is advised to ensure audits that were postponed during the pandemic response are completed as rescheduled.
3.	GQ6(a)	The DI is advised to include detail in risk assessments of the requirement to report incidents to the HTA, where this is applicable.

4.	T2(b)	The DI is advised to liaise with the Coroner to improve the process for receipt of family wishes forms regarding the fate of tissue retained at PM. A model communication pathway can be found in Annex A of Code of Practice B – Post-Mortem Examination.
5.	PFE3(f)	The DI is advised to ensure the newly installed body storage fridges and freezers are included in the routine maintenance schedule once warranties expire.

Background

Luton and Dunstable University Hospital has been licensed by the HTA since July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2016.

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 establishments self-assessment document provided by the DI in advance of the VRA. Policies and procedural documents relating to licensed activities for the mortuary and post-mortem room were reviewed. Ventilation reports, traceability audits, risk assessments, meeting minutes, incidents and consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

There was no site visit inspection as part of this assessment.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, a pathologist who conducts PM examinations, a portering staff member, staff involved in the consent seeking process, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 13 August 2021

Report returned from DI: 13 August 2021

Final report issued: 07 September 2021

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: 12 March 2022

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.