HTA
Human Tissue Authority

Regulation of the Post Mortem sector 2017/2018

Shared learning

About the HTA

The Human Tissue Authority (HTA) regulates and licenses establishments in England, Wales, and Northern Ireland where post-mortem (PM) examinations take place and tissue may be removed and stored for a number of scheduled purposes as set out in the Human Tissue Act 2004.

We publish Codes of Practice and inspect against licensing Standards. Our remit also includes providing advice and guidance to licensed establishments, to help them comply with the relevant regulatory requirements so that the public can have confidence that the bodies of deceased people are treated with dignity and respect.

We would like to thank all of the establishments who submitted data that has contributed to this report.

Overview of the PM sector

The HTA licences 246 establishments in the PM sector, this number is made up of 180 main sites and 66 satellites sites.

Of these 195 are licensed for undertaking PM examinations, 216 are licensed for removal of tissue from the deceased and 9 establishments are licensed for storage only.

Three establishments have removal only licences, mainly to cover removal in cases of sudden unexpected death in infancy and children (SUDIC) in emergency departments or in paediatric units.

In this document

The HTA assesses risk in the sector in a number of ways, including information from the submission of compliance data by establishments every two years, information from HTA Reportable Incidents (HTARIs) as and when they occur, and findings from inspection.

We regularly review this data to identify key findings so that lessons learned can be shared more widely across the sector.

This is the fourth shared learning document we have produced. Our aim is to give an overview of the sector and appropriate advice to enable establishments to address the risks identified.

Executive Summary

Analysis of the data we have collected has identified key themes and areas for improvement that the HTA will use to inform the sector through additional advice and guidance, some of which has been included in this document.

Data from compliance information indicates that bodies are being retained in mortuaries for longer, impacting on refrigerated storage, long-term body storage, and contingency capacity, which establishments have also highlighted as concerns on inspection.

The number and severity of shortfalls identified during site visit inspections has notably increased and appears to be only partly attributable to the revision of Standards that was introduced in April 2017, with the increase in number of shortfalls being most stark for certain specific standards. The details of and possible reasons for this are discussed further in this document.

Two issues that remain predominant among reported HTARIs include accidental damage to bodies and mistaken identification of bodies (resulting in release, viewing or PM examination of the wrong body).

Accidental damage to bodies most commonly occurred during transfer into refrigerated storage, whereas bodies having same and/or similar names was a key factor in mistaken identification. Whilst these are not new issues, and were addressed in the revised standards and related guidance introduced in April 2017, this review gives additional insight into those that occur most commonly to help establishments recognise and address key risk factors.

Part 1 - HTA Compliance submissions

1. Every two years establishments licensed by the HTA in certain sectors are required to submit compliance data. Collection of this information contributes to our oversight of a sector, guides our regulatory approach, informs the scheduling of site visit inspections and supports our system of continuous licensing.

2. The most recent compliance update survey was undertaken in autumn 2017. In the PM sector, this was less detailed than in previous years because an additional in-depth survey of storage and capacity had taken place at the end of 2016.

3. Questions in the 2017 assessment covered six broad areas:
    - Activity
    - Storage
    - Governance
    - Staffing
    - Risk
    - Premises

4. All 180 licensed establishments in the PM sector responded to the 2017 questionnaire. This included nine establishments licensed for storage only who do not undertake post-mortem examinations.

Establishment Activity

5. Data collected in the latest compliance update assessment was for the year to 30 June 2017.

6. Over this period, establishments received 334,314 bodies and performed 92,926 invasive PM examinations. Whilst the HTA does not licence non-invasive post-mortem cross-sectional imaging (PMCSI), 36 establishments reported that they had seen an increased demand for this activity.

7. 49% of establishments stated that there had been an increase in the average length of time bodies were in their care. The most common causes given were:
    - delay in collection by funeral director;
    - delay in getting information from the Coroner; and,
    - delay in death registration over holiday periods.

(Note - some establishments' selected more than one reason from the options given. See Figure 1)

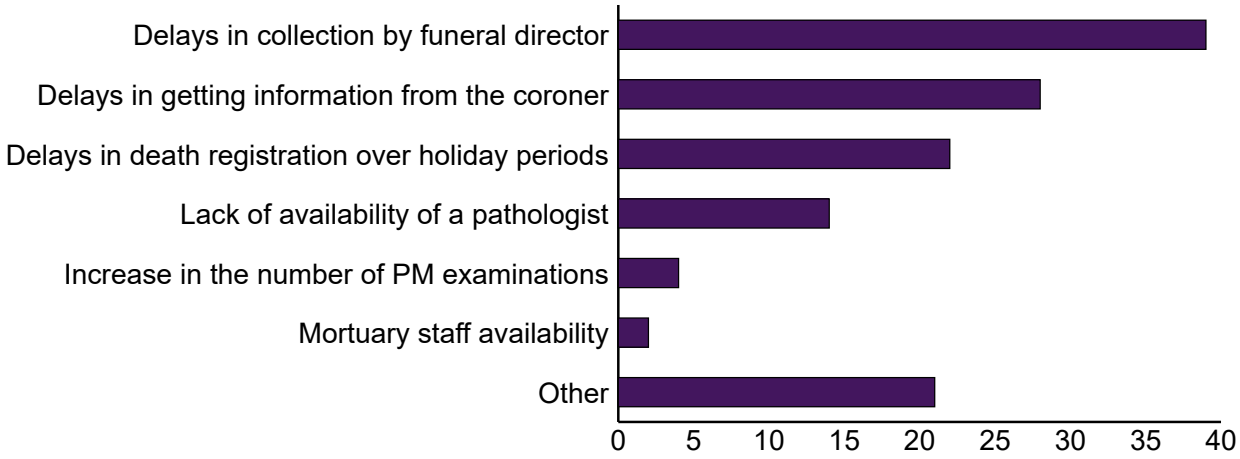

Figure 1: Reasons given by establishments for the increase in the time bodies were stored in the mortuary.

Storage and contingency storage

8. 56% of establishments confirmed that they had sufficient refrigerated storage capacity, with a further 37% stating that capacity was sufficient most of the time; however, 7% of establishments reported that capacity was insufficient.

9. 31% of establishments stated that they did not have sufficient freezer capacity. On inspection, we have also frequently observed a lack of bariatric freezer storage capacity.

10. 14% of establishments reported routinely using temporary storage options as part of their regular storage.

11. The HTA has provided advice on the website for establishments in relation to capacity and contingency storage.

Governance

12. Nine mortuaries (5%) stated that they did not have a schedule of audits; 25% of establishments stated that they were not up-to-date with their audit schedule, with shortage of staff being the main reason given. HTA Inspection findings, documented later in this report, also identified issues with audits.

13. 51% of establishments stated that removal of tissue from the deceased happens in areas other than the mortuary, most commonly in the Emergency Department (ED), with 26% of these establishments not having a Person Designated (PD) in these areas.

14. Just over a third of establishments (34%) stated that they were currently storing tissue for police purposes.

Advice

The HTA advises having PDs in all areas where licensable activity takes place to help ensure the DI has effective oversight in those areas

Staffing

15. As in the previous report, 7% of establishments reported that staffing levels were insufficient for the level of activity undertaken, with 16% of establishments having Anatomical Pathology Technologist (APT) vacancies at the time of submission.

16. The HTA recognises the importance of establishments having sufficient staff with relevant technical skills, knowledge and experience to ensure appropriate understanding and application of the requirements of the HT Act.

Risk

17. 98% of establishments were aware of the HTA publication 'Regulation of the Post Mortem Sector 2014-16: What we have learned?' with only three establishments being unaware. This document included a section advising on risk management that had resulted in 74% of establishments updating their risk assessments.

Premises

18. At the time the data was submitted, 54% of establishments had applied for capital funding in the previous two years, of which 75% were approved, 18% were awaiting a response and 7% were refused.

Part 2 - Revised licensing standards

19. The HTA's revised Codes of Practice and licensing Standards for sectors regulated under the Human Tissue Act 2004 (HT Act) came into force on 3 April 2017.

20. The revised standards are grouped under four headings:
    - Consent (C);
    - Governance and Quality systems (GQ);
    - Traceability (T); and
    - Premises, Facilities and Equipment (PFE).

21. The licensing standards for the PM sector consist of thirteen overarching statements, each of which is then broken down into a number of individual separate standards.

22. This new approach has led to an increase in discrete standards for this sector from 17 to 72, some with examples of what compliance looks like. The aim was to make the standards clearer, easier for establishments to demonstrate compliance, and also to enhance the HTA's ability to make use of compliance information in judging risk.

23. The revised standards were also aligned with professional guidance.

24. Some of the revised standards were set at a higher level than previously, in order to mitigate risks identified from our experience of regulating the sector through inspection and management of incidents.

25. The HTA's criteria for classification of the severity of shortfalls remains unchanged.

Part 2.1 - Inspection findings

26. The analysis of inspection findings under the revised standards is based on the 59 site visit inspections in the PM sector in the year to 31 March 2018. Each of these inspections were undertaken at different establishments. Of these 59 establishments, four were not licensed for PM examination, including one which was licensed for storage of relevant material only.

27. Inspection findings from the 99 routine site visit inspections undertaken in this sector from 1 April 2015 to 31 March 2017 were used as a reference dataset. Of those inspections, five establishments were not licensed for PM examination including three which were licensed for storage of relevant material only.

Shortfalls

28. In the 59 routine inspections in the year to 31 March 2018, a total of 510 shortfalls were identified.

29. In the 12 months to 31st March 2017 (the period immediately before the new standards came into force), shortfalls were identified at 75% of inspected establishments. The vast majority (90%) of these shortfalls were minor, with 10% of shortfalls being major. No critical shortfalls were identified during this period.

30. The number and severity of shortfalls identified in the sector in the year to 31st March 2018 has increased compared to the previous 12-month period.

31. The increase in the number of shortfalls identified since April 2017 may in part be due to how the standards are now structured, with a significant increase in the number of individual standards that have to be met, resulting in findings previously reported against one higher-level standard now being reported against several lower-level standards.

32. Similarly, the higher number of standards may also account for some of the increase in the number of shortfalls.

33. In the year to 31 March 2018, 69% of shortfalls were classified as minor, 29% were categorised as major and 2% being categorised as critical. Major shortfalls were identified in 66% of inspections in the PM sector (39 of 59 establishments). Critical shortfalls were identified at five establishments, representing 9% of establishments inspected in the sector.

34. As noted above, a number of shortfalls against standards were identified repeatedly at establishments across the sector. These will be discussed, and advice given, later in this document.

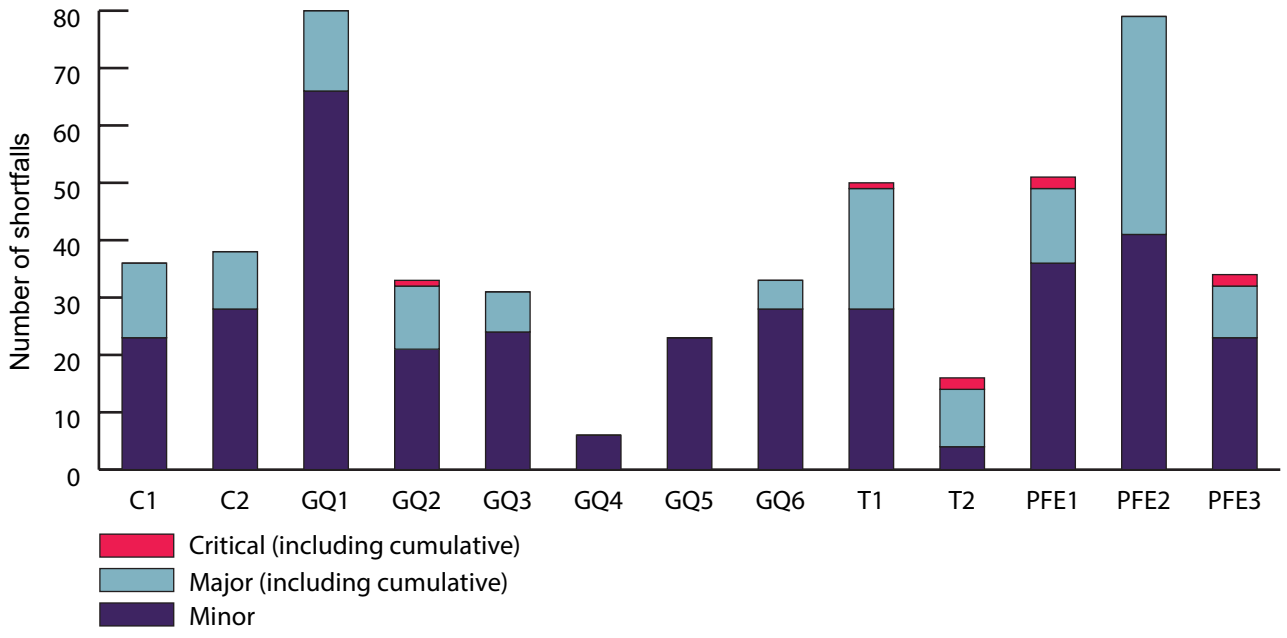

Figure 2: Shortfalls identified against each overarching standard, y/e 31 March 2018

Part 3 - HTA Reportable Incidents (HTARIs) 2017-2018

35. The HTA received 226 incident notifications in the year to 31 March 2018. Following the review of each incident by the HTA, 12 of these were categorised as near misses and 72 did not meet the definition of a HTARI, either because they did not fall within one of the reportable incident categories or because they were not of sufficient severity to warrant consideration by the HTA.

36. An example of an incident reported to the HTA as a reportable incident, but not classified as such by the HTA, is accidental damage to a body that happened as part of the care after death procedure on the ward. Whilst serious and warranting internal investigation, the matter falls outside the scope of HTA's regulatory oversight.

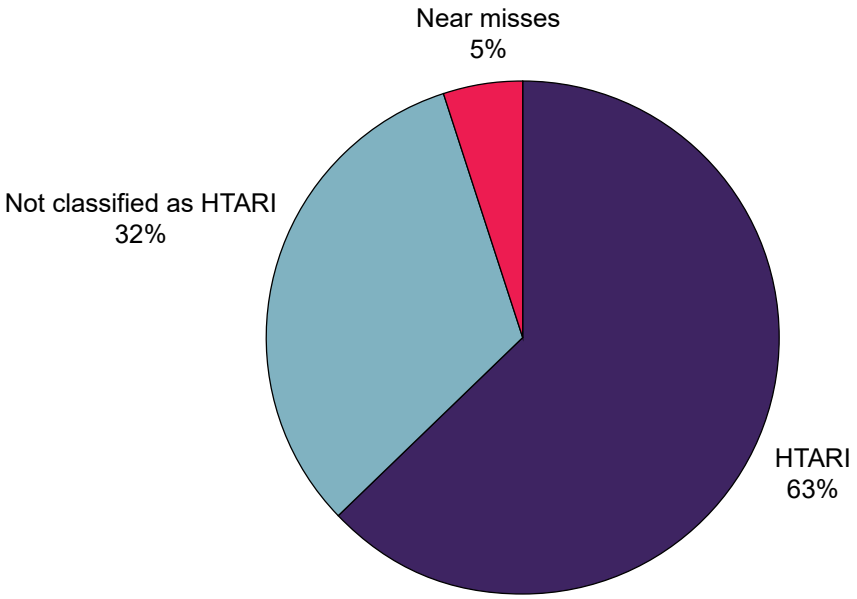

Figure 3: Breakdown of categorisation of incidents reported to the HTA in the year to 31 March 2018, following HTA review

37. Accidental damage and mistakes in identification of bodies (release, viewing or PM on the wrong body) are the two categories with the highest number of incidents reported in the year to 31 March 2018.

38. Nearly a third of all incidents reported to the HTA were not classed as reportable incidents for HTA purposes.

Advice

Before reporting an incident to the HTA, please refer to the guidance on our website to help assess whether an incident is a HTARI. If further advice is required, please contact the HTA on 020 7269 1900 or email enquiries@hta.gov.uk

HTARIs reported by category

HTARI classification	2017/18 total	2016/17 total
Accidental damage to a body	49	35
Discovery of an additional organ(s) in a body on evisceration for a second PM examination, or during the repatriation or embalming process	0	0
Disposal of retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	1	1
Disposal of retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	3	3
Disposal or retention of an organ against the express wishes of the family	2	1
Discovery of an organ or tissue following PM examination and release of a body	6	5
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	0	1
Loss of an organ	4	3
Major equipment failure	10	4
PM examination conducted was not in line with the consent given or the PM examination proceeded with inadequate consent	2	2
PM examination of the wrong body	3	3
Release of the wrong body	11	13
Removal of tissue from a body without authorisation or consent	2	3
Serious security breach	10	3
Viewing of the wrong body	9	9
PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given	0	0
Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	30	24
Total	142	110

Accidental Damage

39. Whilst the 'Any other incident category' captures a range of incidents, accidental damage represents the largest single identifiable share of incidents (49 out of 142, nearly 35%). These incidents occurred when bodies were being moved, for example, transferred into or out of refrigerated storage and during PM examination.

Advice

Establishments should ensure that only staff who are trained and signed-off as competent in the transfer and movement of bodies, including in and out of the body store, undertake this activity. The training should also include information on how to recognise bodies that may not fit easily into standard fridge spaces, such as patients who have unusual body morphology.

40. The next substantial category of HTARIs received in the year to 31 March 2018 is the 'Any incident' category, which accounted for 30 out of 142 (21%) of all reported incidents. A review of these incidents did not identify any recurring themes. The HTA continue to keep incidents reports in this category under review.

Errors in identification of bodies

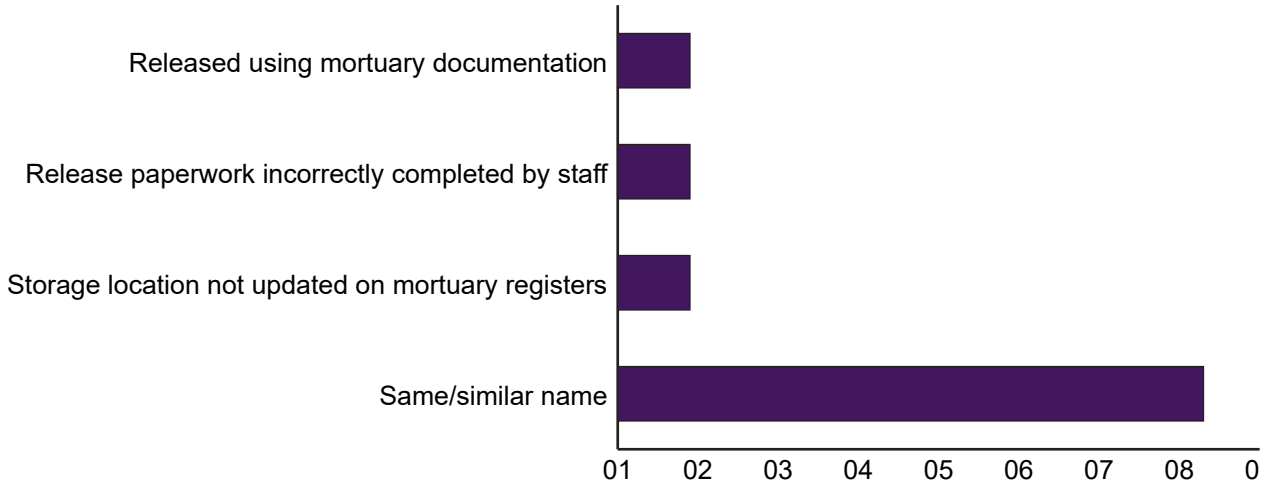

Figure 4: Factors contributing to the release of a wrong body

41. Almost three quarters of incidents in which the wrong body was released to funeral directors involved bodies with the same and/or similar names. This reinforces the importance of having an effective system for dealing with bodies having the same and/or similar names and the value of using three identifiers, one being unique, for each body.

Advice

Establishments should check both forenames and surnames (and similar sounding as well as spelling of names) when identifying whether they have bodies with same and/or similar names.

Establishments should have a consistent approach to recording names (including on temporary records, such as white boards or fridge doors), for example, being consistent about the sequence of names (forename, surname or surname, forename) and this should be clearly visible to anyone completing or using this information. This mitigates the risk of confusion where a forename could also be a surname, for example Martin Thomas and Thomas Martin.

Part 4 – Themes

An analysis of shortfalls and HTARIs in the PM sector for the year to 31 March 2018 has highlighted some key themes.

As noted previously, there are four overarching standards against which establishments are assessed at inspection: Consent, Governance and Quality systems, Traceability, and Premises, Facilities and Equipment. All of these have been linked to incidents.

Consent (C)

The consent standards relate to the process, documentation and training for those staff seeking consent for PM examination. 74 shortfalls were identified out of 59 inspections.

Key Findings:

- References to next of kin (NOK) as well as the hierarchy of qualifying relationships, which could lead to confusion about who is the appropriate person to give consent under the HT Act;
- a lack of documented Standard Operating Procedures (SOPs) for the process and/or staff awareness of the SOP;
- options for the fate of blocks and slides not clearly defined;
- lack of training and refresher training on the requirements of the HT Act;
- staff records not demonstrating up-to-date training; and,
- lack of competency assessments for consent seekers.

Advice

Given this analysis, the HTA has the following good practice advice for establishments:

Mortuaries/histopathology departments should be clear about exactly what services they can offer. For example, if there is no research activity undertaken, this should not be listed as an option for retained organs/tissue.

Those giving consent should be made aware of how long any tissue will be stored and what is expected to be the fate of tissue in differing circumstances, for example:

if it is not used for a scheduled purpose for which they have given consent, it will be disposed of after a specified time period;

after it has been used for the intended purpose; and,

if it has been stored, what will happen to it after the end of the expected storage period.

Different options for the use of tissue should not be combined as a single choice, for example, use in research and storage for future use should be listed separately to give relatives the opportunity to make individual choices.

PM consent training and competency assessments for consent seekers can take place face-to-face, using written material or online, providing it meets the requirements of the HT Act. An individual with understanding of what is involved in a PM examination and the options concerning the fate of any tissue should be present when consent for PM examination is sought.

Governance & Quality (GQ)

The Governance and Quality standards cover a number of key areas concerning the effective management of a licence and the activities covered by the licence. 206 shortfalls were identified in this category out of 59 inspections. These were predominantly under:

GQ1 – 'All aspects of the establishment's work are governed by documented policies/SOPs';

GQ2 - 'There is a documented system of audit';

GQ6 - 'Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored'.

Key findings – GQ1:

- SOPs did not accurately reflect actual practice;
- SOPs had insufficient detail to ensure that all essential steps in the process would be undertaken;
- a lack of methodology to record that staff had read and understood SOPs;
- SOPs on PM examinations not being clear that a pathologist must see the body before evisceration;
- a lack of DI oversight in areas where licensable activity takes place; and,
- no minuted meetings of staff working under the licence.

Based on these findings, the HTA's advice for good practice are given below:

A SOP should contain sufficient detail to enable a suitably competent person new to the establishment to undertake the task.

Persons Designated (PDs) play an important role overseeing activities in areas where the DI does not have regular involvement, such as in maternity units or ED.

All areas outside the mortuary where licensable activity takes place should have a PD, as should any premises remote from the hub site, such as a satellite site. The DI should have regular contact and hold regular meetings with PDs.

If the Mortuary Manager is not the DI, it is good practice for them to be a PD to ensure that any HTARIs can be reported within the required time scale, even if the DI is not available.

Key findings - GQ2:

- establishments not having an audit schedule;
- audits being undertaken but not recorded;
- audits were incomplete in that there was no follow up investigation process to identify the root causes when anomalies were found; and,
- failure to make full use of the value potentially to be derived from audits as there was no mechanism to share audit investigation findings.

The HTA's good practice advice based on these findings is as follows:

Process audits are a good way to assess practice against SOPs. These types of audit can help identify whether staff need additional training (helping to identify competency issues) or whether an SOP needs to be updated.

In addition to process audits, audit calendars should include audits of traceability of bodies from the point of arriving at the mortuary, through to PM examination and release. Tissue audits should include checks against the consent given by the highest-ranking individual in the hierarchy of qualifying relationships. Audits should also be conducted for pregnancy remains from point of collection through to disposal.

Traceability audits should look at a representative number of samples, not just one or two cases.

Establishments storing tissue under the control of the police for criminal justice purposes should include these in their tissue audits and regularly follow-up these cases with the police or Coroner to establish whether the tissue still needs to be retained or if it can be disposed of or returned to the family, in accordance with their wishes.

Key Findings – GQ6:

- only health and safety risk assessments were carried out;
- risks to bodies or tissue were not considered, for example accidental damage, release of the wrong body or security breaches;
- control factors referenced SOPs but the SOPs had insufficient detail to prevent the incident, for example, a SOP for viewings describing how to prepare the body, with no detail of the number of identifiers required to be checked or how to obtain this information from whoever has arrived for a viewing; and,
- significant risks were not escalated within the establishment (such as to the Health Trust, Health Board or Local Authority risk register).

The HTA's good practice advice arising from these findings are given below:

Risk assessments need to include licensable activities and to the same standard and detail as health and safety risk assessments. The HTARI categories can be used as a guide to develop these to ensure all areas are assessed.

It is important to have clear documentation and training for all staff, including porters and those undertaking out-of-hours activity, such as site managers, to ensure they are aware of the risks associated with the activities they are undertaking and are aware of which incidents need to be reported to the HTA.

Traceability (T)

The Traceability standards cover the systems and records for the traceability of bodies and tissue and disposal. Out of 59 inspections 66 shortfalls were identified under this standard, 28 of these were under standard T1(c) in relation to the requirement for three identifiers to be used.

Key findings:

- establishments did not use three identifiers for release or, for some who attempted to use three identifiers, these were not sufficiently robust, such as two being provided by the funeral director with the third being taken from mortuary internal documentation;
- release using the Coroner's documentation or the 'green form', neither of which has sufficient identifiers; and,
- only a name being taken for viewings of the deceased (this was also reflected as an issue in the number of viewings of the wrong body being reported as HTARIs).

The HTA's good practice advice arising from these observations are as follows:

Funeral directors should bring three points of identification for the body they wish to collect, which should be compared against the identity tags on the body. General Data Protection Regulations requirements restricting the storage and use of personal data do not extend to the deceased .

Establishments should liaise with the Coroner to ensure three points of identification are stated on their release documentation. Age is not considered a robust identifier; date of birth should be supplied where possible.

For viewings, a system should be in place that obtains three identifiers from those requesting a viewing from the outset. Feedback from establishments that have introduced such a system has indicated that people understand the need for this. If there are requests for viewings where people cannot provide three points of identification, other information (such as place of death) may assist the establishment in assuring itself that the correct body is being prepared for viewing.

Updated guidance for T1c is available on our website.

Premises facilities and Equipment (PFE)

The Premises, Facilities and Equipment standards include storage arrangements for bodies and maintenance of the premises and equipment to ensure dignity of the deceased is maintained. 164 shortfalls out of 59 inspections were identified.

Key findings:

- fridge and freezer alarms not being tested, or if they were tested, this was not recorded;
- testing only challenged the alarm itself with the follow-up call-out procedure not being tested to ensure that it also worked correctly;
- fridges and freezers did not have a lower alarm trigger point;
- alarms were routed to areas that were not staffed out-of-hours; and,
- fridge and freezer temperature records were not reviewed to identify trends.

The HTA's good practice advice based on these observations are given below:

Alarms should be regularly tested, including any follow-up procedure, and the outcome of these tests should be recorded.

Fridge and freezer temperatures should be regularly recorded and reviewed in order to capture any anomalies, such as an increase in the average temperature. This could help identify any problems early and potentially avoid the risk of more significant problems, such as complete breakdowns.

Another repeat finding under premises was deterioration due to age and wear-and-tear leading to the exposure of porous surfaces within the mortuary. Some of the main causes identified were:

- rusting of equipment and inside fridges;
- concrete or wood becoming exposed after being damaged by trolleys repeatedly knocking against them;
- older fridges being constructed in such a way that porous material was incorporated into the framework, for example wood in the doors;
- gaps where different surfaces meet, such as the PM suite flooring and an adjoining wall, in which fluids could become trapped; and,
- lack of cleaning schedules and inadequate cleaning, particularly of the drains in the PM suite and the insides of fridges.

The HTA's good practice advice based on these observations are given below:

Establishments should pay particular attention to any porous areas when completing health and safety risk assessments. Porous surfaces cannot be properly cleaned and decontaminated presenting a potential health and safety risk to staff.

Forward planning of preventative maintenance and taking action to deal with areas that require attention as soon as possible will help prevent larger scale issues.

Issues identified in the compliance assessments in relation to storage were also reflected in inspection findings:

- establishments not transferring bodies to frozen storage in line with HTA guidance due to a lack of freezer space, particularly for bariatric cases;
- insufficient refrigerated storage capacity, for normal and bariatric bodies;
- refrigerated temporary storage units becoming part of regular storage, leaving little contingency storage; and
- erection of temporary units in less than ideal places, such as the PM suite.

Advice

Establishments are reminded about the HTA's sector guidance advising that in order to maintain the integrity and dignity of bodies, they should be transferred to freezer storage within 30 days, unless further examination or release of the body is imminent.

Establishments with insufficient storage space, especially bariatric or freezer space, should endeavour to have written agreements with other establishments to supplement capacity when needed.

If there is no bariatric storage available for bariatric bodies, chiller blankets should be available for immediate management prior to transfer of the body to appropriate storage.

Storage issues, in particular concerning freezer and bariatric storage capacity, should be escalated as appropriate to the relevant Trust, Health Board or Local Authority risk register.

Another issue frequently identified in this category concerned regular maintenance of equipment and records of testing for ventilation systems. Generally, the issue was not that this was not happening but rather that the work was managed by the Estates Department, with the DI or Mortuary Manager not having access to the reports and so not being able to confirm whether maintenance was up-to-date.

Advice

The DI and staff working in the mortuary should have a schedule of when any maintenance and/or testing is due for equipment and receive copies of the reports. This will provide assurance that maintenance happens in a timely manner, issues identified are rectified swiftly and that the ventilation system is working to the required standard (10 air changes an hour).

In relation to personal protective equipment (PPE), facemasks should be a filtering face piece, level 3 (FFP3) and face-fitted. If an individual has facial hair or is unable to work with this equipment, a fully ventilated hood alternative should be used.

Establishments should follow the HSE guidance 'Managing Infection Risk When Handling the Deceased' issued in July 2018.

Conclusion

This publication has reviewed and analysed data collected from licensed establishments through the biennial compliance submissions, incident reports and inspections during the year to 31 March 2018, the first year following the introduction of the new HTA standards for the PM sector.

As discussed in this document, the first year since the introduction of the new standards has seen a rise in the number and severity of shortfalls identified during site visit inspections. This rise may only be partly attributable to the change in standards, which are greater in number and more specific, suggesting that this may be coupled with an underlying rise in non-compliance with HTA standards.

Inspection data indicates that establishments have not necessarily updated their practices and procedures to ensure they are sufficient to meet the revised standards. Our review of inspection shortfalls identified recurrent themes, for which we have issued further advice and guidance to support and help establishments achieve the required standards. In addition, the HTA are in the process of reviewing and updating the guidance that supports each individual standard to improve the information about what is required to meet each standard.

In addition to the issues identified from compliance submissions and inspections of premises, the number of HTARIs has also increased, with accidental damage to and incorrect identification of bodies still being the most common. We will continue to monitor all incidents reported to us, to share learning and provide advice and guidance to the sector.

It is hoped that the information and advice contained in this document will assist DIs and establishment staff, helping to inform procedures and enable them to improve their practices.

Establishments are encouraged to actively review the HTA's codes of practice, Code A: Guiding and fundamental principles of consent and Code B: Post-mortem and the updated Standards, to help ensure their practices and procedures are sufficient to meet the HTA's requirements.