

Site visit inspection report on compliance with HTA minimum standards

Pathology, St Helier Hospital

HTA licensing number 12345

Licensed under the Human Tissue Act 2004 for the

- **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; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

16 August 2012

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

A non-routine inspection of St Helier Hospital (the establishment) was carried out following a serious untoward incident relating to a failure in refrigerated storage. The inspection team found that the establishment continued to be compliant with HTA standards around body storage, maintenance and temperature monitoring since their last inspection. Satisfactory action had already been taken by the DI to prevent a reoccurrence of the incident and additional actions, beyond what is required by HTA minimum standards, were being considered to further mitigate risks.

Although the HTA found that the establishment had met the majority of the HTA standards, shortfalls were found in relation to governance and quality systems and premises, facilities and equipment standards. Three minor shortfalls against HTA standards for premises have combined to make a major shortfall, where the facilities and equipment show signs of wear and there is the potential for effective cleaning and decontamination to be compromised.

Minor shortfalls were also identified in relation to aspects of the establishment's standard operating procedures (SOPs) and processes used for identification/tracking.

Since the last inspection, a condition on the licence relating to consent training has been met in full and the majority of advice given by the HTA has been implemented. The only exception to this was the extension of the use of the unique mortuary number to ensure robust identification procedures.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Paragraph 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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

St Helier Hospital carries out approximately 320 Coroner's post-mortem (PM) examinations each year; no hospital consented PM examinations have been carried out this year and only one was undertaken in 2011. Paediatric and perinatal cases are transferred for PM examination to other HTA-licensed establishments.

Tissue samples are transferred to another HTA licensed facility for processing and analysis, usually by the pathologist conducting the PM examination who is based there, or a contracted courier. This is not the case for tissue from hospital consented PM examinations, which is

processed and stored on site. Tissue blocks and slides or wet tissue samples (including whole organs) are only received back following examination if the bereaved have requested them to be repatriated with the deceased or returned to the family. Fluid samples taken at PM examination are usually sent offsite for analysis and any residual sample is disposed of appropriately.

This was the second inspection of the establishment; the first routine inspection having been undertaken in 2009. The inspection was organised at short notice in response to a serious untoward incident (SUI) involving failure of a refrigerated body store unit. The aim of the inspection was primarily to seek assurance that HTA standards on premises, facilities and equipment were being met. However, as a routine inspection was scheduled to take place before the end of this year, the HTA assessed compliance with all HTA standards.

The inspection comprised a visual inspection of the mortuary and body store, interviews with members of staff and review of relevant documentation. Audit trails were conducted using the mortuary register and other paper records of three deceased persons received into the mortuary and located in the body store. The records of tissue samples collected at PM examination and subsequently taken off site for analysis and, in one case, returned for repatriation with the body, were reviewed. The computer system shared with the laboratory processing the samples was checked; however the corresponding record did not indicate the number of slides made. No anomalies were found apart from the absence of a sticker indicating a deceased person with the same or similar name (more detail is provided under Advice against GQ3). However, the establishment staff routinely identify deceased using only a single identifier, which the HTA does not consider adequate (see shortfall against standard GQ6 below).

Through discussions with the DI, the inspection team learnt that small tissue samples are being removed within the Accident and Emergency or Maternity Department under the authority of the Coroner. The HTA informed the DI that the current licence needs to be extended to take in this area of the premises and this change has since been made to the licence.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	<p>The establishment's SOPs cover the majority of licensable activities; however, there are some cases where practice has changed in the past 12-18 months and SOPs have not been updated accordingly. An example is a change in the hospital to which samples from adult PM examinations are taken for analysis.</p> <p>In addition, one pathologist routinely carries out coroners PM examinations at the establishment. When he is on leave and a locum stands in, tissue samples may be taken to another hospital for analysis. This variability in practice is not reflected in SOPs.</p>	Minor
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	<p>Each body admitted to the mortuary is assigned a unique identification number. This number is recorded in the mortuary register, but is not recorded onto the deceased's identification tags or notice of death. Identification procedures are based on a check of the name of the deceased and other details where available, but do not make use of the unique number. There is a risk that identifying the deceased on name alone could lead to an error, particularly if there is a deceased with the same or a similar name in the mortuary (see advice against GQ6 below).</p> <p>Where tissue samples are returned to the mortuary after histological examination for repatriation with the deceased or return to the family, their receipt is recorded. However, the number of blocks and slides is not recorded nor correlated with histology records to ensure that all blocks and slides have been returned.</p>	Minor Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	Three minor shortfalls relating to equipment and facilities combine to make a major shortfall against this standard.	Major

	<p>The floor of the post-mortem room is comprised of large floor tiles, many of which are cracked or showing signs of wear and discolouration in areas where water tends to pool. These factors may inhibit effective cleaning and decontamination of the floor.</p> <p>In addition to the three fixed PM examination tables, a further six trolleys are routinely stored in the post-mortem room, despite a routine workload of three or four PM examinations a day and a maximum of six. The HTA observed that at least two of the trolleys showed signs of wear, which may present an infection risk.</p> <p>Unassembled temporary body storage racking, which provides extra storage in the event that the body store reaches capacity, is stored in one corner of the post-mortem room. The storage of non-essential items in the post-mortem room restricts the movement of staff around the mortuary and compromises their ability to clean and decontaminate the area affectively after each session.</p> <p>Minor shortfall</p> <p>A risk assessment of the premises has not been carried out.</p> <p>Minor shortfall</p> <p>Establishment staff frequently use wooden measuring sticks to measure the deceased. Since wood is porous and these instruments may come into contact with body fluids, there is a risk that they will not be effectively decontaminated.</p> <p>Minor shortfall</p>	
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Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C1	The establishment is awaiting the new SANDs consent form to replace its outdated forms. The NHS form currently used to obtain consent for paediatric hospital PM examinations states that blocks and slides will be routinely stored as part of the medical record. The DI is advised to ensure that the new SANDs consent form and information booklet are implemented as soon as they are available.

2.	GQ1	The DI is advised to ensure that changes in practices in response to the recent serious untoward incident are reflected in the relevant SOPs and other documents as soon as practicable.
3.	GQ3	The establishment has implemented a short-term change in practice for out of hours viewings, whereby the hospital Chaplain supervises the viewing and ensures appropriate checks are made on the identity, as well as the dignity and integrity of the deceased. Longer term, the DI is advised to identify a small group of competent staff that will take responsibility for out of hours viewings and restrict access to the mortuary to competent staff only. Consideration should also be given to nominating one of these staff as a Person Designated under the Human Tissue Act, who would report any issues encountered out of hours to the DI.
4.	GQ6	<p>The establishment has a system for identifying same or similar names whereby they are highlighted in the mortuary register and a sticker is placed on the shrouds of the deceased to alert staff; however in the case selected by the HTA as part of the audit, the shroud and notice of death form of a deceased with the same surname as another deceased in the mortuary, did not contain a sticker.</p> <p>The DI is advised to ensure that staff adhere to the procedures set out, which help prevent misidentification of the deceased.</p>
5.	PFE3	The DI is advised to incorporate into the relevant SOP, and add signs in the body storage area, the normal working range of temperatures for the fridge and freezer units. The signs should also indicate the action to be taken and contact details of relevant staff if alarms are sounding, or the temperature is found to be out of range.
6.	PFE3	One of the fridge door locks does not operate properly. The establishment staff have contacted the maintenance company, who will be attending to replace the lock as it has a known manufacturing fault, and a sign has been attached to the fridge to indicate to porters that it is currently out of use. The DI is advised to check regularly all other similar locks so that they can be fixed promptly if necessary.
7.	D1	The DI is advised to review 'SOP27 Samples retained at autopsy' and add the action to take with respect to tissue samples removed at PM examination if the wishes of the bereaved are not known. In the absence of appropriate consent from the person ranked highest in the list of qualifying relationships to store the tissue for a scheduled purpose, the tissue samples must be sensitively disposed of in accordance with the HTA code of practice on disposal (paragraphs 31-56).
8.	Licence	During the inspection, the HTA found that in cases of sudden infant death, a number of samples may be removed from the baby's body whilst it is still within the accident and emergency department. Since the current HTA licence refers solely to the Pathology Department as the licensed premises, the DI was advised to contact the HTA to request a variation to the licence so that it encompasses the whole hospital site. The DI is further advised to identify a Person Designated to oversee the licensed activities carried out in this department.
9.	-	The DI and his colleagues are advised to read the HTA e-newsletter on a regular basis to ensure they maintain an up to date knowledge of issues affecting establishments in the PM sector and review their own processes where appropriate.

Concluding comments

On completion of a non-routine inspection of St Helier Hospital the inspection team found that the establishment was compliant with HTA standards around body storage, maintenance and temperature monitoring. The Designated Individual had already taken action to prevent a reoccurrence of the recent SUI and proposed several actions for improving practices further. These include the installation of alarm systems which connect to switchboard for the remaining two fridges (currently not in use) without this facility and carrying out a validation test on each of the refrigerators to determine how long it will remain within an acceptable temperature range if it stopped working. These actions will be followed up as part of the ongoing SUI investigation.

During the inspection a number of areas of good practice were identified. The DI has introduced training on the HTA and obtaining consent for post-mortem examination as part of the mandatory training programme for all consultants and registrars (year one). Apart from raising awareness about the HTA and the requirements of the Human Tissue Act 2004, this informs staff of the internal process for obtaining consent for a hospital PM examination, including the need for a discussion between the requesting clinician and the pathologist before approaching the family of the bereaved, to ensure that they are as informed as possible.

Staff in the maternity department have a paediatric bereavement checklist which is signed off at each stage and ensures that all steps of the process following death, including completion of forms and obtaining post-mortem samples (where necessary), are duly completed.

The histology department and mortuary are accredited by Clinical Pathology Accreditation (CPA), whose previous inspection raised a number of actions which were promptly addressed, well before their deadline. The same prompt action is taken in response to internal audits. Both the non-compliance and the corrective actions taken have been well documented in the audit reports.

There are a number of areas of practice that require improvement, including one major shortfall and three minor shortfalls. The HTA has given advice to the Designated Individual with respect to changes required to the licence, amendments to SOPs and further improvements to practices.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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.

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.

Report sent to DI for factual accuracy: 06/09/12

Report returned from DI: 18/09/12

Final report issued: 25/09/12

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: 05 December 2012

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
<ul style="list-style-type: none">• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.• There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination).• There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is made clear who should be contacted in this event.• Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use).• Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained.• Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
<ul style="list-style-type: none">• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent.• Refresher training is available (e.g. annually).• Attendance at consent training is documented.• If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
 - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
 - record keeping
 - receipt and release of bodies, which reflect out of hours arrangements
 - lone working in the mortuary
 - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
 - ensuring that tissue is handled in line with documented wishes of the relatives
 - disposal of tissue (including blocks and slides)

(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

<ul style="list-style-type: none"> • There is a documented training programme for new mortuary staff (e.g. competency checklist).
GQ4 There is a systematic and planned approach to the management of records
<ul style="list-style-type: none"> • There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record. • There are documented SOPs for record management.
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail
<ul style="list-style-type: none"> • Bodies are tagged/labelled upon arrival at the mortuary. • There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records). • Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded: <ul style="list-style-type: none"> ○ material sent for analysis on or off-site, including confirmation of arrival ○ receipt upon return to the laboratory or mortuary ○ number of blocks and slides made ○ repatriation with a body ○ return for burial or cremation ○ disposal or retention for future use. • Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly
<ul style="list-style-type: none"> • Staff are trained in how to use the incident reporting system. • Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA • The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents. • The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed. • Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
<ul style="list-style-type: none"> • All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed. • Risk assessments include risks associated with non-compliance with HTA standards as well as

health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
 - There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).
- (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)*

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
 - fridges / Freezers
 - hydraulic trolleys
 - post mortem tables
 - hoists
 - saws (manual and/or oscillating)
 - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
 - Disposal records include the date, method and reason for disposal.
 - Tissue is disposed of in a timely fashion.
- (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)*

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 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 Human Tissue Act 2004 (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:

- (1) A notice of proposal being issued to revoke the licence
- (2) 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.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) 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 CoPs, 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 or 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. You 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 desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.