HTA
Human Tissue Authority

Regulation of the Post Mortem Sector 2014–16

What we have learned

October 2016

Contents

PART 1: Review of Post Mortem Sector compliance data, 2014-2015

Introduction

About the HTA

The Human Tissue Authority regulates, through licensing, over 850 establishments involved in the removal, storage and use of human tissue and organs. For the purposes of licensing, we group these by sector, such as post mortem, research, public display and anatomy. We also give approval for organ and bone marrow donations from living people. You can read more about our work at www.hta.gov.uk

The Post Mortem Sector

The post mortem (PM) sector comprises around 250 establishments. It is one of our larger sectors and considered to be one of the highest risk. This is not because it is a particularly non-compliant sector, but because it has the potential to cause significant distress to families, and reputational harm to establishments, when things go wrong.

Our regulation of the PM sector focuses on working with establishments to help them deliver services that are of high quality, and

that have systems in place to mitigate the risk of a serious incident occurring.

We are assisted in this work by our Histopathology Working Group (HWG), which is comprised of senior staff from the HTA and representatives of key stakeholder groups, including:

- The Royal College of Pathologists
- The Coroners Society of England and Wales
- The Association of Anatomical Pathology Technology
- and The Forensic Science Unit of the Home Office.

The shared aim of the HWG and the HTA is to ensure that regulation builds and maintains public confidence. Specifically, public confidence that deceased people – and the bereaved – are treated with dignity and sensitivity when they come into contact with mortuary services, and that their wishes are respected.

Compliance information

In July and August 2015, the HTA completed its biennial collection of compliance information for the PM sector. This summary report collates the findings and provides an overview of the themes that emerged.

The report also includes an analysis of HTA Reportable Incidents (HTARIs) that the HTA was notified about during the period 1 April 2014 to 31 March 2016, along with brief guidance on risk assessment and root cause analysis and examples of risk assessments focussing on three key areas of risk:

1. security
2. misidentification, and
3. accidental damage to a body.

These example risk assessments can be used by establishments for comparison with their existing risk assessments. We hope they will provide useful insight and contribute to the development of establishments' own risk assessments, both in relation to the particular topics covered and other areas of identified risk.

HTA Advice and guidance

The HTA's remit includes helping licensed establishments comply with regulatory and statutory requirements by providing on-going advice and guidance.

This report is aimed particularly at Designated Individuals (DI), Persons Designated (PD), and any staff working under their direction in the conduct of licensed activities: predominantly pathologists and anatomical pathology technologists. The contextual sector information and the learning gained from the investigation of HTARIs will provide a useful information resource and may help them mitigate the risks associated with mortuary practice.

It may also be of use to other professional groups not subject to HTA regulation but involved in the provision of PM services, for example: coroners, their officers, funeral directors and bereavement services.

Thank you for your contribution

The HTA recognises that the completion of compliance reports can be time consuming. We are grateful to all those establishments that completed the exercise fully and on time and to those that have reported HTARIs. The information they provided has informed our risk scoring of establishments, which, in turn, enables us to develop our inspection schedule for the year ahead.

The Post Mortem Sector – some facts and figures

Licensing arrangements

At the time of our compliance exercise in the summer of 2015, our PM sector comprised 251 licensed establishments, of which six provided archive storage only.

Of the total number:

- 131 were 'stand-alone'
- the others – just under half – had a hub-satellite arrangement for the purposes of HTA licensing, with:
  - 52 'hubs', and
  - 68 'satellites'[1].

Under this hub-satellite arrangement, the hub takes responsibility for the governance of licensed activities across the different sites.

We recommend that the DI has dedicated time for effective supervision of licensed activities taking place at satellite sites and that there are systems to ensure effective communication between the DI, pathologists and mortuary staff who are based at different locations. We also recommend that the DI undertakes regular visits to satellite sites and that there are PD located at these sites to oversee activities on behalf of the DI.

Due to our proportionate approach to licensing, establishments in this sector are able to store material for purposes other than determining the cause of death, for example research and teaching. In fact, around 20% of establishments store material for research purposes under their PM Sector licences.

Around 30% of our licensed establishments in this sector are also storing material for the police, over which we maintain oversight under an agreement with the Home Office.

Around 22% of licensed establishments are part of a pathology network. In these cases, the premises usually remain the responsibility of each establishment, but the DI and staff may be employed by the network. Whatever the arrangement, it is important that the Designated Individual is able to carry out their duties effectively, ensuring that the premises are suitable for the activities being carried out.

Just over 50% of establishments' licences extend beyond the mortuary to other areas, such as A&E departments where removal of tissue samples from the bodies of deceased infants may take place under a protocol governing sudden unexpected death in infants.

Having a Person Designated in these areas also helps ensure that there is compliance with regulatory requirements.

Post Mortem (PM) examinations

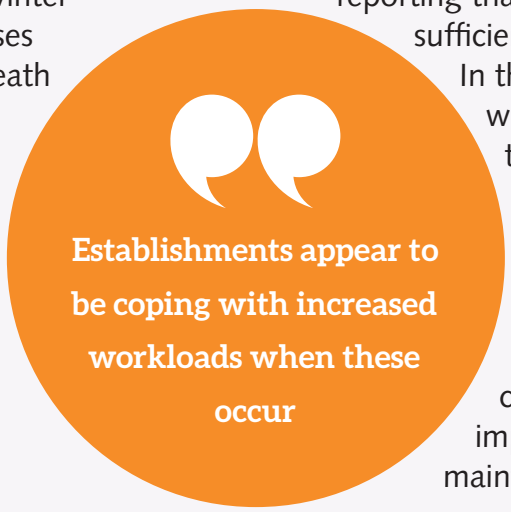
In 2014-15, mortuaries licensed by the HTA admitted around 330,000 bodies, and performed over 100,000 PM examinations, almost all of which were for HM Coroner. A large proportion, around 40%, routinely receives cases from multiple coronial districts; 40% carry out forensic PM examinations and a little over 10% carry out perinatal and/or paediatric PM examinations.

The number of hospital consented adult PM examinations remains negligible, amounting

1 Note that returns from 'hub' sites included information relating to their satellites.

to less than 1% of the total number conducted each year.

Statistics from the Office of National Statistics (ONS) show that an estimated 43,900 excess winter deaths occurred in England and Wales during winter 2014-2015; this was the highest number since winter 1999 – 2000. Respiratory diseases were the underlying cause of death in more than a third of all the excess winter deaths and 30% of establishments reported an increase in the number of PM examinations compared with the previous year. 29% of establishments stated that their level of PM activity had decreased. The remainder reported that the number had remained roughly the same.



Information about winter planning can be found in the guidance document we produced earlier this year here.

Staffing levels

The majority of establishments reported that staffing levels are sufficient for the level of PM activity all or most of the time. However, 7% reported that their staffing level is consistently insufficient to support the number of PM examinations being undertaken. This will be reviewed at these establishments' next HTA inspection.

Only 21% of establishments that noted an increase in the number of PM examinations reported an increase in the number of permanent staff; 15% reported a decrease. Of those where activity had increased but there was a decrease in staff, only two thought there were insufficient numbers of staff for the level of activity, so establishments appear to be coping with increased workloads when these occur.

We asked about the staffing levels needed to cover non-PM examination related activity, such as the on-going work necessary to maintain compliance with regulatory requirements. More than 92% stated that staffing levels were sufficient in this area, with only around 3% of establishments reporting that they did not have sufficient resources for this work. In the months ahead, the HTA will be developing resources to support DIs and others; in doing so, we will be engaging with them to understand more about the burden placed on them by regulation and steps we could take to minimise its impact whilst continuing to maintain standards.

Key areas interest for the HTA

Communication with the coroner

When tissue is taken during a PM examination for examination by the pathologist, licensed establishments rely on the coroner's office to inform them what the family would like to happen to the tissue once coronial authority ends. While the Coroners (Investigation) Regulations 2013 require the coroner to find out the wishes of the family in relation to tissue retained, they do not require that they inform the establishment of these wishes. A good working relationship with the coroner's office is therefore important to prevent unnecessary storage of tissues samples and possible distress to families.

It follows that good communication between the mortuary and the coroner's office is crucial to ensuring that tissue samples are dealt with promptly and in line with the wishes of the deceased person's family.

Establishments told us that, in general, they receive timely information from their coroner(s) about the wishes of the next of kin with regard to disposal of tissue samples, with 93% stating they received, or usually received, information promptly. This is a significant improvement on previous years. Approximately 85% reported that they have a system in place to follow up with the coroner if the wishes of the next of kin are not received, and 57% have meetings with the coroner or their officers on a regular/ annual basis.

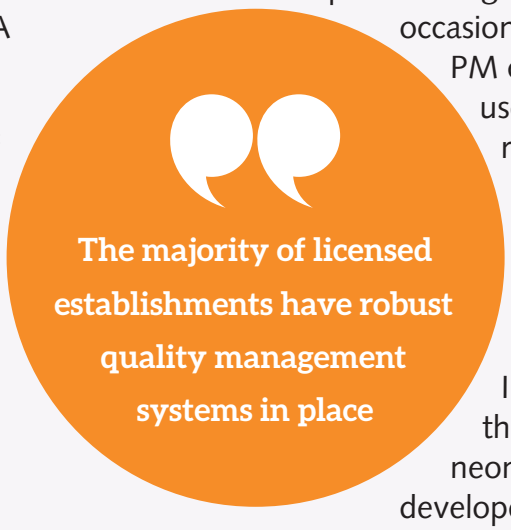
By the end of this year, the HTA will have participated in seven training events for coroners' officers, organised by the Chief Coroner and the Judicial College. In explaining the remit of the HTA and our work in the regulation of PM examinations, we have emphasised the importance of good communication with mortuaries.

We have been grateful for the opportunity to engage with coroners' officers in this way and now have a better understanding of the challenges they face every day as they deal with increasingly heavy caseloads and limited resources. We hope that this shared understanding will lead to further improvements in communication flows in future.

Consent arrangements

In those establishments whose staff are responsible for seeking consent for adult PM examinations, just over 55% have a core team of trained staff who provide support to clinicians seeking consent. Elsewhere, only clinicians who have received PM consent training are authorised to seek consent. The HTA continues to require those seeking consent for PM examination to have received training and encourages establishments to have a core team able to take on this task. As part of our learning resources we plan to develop consent training materials, which may help facilitate this.

The HTA expects establishments to review their consent forms and supporting documentation on a regular basis. We are encouraged that 62% of them reported that they had reviewed their consent forms and information booklets since 1 January 2014 as part of a regular cycle of review. On occasion, we find out-dated NHS PM consent forms are still in use; these do not reflect the requirements of the HT Act and should be replaced. Our model PM consent form is available on the HTA website here.



In 2014, with input from the HTA, the stillbirth and neonatal death charity, SANDS, developed information booklets and consent forms to assist those involved in seeking consent from parents. 54% of establishments who seek consent for perinatal PM examinations reported that they had incorporated the SANDS consent form and information into their process.

Quality management and audit

The majority of licensed establishments have robust quality management systems in place, evidenced by the low number of shortfalls against the relevant standards.

The HTA requires there to be a programme of audit activity, which ensures compliance with operational procedures and regular checks on stored tissue. We recommend that procedural audits are undertaken, whereby staff are assessed whilst they are undertaking

a particular activity against the documented procedure. This can identify areas where training may be required or where a process needs to be amended. As a minimum, regular audits of key procedures such as receipt and release of bodies and identification of the deceased should be performed. If we find on inspection that audits are not undertaken, this might result in a shortfall against HTA standards.

Figure 1 below shows that the majority of establishments did undertake a range of procedural audits in the previous year.

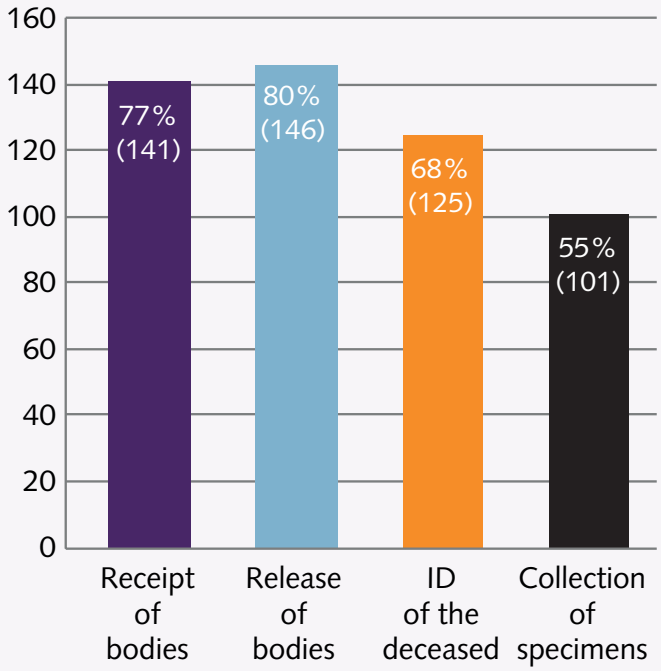


Figure 1: Establishments' audit activity 2014/15 – procedural audits (n = 183)

Traceability

Effective systems of traceability are crucial to mitigating the risk of a serious incident, such as the loss of an organ or errors in identifying the deceased. The HTA expects establishments to have effective systems of traceability and to carry out audits of these to test them. Audits should demonstrate that staff are following relevant standard operating procedures (SOPs) and that errors or deviations from procedure are identified and addressed.

Traceability is always a focus on HTA inspections. Not only do we conduct an audit of a sample selection of bodies in the mortuary, checking their details against the information in the mortuary register and other records, we also undertake a traceability audit of tissue samples taken during PM examination to confirm that the samples can be accounted for and that the wishes of the family have been met.

Most establishments regularly conducted audits of traceability systems, as demonstrated in **Figure 2**. Where discrepancies are identified during any audit, establishments should have a process in place to investigate the root cause and to implement a corrective and preventative action plan.

Those that don't undertake traceability audits should make it a priority to include traceability in their schedule of regular audits.

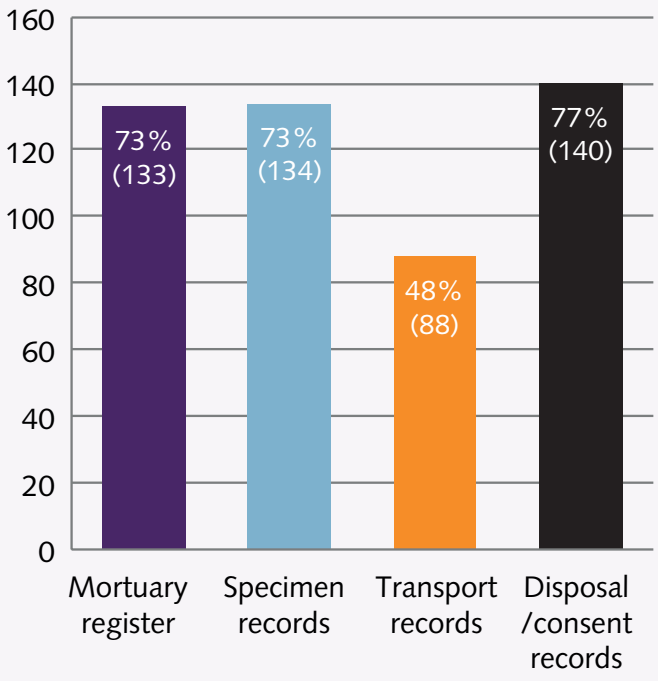


Figure 2: Establishments' audit activity 2014/15 – traceability audits (n = 183)

Risk management

Shortfalls or advice and guidance are frequently given when establishments cannot demonstrate that they have assessed the risks to the deceased in their care or that risks have not been considered in the development of SOPs.

Although the majority of establishments have carried out assessments of risks to the deceased, as well as risks to members of staff, this continues to be an area where improvements could be made, as was the case at the time of the previous compliance update.

Around 23% had not assessed the risk of conducting a PM-examination on the wrong body and 16% had not assessed the risk of releasing the wrong body. Whilst the majority of establishments will already have mitigating actions in place to reduce these risks, without completing thorough risk assessments, they cannot be assured that they have identified and mitigated these risks fully.

The HTA recommends that establishments consider the HTARI categories when reviewing their risk assessments to ensure they identify where there is the potential for a serious incident to occur.

Body Identification Processes

As noted earlier, misidentification of a body is a key mortuary risk, which can lead to viewing by the family of the wrong body, a PM examination being conducted on the wrong body, or release of the wrong body – all very distressing for families and staff. Consequently, methods of identification are a focus for the HTA on inspection, which frequently result in advice or a shortfall if clear instructions on how to accurately identify the deceased are not included in SOPs or observed by staff.

The HTA recommends at least three identifiers are used, with one being unique, such as NHS/hospital number or an address for community deaths. Around 90% of establishments reported that they use three or more identifiers.

If there are effective procedures in place for identification of the deceased, which are understood and observed by staff, errors should not occur. An additional safeguard against error is a system to highlight bodies of deceased individuals with the same or similar names. From the information we have gathered, it appears there is a heavy reliance on manual checks of the mortuary register against the mortuary whiteboard. A small number of establishments stated that they rely on staff members remembering the names of the deceased in the mortuary; this clearly increases the risk of error and will be taken up with those establishments at their next inspection.

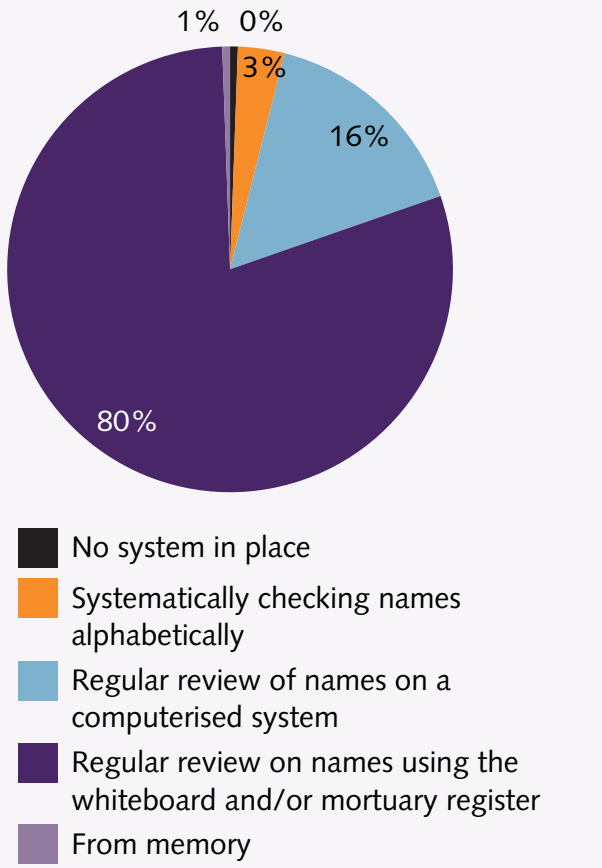


Figure 3. Establishments' systems for identifying same or similar names (n = 183)

Once same or similar sounding names have been identified, there are a number of different ways this is highlighted to mortuary staff to help mitigate the risk of error (see **Figure 4**). Some establishments use a combination of these to maximise the effectiveness of same/similar name procedures.

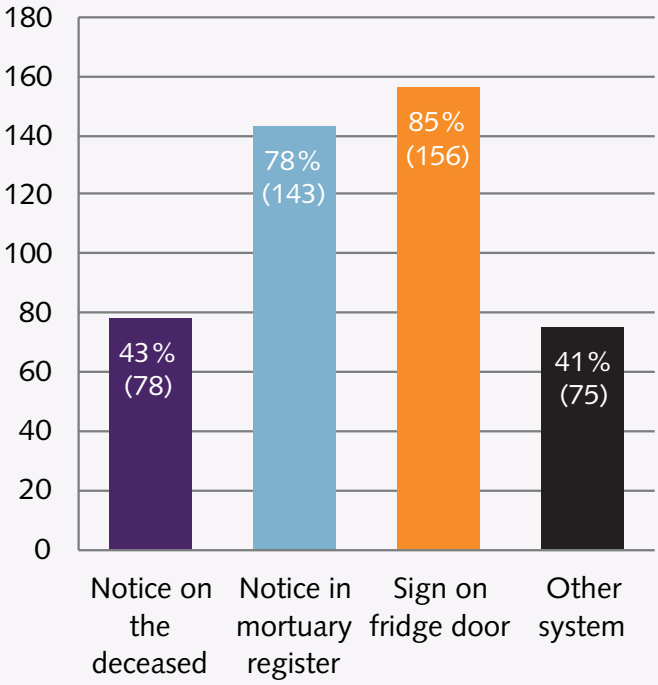


Figure 4: Establishments' systems for highlighting same or similar names (n = 183)

Body release procedures should ensure that the risk of releasing the wrong body is mitigated. As set out later in this report, HTARI notifications relating to wrong body release remain prevalent.

Along with robust identification and same name procedures, careful checks with funeral services staff will help prevent errors. The vast majority of establishments told us that they require written documentation from funeral directors when releasing a body. Although this is not a legal requirement, it is a mitigating step in reducing the risk of release of the wrong body. Training for funeral services staff on relevant mortuary procedures is recommended.

Porter training

Mortuaries based within hospital premises are often accessed by portering staff who admit bodies from wards out of hours. We have observed that placing and removing bodies into and from refrigerated storage, an activity that is often undertaken by porters, can result in accidental damage. Whilst 82% of establishments reported that the training of porters was undertaken by mortuary staff, our experience on inspection has highlighted that practice varies. In some cases, mortuary staff train each porter individually and may observe their practice before signing them off to undertake tasks. However, it is common for the head porter only to be trained by mortuary staff, with responsibility left to them to cascade training to other/new staff.

The HTA recommends that all porters are subject to training in relevant mortuary procedures on induction, and intermittently afterwards, and that this training is delivered by mortuary staff. In circumstances where porters are accessing the mortuary out of hours, or unsupervised, a record should be made of their access to the mortuary. Procedural audits of porters undertaking mortuary duties are also strongly recommended.

Visual aids such as flowcharts or signage in the mortuary may also help mitigate the risk of errors by porters when handling bodies. For example, the risk of damage to a body is greater when the body of the deceased is particularly fragile, for example because of oedema or unusual body morphology.

We are encouraged that many establishments have taken steps to alert portering staff of conditions that need to be considered when handling bodies.

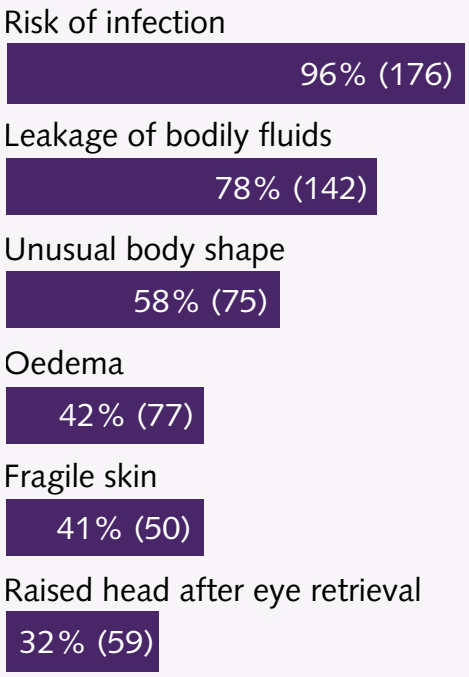


Figure 5: Use of condition of body alerts to highlight risks to bodies when placing them or removing them from storage (n = 183)

Body storage

The HTA has a statutory duty to ensure that premises are suitable for the activities being carried out. On inspection, we routinely assess the PM suite and body storage areas to ensure that they are clean, well maintained and secure. We are also interested in storage capacity and contingency arrangements.

We published a report containing information relating to storage capacity and contingency in November 2015, which is available on our website here. As we move into winter, DIs should remind themselves of the content of the report and in particular the recommendations made by the HTA on steps that can be taken in readiness for winter peaks in activity.

Refrigerated and freezer storage units should be subject to regular monitoring. Ideally, they should be alarmed to ensure that any major deviations in temperature can be rectified promptly. Establishments have a range of alarm systems in place for mortuary storage (see **Figure 6**).

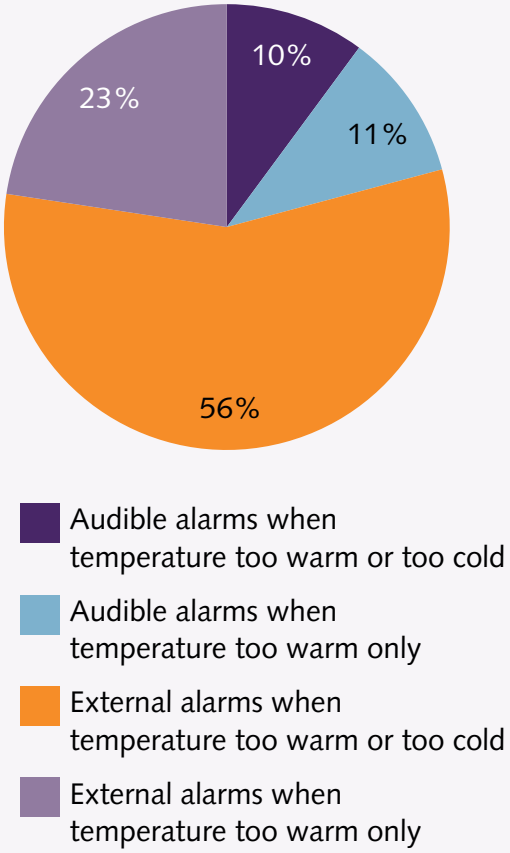


Figure 6: Fridge alarm systems in use (n = 183)

In addition to regular monitoring of mortuary fridges and inclusion of these in critical equipment check lists, we recommend that maternity department fridges are subject to a similar system of oversight, where these are used to store the bodies of infants prior to PM examination.

Security

Establishments are mindful of the need to have secure access. However, we have seen from reported incidents that, at times, these systems can fail. Nearly 80% of establishments reported that they check their mortuary door locks at least once a week; those that do not should consider implementing regular checks as part of their routine security procedures to ensure that

door locks work and that staff observe door locking procedures.

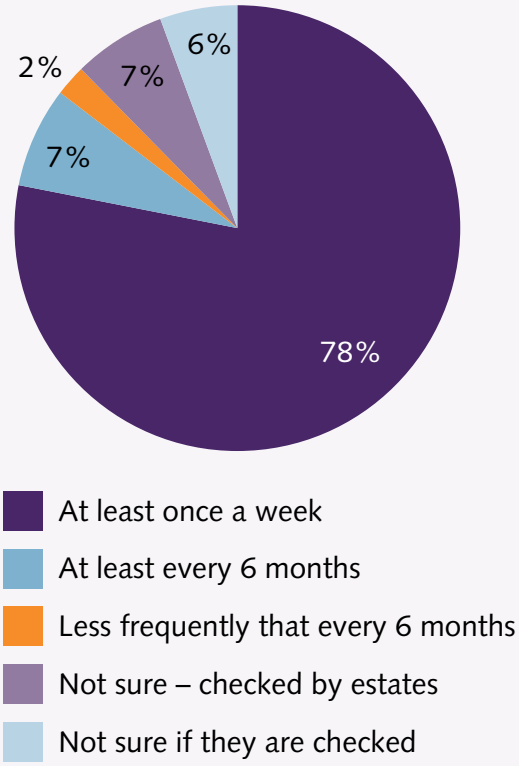


Figure 8: Frequency of checks on mortuary door locks (n = 183)

Disposal

As previously mentioned, when tissue samples are retained by the pathologist for further examination, the family must be asked what they would like to happen to the tissue when it is no longer needed for this purpose. Where they request that the tissue is disposed of by the establishment, this must be done separately from clinical waste and promptly. To ensure that tissue samples are not kept against the wishes of families, establishments are advised to undertake regular audits of tissue holdings and disposal procedures.

The disposal of pregnancy remains should be in line with guidance issued by the HTA in Spring 2015 here.

The HTA was encouraged to learn that around 83% of establishments were aware of the guidance and 58% had updated their procedures in response. The HTA is a project partner in the University of Birmingham's research project: "Death Before Birth: Understanding, informing, and supporting the choices made by people who have experienced miscarriage, termination, and stillbirth". This aims to examine how people in England who have experienced miscarriage, termination following a diagnosis of fetal abnormality, and stillbirth reach decisions concerning the disposal of the remains of pregnancy, how their perceptions of the law impact on their decision-making, and how they communicate their experiences and choices to those there to support them. The project team is based at the University of Birmingham and the University of Bristol, and funded by the Economic and Social Research Council.

The project will review the extent to which the HTA's guidance has been adopted and whether it meets the needs of women. We will report back to the sector at the end of this project, in around eighteen months time.

Inspection findings

As well as the information received from compliance updates, the HTA monitors compliance with standards through its inspection programme. We undertake between 40 and 50 PM sector inspections each year, which are scheduled taking information from a range of sources and considering:

- The establishment's compliance score and the number of 'red flag' answers; these are answers that suggest shortfalls in areas of highest risk
- the date of their last inspection
- whether the Trust is in Special Measures
- whether they had to invoke their

contingency arrangements in the last 12 months and for how long
- whether there has been a recent change of DI
- their history of HTARI notifications (including whether they have never reported a serious incident to the HTA).

Between April 2014 and March 2016, we conducted 93 inspections. We found that overall compliance in the PM sector continues to be high, with only 18 major shortfalls having been identified in this period.

A major shortfall may pose a risk to human safety and/or the dignity of the deceased or indicate a failure to carry out satisfactory procedures. Eight major shortfalls related to storage facilities (PFE3) and three to a lack of risk assessments (GQ8). Two major shortfalls related to aspects of the premises that were not deemed fit for purpose (PFE1). In these cases, establishments did not have adequate security measures in place to ensure the safety of the deceased or of the staff working in the premises; entrances to the mortuary were not secure and there were inadequate safeguards for staff working alone. The remaining five major shortfalls were associated with consent (C1, C2 and C3), tissue traceability (GQ6), and recording of adverse events (GQ7). No critical shortfalls were identified.

Consent, traceability and the suitability of storage arrangements continue to be the focus of enquiry during inspections, reflecting the scope of our HTARI categories.

PART 2: HTA Reportable Incidents

Shared learning

Licensed establishments are required to notify the HTA within five days of a serious incident or 'near miss' being discovered. For HTA reporting purposes, a serious incident is anything that falls within the reportable incident categories defined by its Histopathology Working Group here.

HTARI reports are a rich source of information from which valuable lessons can be learned. This is the third 'shared learning' report produced by the HTA since it began collecting incident data in 2010, and covers the period April 2014 to March 2016. We are grateful to all those establishments that submitted HTARI notifications and encourage others to do so, not least because they provide valuable information about how things can go wrong and what can be done to make sure that they and others get things right.

HTA Reportable Incidents (HTARIs) 2014-16

The HTA received 308 incident notifications during 2014/16 from 101 establishments (around 55%). Of these, upon review 119 did not meet the definition of an HTARI: 14 were near misses and 105 were non-reportable incidents for HTA purposes. This means that either they were not considered to fall within one of the reportable incident types, or they were not of sufficient severity to warrant consideration by the HTA. An example of a non-HTARI is accidental damage to the body of a deceased person that happened as part of the care after death

procedure on the ward. In this case, whilst serious and warranting internal investigation, the matter falls outside the scope of HTA's regulatory oversight.

Whilst not reportable to HTA, we expect any serious incident that does not fall within our reporting classifications to be investigated by establishments in line with their internal incident reporting procedures and to be escalated appropriately. This is an aspect of governance that we review routinely during inspections.

Every incident will have been distressing for the families affected, as well as for the staff involved. However, set against the total number of post-mortem examinations conducted each year (around 95,000 in England and Wales) and the number of deceased who come into the care of mortuaries (estimated to be around 330,000), this remains a small number.

There are two types of incident that remain prevalent amongst those reported during the two years: accidental damage to a body and incidents resulting from misidentification (release, viewing or PM examination on the wrong body.

HTARIs reported in 2014-16

HTARI category	2014-2015	2015-2016	Total No.
Accidental damage to a body	31	27	58
Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	19	17	36
Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination	0	0	0
Discovery of an organ or tissue following post-mortem examination and release of body	1	5	6
Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	8	3	11
Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	1	0	1
Inadvertent disposal or retention of an organ against the express wishes of the family	1	0	1
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	1	4	5
Loss of an organ	0	0	0
Major equipment failure	9	5	14
Post-mortem examination conducted was not in line with consent given or the post-mortem exam proceeded with inadequate consent	4	0	4
Post-mortem examination of the wrong body	1	1	2
Release of the wrong body	14	15	29
Removal of tissue from a body without authorisation or consent	0	0	0
Serious security breach	5	3	8
Viewing of the wrong body	4	10	14
Total	**99**	**90**	**189**

The HTA cannot be certain that all incidents are reported to us. Given the throughput of bodies in licensed mortuaries and the number of PM examinations every year, we believe there is underreporting. However, the incidents that are reported provide sufficient detail for us to identify learning points from which others can benefit.

We regularly remind mortuary staff of their reporting obligations and actively encourage those who are in doubt about whether an incident should be reported to contact us for advice. We are currently exploring the potential causes of under reporting, which may in time result in modifications to our current approach.

Year on year, there was very little difference in the proportions of HTARIs across the different incident categories, with accidental damage remaining the largest single group.

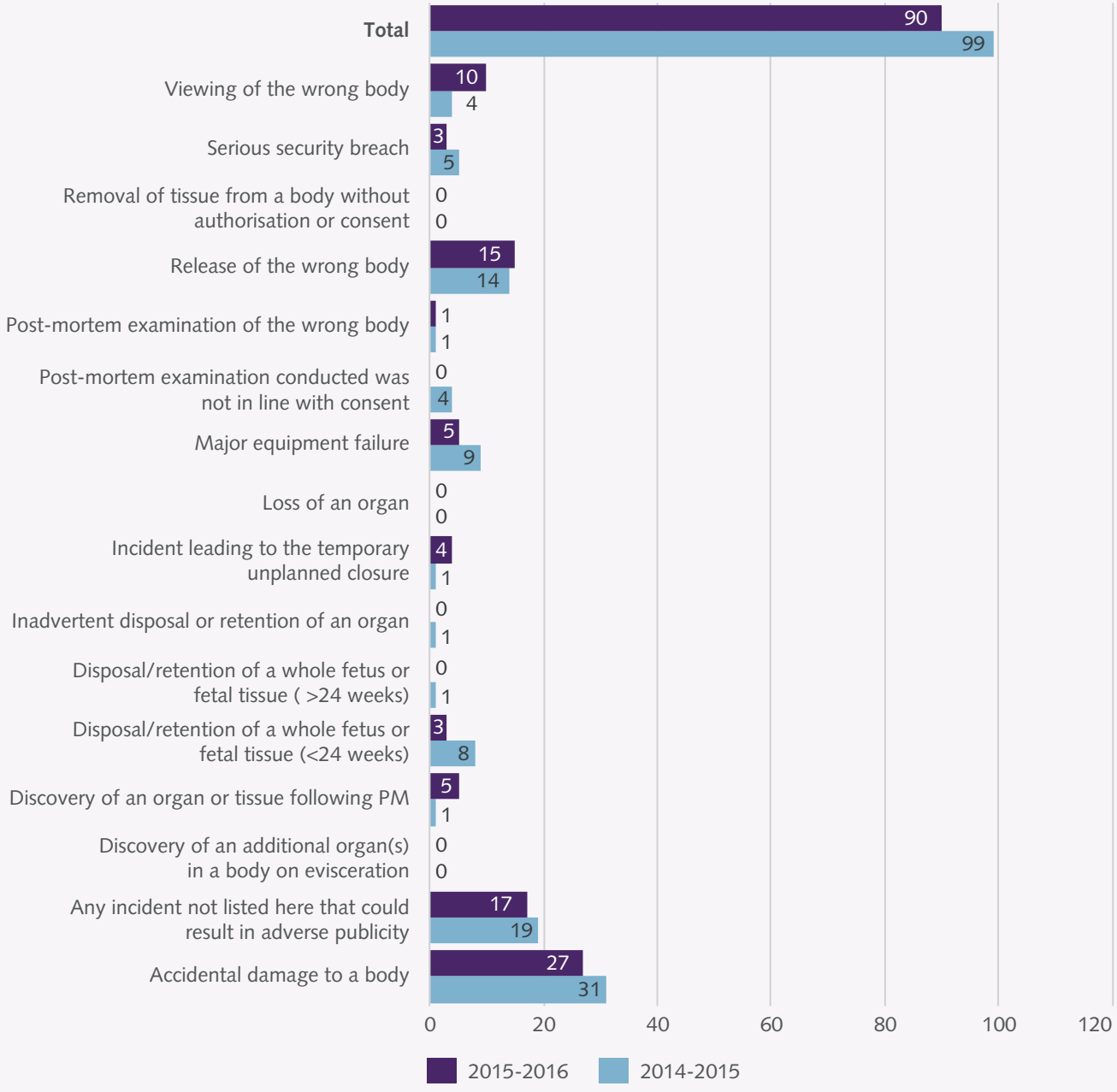


Figure 9: Break down of HTARIs between 2014 – 15 and 2015 – 16

Misidentification

Taken together, the three categories 'release of the wrong body', 'post-mortem examination of the wrong body' and 'viewing of the wrong body' can be considered the second largest group, as they all result from misidentification of the deceased. Contributing factors for these HTARIs include insufficient identifiers used in key processes, weak systems for identifying same/similar names and relying on verbal information when releasing a body or preparing for a viewing of the body. That notwithstanding, human error is often the biggest factor when errors in identification occur.

The HTA recommends that all establishments: (i) use at least three identifiers, including one that is unique; (ii) ensure that two people perform identification checks; (iii) maintain accurate mortuary records that are audited regularly; and (iv) ensure there is an effective system for managing same/similar names.

The 'Any incident' category

The third highest reportable incident category is: 'Any incident … that could result in adverse publicity that may lead to damage in public confidence'. Analysis of these notifications did not identify any specific incident types that warrant the inclusion of an additional HTARI category. However, we are seeing more incidents that involve other departments where activity takes place that falls within the scope of the establishment's HTA licence; for example, in maternity departments, where the bodies of still born babies may be stored so that parents can spend time with them prior to transfer to the mortuary for examination. The HTA recommends that Designated Individuals identify PD in any areas where licensable activities taken place, to ensure compliance with HTA standards and to reduce the risk of an incident occurring.

Taken together, the three categories 'release of the wrong body', 'post-mortem examination of the wrong body' and 'viewing of the wrong body' can be considered the second largest group, as they all result from misidentification of the deceased.

PART 3: Useful tools to aid risk management

Investigation and Root Cause Analysis

When an incident happens we expect an investigation to be carried out which should, as a minimum identify:

- Root causes (what went wrong)
- Contributory factors for each root cause identified (why did it go wrong)
- Corrective actions taken immediately in response to the incident
- Additional actions planned, including those responsible for completing the actions and deadlines/timeframes for completion where relevant
- Preventative actions taken, or which will be taken, to ensure a similar incident does not happen again including those responsible for completing the actions and deadlines/timeframes for completion.

There is often a combination of a physical cause (the facilities, equipment or material items failed in some way); a human cause (someone does something wrong, or does not do something that should be done); and an organisational cause (a fault in a system, process, or policy that people use to make decisions or that describes the job).

Effective root cause analysis (RCA) looks at all three types of cause and should identify obvious failures as well as any that might have contributed that are not so immediately evident.

Consider the example of damage to a body caused by the body falling to the floor.

Physical: the brakes on the hydraulic trolley fail and the trolley moves when transferring the deceased from the fridge, resulting in the body falling to the floor.
Human: the annual maintenance check of the trolley by the estates department does not take place because of sickness absence; the porters do not check the brakes of the trolley and so are not aware that they are not working when they attempt to place a body onto the trolley.
Organisational: the estate department's procedure relating to mortuary equipment maintenance does not set out the actions to take, and whom to inform, should the maintenance schedule not be able to be kept for any reason.

This example illustrates how a combination of causes can lead to the occurrence of a serious incident, in this case damage to a body sustained as the result of the body falling to the floor. It demonstrates the importance of understanding the root cause that led to the incident.

'Five Whys'

A common approach to RCA, and one that we consider appropriate for the mortuary setting, is the 'Five Whys' model. This involves a process of asking 'why?' enough times to determine the root cause of a particular incident. The exact number of times to ask 'why?' depends on the complexity of the issues; five times is a useful guide.

Consider accidental damage to a deceased person's arm whilst the body is being placed into the fridge.

Why did it happen? Because the body was forced into the fridge
Why? Because the arm was caught against the frame of the fridge unit, impeding movement of the tray
Why? Because the arm had come loose from the shrouding when the doctor came to certify the death of the deceased and had not been secured
Why? Because there was no guidance for mortuary staff to check that the body is secure and centred on the tray when placing a body back into refrigerated storage or what to do if there is resistance when placing the tray into the fridge.
Why? Because placing bodies into the fridge had not been risk assessed.

The HTA reviews each investigation report. With a fresh pair of eyes, we consider whether it includes a sufficient analysis of contributory factors and causes. We also consider whether, based on review of other similar incidents, the investigation has been successful in identifying the root cause.

Once the HTA is satisfied that an effective RCA has been completed, we assess whether the corrective and preventative action plan compiled by the establishment is sufficient to mitigate the risk of a similar incident happening again. If not, we will advise on additional steps that should be taken. We have the benefit of reviewing all investigation reports and the mitigating actions that establishments have taken and feel a strong responsibility to share these more widely.

Risk assessment

Risk management is an essential part of good governance.

We know from our inspections that whilst most PM establishments have undertaken comprehensive health and safety risk assessments, many are still not giving sufficient consideration to the risks to the deceased as part of their risk assessments. This means that mortuary procedures may not fully mitigate the risk of an HTA-reportable incident occurring.

Effective risk assessments identify the risk, the causes and potential effects. They consider what can be done to prevent the risk from materialising, how the solution will be implemented, who will be responsible for completing any actions and the time scales for completion.

In drafting this report, we have reviewed the incidents reported to us and selected three categories to use in example risk assessments included as appendices:

1. misidentification,
2. accidental damage to a body, and
3. security breach.

We have set out the most commonly cited contributory factors and the mitigating actions (controls) that have been taken to help minimise the risk of re-occurrence.

We have used the format recommended by the Health and Safety Executive, which is likely to be familiar to mortuary staff. The examples use HTARI categories as a starting point; in each case, we invite you to ask the question: how likely is it that this incident could happen in our mortuary?

Some organisations use a scoring system to help them prioritise and manage risks based on the likelihood of the risk materialising, weighed against its impact. If this is the case at your establishment, we recommend that you adopt this as the framework for undertaking your mortuary-related risk assessments.

Risks should be recorded in a risk register and regularly reviewed. Where mortuary risks are such that they could threaten the reputation of the establishment or compromise its ability to meet strategic objectives, the Board may consider inclusion of key mortuary risks in the corporate risk register. This ensures that the risk is 'owned' by senior staff and that there is regular review of mitigation and assurance.

Conclusion

The HTA recognises that accidents happen and mistakes are made. Our experience of inspecting mortuaries is that, for the most part, they are staffed by committed and able people, who do their best to care for the deceased and respond with sensitivity to the needs of the bereaved. They have a good understanding of the regulatory framework and the standards they are expected to meet to satisfy the HTA's requirements. We are confident that they will use the information contained in this report to reflect on their practice, consider their procedures and make improvements, so that everyone benefits from the lessons learned when things go wrong.

Our experience of inspecting mortuaries is that, for the most part, they are staffed by committed and able people, who do their best to care for the deceased and respond with sensitivity to the needs of the bereaved.

Example mortuary risk assessment 1: Accidental damage to a body

Department: Date of Risk Assessment:

Conducted by:

Potential causes	Potential effects	Existing controls	Other actions needed to control risk	Action: by whom	Action: by when	Action: completed
Lack of training and instruction for mortuary staff and porters on moving and handling bodies	• A body of unusual shape or a bariatric body being placed or forced into fridge spaces that are unsuitable resulting in damage to body • A body with oedema or fragile skin being damaged from handling without due care and attention • A failure by staff to use mortuary equipment properly, resulting in a body being dropped from a tray whilst being placed into or removed from refrigerated storage or onto/off a PM table	• Porter training highlights the body types and conditions that they may be required to deal with and the procedures to follow in each case • Porter training includes use of mortuary equipment • Risk assessments of equipment inform training for staff required to use the equipment and mortuary procedures	• Acquire a mortuary frame for staff to use to check if the body will fit into a standard fridge space • Include in the relevant SOP instructions on what to do when dealing with specific body shapes/ conditions (e.g. removing the tray above a bariatric patient to ensure the body fits comfortably into the space) • Ensure that incidents resulting in damage to a body are reviewed and lessons learned are shared with relevant staff • Observe all new porters using mortuary equipment and sign them off as competent to do so			

Potential causes	Potential effects	Existing controls	Other actions needed to control risk	Action: by whom	Action: by when	Action: completed
Failure by doctors to secure the shrouding on bodies when checking the deceased to sign the relevant certificates	• Body shrouding loosened, resulting in the deceased's arm(s) being unsecured and damaged by contact with the side of the fridge	• Mortuary staff are present when doctors attend	• Place signage in the mortuary to act as a reminder to all staff of the importance of securely shrouding bodies • Recheck bodies after attendance by doctors			
Alarms not set for upper and lower fridge/freezer temperatures	• Integrity of bodies being affected by fluctuation in temperatures, possibly compromising PM examination or families' ability to view them	• Temperature trend monitoring and regular testing of fridge/ freezer alarms	• Make reference to temperature ranges in relevant mortuary procedures, including upper and lower temperature ranges			
Fridge and freezer storage not of sufficient capacity	• Bodies not being placed into appropriate storage, resulting in decomposition (e.g. because of lack of bariatric or freezer storage) • Bodies not being able to be viewed by family • Dignity of the deceased compromised	• Procedures set out the maximum period for which bodies should be stored in refrigerated storage • Regular communication with coroner's office helps ensure timely release of bodies • Fridge and freezer capacity regularly reviewed to ensure that it is sufficient	• Make formal arrangements for access to contingency storage, both on a routine basis and at peak times • Review guidance from the HTA on capacity and contingency and identify additional mitigating steps that might be taken • Assess capacity and consider whether a case should be made for capital funding to increase capacity			

Potential causes	Potential effects	Existing controls	Other actions needed to control risk	Action: by whom	Action: by when	Action: completed
Faulty brakes on hydraulic trolley or misuse of trolley	• Sudden movement of the trolley during transfer of a body causing the body to fall to the floor • Injury to staff whilst moving bodies • Accidental damage to the body	• Equipment faults reported to Estates Department as soon as they are identified • Staff trained on use of hydraulic trolley	• Compile a list of critical equipment subject to regular maintenance and servicing • Agree terms of service with the Estates Department • Remind staff to test the brakes of trollies before use and incorporate testing of brakes into relevant procedures			
Accidental damage caused to a body during a post-mortem procedure conducted by staff with insufficient level of competence	• Poor reconstruction or unnecessary cuts to a body visible to family members attending for a viewing	• Trainees complete a documented programme of training covering all mortuary procedures • Trainees supervised until deemed to be competent following an assessment of competence in key areas	• New recruits to be made subject to a competence assessment before being allowed to work unsupervised • Introduce a system of peer review to encourage self-reflection and quality improvement			

Example mortuary risk assessment 2: Misidentification

Department: Date of Risk Assessment:

Conducted by:

Potential causes	Potential effects	Existing controls	Other actions needed to control risk	Action: by whom	Action: by when	Action: completed
Failure by staff to follow procedures relating to body identification	• Identification of the deceased being checked by one person rather than two • Only one identifier being used, resulting in error	• Procedural audits to check that staff are following SOPs	• Involve staff in writing, reviewing and updating SOPs • Regular meetings with staff to clarify procedures			
Inaccurate or incomplete information attached to the body on the ward	• Mortuary staff proceeding with PM examination, viewing or releasing a body in error • The wrong baby being released to funeral directors caused by insufficient identification information	• Check by two staff of the identity of the deceased on receipt of the body into the mortuary • Mother's name included on identification label attached to the body of a deceased infant	• Review nursing procedures against Hospice UK's care after death guidance • Introduce 'Mortuary Body ID form' to be completed by nursing staff/ attending coroner's officer who must sign prior to receipt of the body into the mortuary • SOP governing body receipt to include the process for referring errors back to the ward/coroner's office for resolution before any further activity is taken in relation to the deceased • Record the names of both the mother and father along with the baby's name, if there is one • Introduce annual refresher training for staff on key mortuary procedures			

Potential causes	Potential effects	Existing controls	Other actions needed to control risk	Action: by whom	Action: by when	Action: completed
Failure to check with family whom they have come to see	• Shock and upset of the bereaved at seeing the body of someone other than their relative • Reputational risk if the family complains or the error generates media interest	• Pre-arranged viewings at specific times • Requirement to check additional information such as DOB or address before preparing the body for viewing	• Strengthen procedure by asking visitors for viewings to confirm name, DOB and address details of the deceased on arrival; do not just rely on details given when the viewing was arranged or provided by bereavement services			
Deceased with same/similar names not appropriately flagged	• Post-mortem examination, viewing or release of the wrong body	• Regular checks of bodies in storage to ensure that same or similar sounding names are flagged • Two-person checks of identification details when bodies removed from storage	• Introduce an identifier which is unique to the deceased • Improve the system for identifying same/similar names on admission to mortuary, e.g. – Use an electronic system that flags up similar/same names) – Place a visual indictor on the body shroud to alert staff – Place magnets on the doors of fridges containing bodies of deceased individuals with same/similar names – Place a mark or identifier in the mortuary register and/or whiteboard to identify same/similar names			

Example mortuary risk assessment 3: Serious security breach

Department: Date of Risk Assessment:

Conducted by:

Potential causes	Potential effects	Existing controls	Other actions needed to control risk	Action: by whom	Action: by when	Action: completed
Doors that should be locked being left open by mortuary staff for ease when moving around the mortuary or for ventilation	• The mortuary being accessed by non-mortuary staff and visitors	• SOP requires that doors are kept locked and subject to access controls	• SOPs to prohibit self-closing doors being propped open • Review of ventilation and air conditioning, to result in improvements if necessary			
Family members left alone with deceased during a viewing inadvertently accessing the body store	• Risk to staff • Distress to family members • Potential breach of confi-dentiality caused by visibility of details on the mortuary whiteboard	• Out of hours viewing without the attendance of an APT is discouraged	• Control access by locking the door between the viewing room and the body store and PM suite			
Unauthorised access by contractors and maintenance staff	• Risks to the dignity of the deceased by them being seen by unauthorised individuals • Potential breach of confiden-tiality	• Mortuary staff have clear guidance on who is allowed access to the mortuary and in what circumstances • Doors are operated through swipe card or pin codes to gain access	• Contractors' visits to be booked in advance • Contractors not to be left alone on mortuary premises			