HTA
Human Tissue Authority

Guidance on HTA Reportable Incidents (HTARIs) in the Post Mortem sector

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Contents

Overview

Establishments licensed in the Post Mortem sector are required to notify the HTA of serious incidents and near-miss incidents that may affect the dignity of the deceased and damage public confidence. Incidents that are required to be reported to the HTA are termed 'HTA Reportable Incidents' (HTARIs).

This document provides guidance for licensed establishments on reporting and managing HTARIs and near-miss incidents.

This guide is presented in four sections:

- Part 1 – Reporting requirements
- Part 2 – Notify the HTA of an incident or near-miss
- Part 3 – Investigation and follow-up reports
- Part 4 – Further information

Contact the HTA on 020 7269 1900 or enquiries@hta.gov.uk, if you:

- are unsure whether an incident or near-miss needs to be reported to the HTA; or
- require further guidance on submitting a notification.

Part 1 – Reporting requirements

Establishments licensed in the Post Mortem sector must notify the HTA **within five working days** of a serious incident or near-miss occurring or being discovered[1].

HTARIs

HTARIs are serious incidents that may affect the dignity of the deceased and damage public confidence. Refer to the HTARI classifications section for details.

Near-miss HTARIs

A near-miss HTARI is:

- an incident that was prevented from happening by chance or a factor external to the establishment's own procedures; or
- an incident that occurred but there was no adverse outcome.

An incident prevented from occurring by the establishment's own procedures is not considered a near-miss HTARI and does not need to be reported to the HTA.

Designated Individuals (DIs) are responsible for ensuring the HTA is notified of HTARIs and near-miss HTARIs in areas covered by the HTA licence.

Staff should know how to identify and report incidents, both internally and to the HTA. This includes staff working under the licence in areas outside of the mortuary, such as Pathology, Maternity and Accident and Emergency departments.

Refer to the HTA website for guidance on the licensing standards relating to managing and reporting incidents.

[1] The requirement to notify the HTA of HTARIs is made in line with Standard Condition 3 (Annex B) of Post Mortem sector HTA licences: "The HTA shall be provided, within fourteen days of a request in writing being made (**or within such other period as the HTA may determine**), with such information as is specified in the written request or in Directions, to enable it to undertake its regulatory functions and duties and to enable it to exercise its powers under the Act."

HTARI classifications

HTARIs and near-miss incidents fall into the following classifications:

HTARI classification	Further information
Accidental damage to a body	This means any damage to a body that has the potential to cause distress to the family or may lead to damage in public confidence, when the body is: • in an area of the establishment covered by the HTA licence; and, or • in the care of staff working under the licence, or staff trained in the process by those working under the licence. This includes damage to a body during post-mortem examination, for example during evisceration or reconstruction of a body. *Examples of incidents that are not HTARIs in this category are:* • *Damage to a body on a ward (unless the ward is covered by the HTA licence – for example, a maternity ward – in which case, the incident should be reported to the HTA);* • *Damage to a body when the body is in the care of funeral directors in an area not covered by the HTA licence; and* • *Damage to a body during post-mortem cross-sectional imaging (for example, damage caused when the arms of the body are raised to prepare the body for the scanning procedure).*
Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	This means any incident that may lead to damage in public confidence, and relates to: • an area of the establishment covered by the HTA licence; and, or • a process undertaken by staff working under the licence, or by staff trained in the process by those working under the licence. Examples of incidents in this category include a serious complaint or adverse publicity.

Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination, or during the repatriation or embalming process	This means any incident of an additional organ(s) being discovered in a body. This includes discovery of an additional organ(s) in a body by a funeral director, following release of the body from the establishment.
Discovery of an organ or tissue following post-mortem examination and release of body	This means when organs or tissue (including tissue blocks and slides) are retained following post-mortem examination when they should have been repatriated with the body, disposed of or released for burial or cremation.
Disposal or retention of an organ or tissue against the express wishes of the family*	This means when organs or tissue (including tissue blocks and slides**) are disposed of or retained against the wishes of the family.
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	This means any incident that leads to unplanned closure of the mortuary and has, or could have, a significant impact on service delivery. This may include staffing issues, flooding or fire.
Loss, disposal or retention of a whole fetus or fetal tissue (**gestational age greater than 24 weeks**) against the express wishes of the family*	This means any incident of this category: • in an area of the establishment covered by the HTA licence; and, or • when the fetus or fetal tissue was in the care of staff working under the licence, or staff trained in the process by those working under the licence.
Loss, disposal or retention of a whole fetus or fetal tissue (**gestational age less than 24 weeks**) against the express wishes of the family*	This means any incident of this category: • in an area of the establishment covered by the HTA licence; and, or • when the fetus or fetal tissue was in the care of staff working under the licence, or staff trained in the process by those working under the licence. *Pregnancy tissue of less than 24 weeks gestation is tissue from the living. Incidents in this category may indicate wider systems problems, and so may be reviewed by the HTA.*

Loss of an organ or tissue	This means when organs or tissue (including tissue blocks and slides) are lost or disposed of. This includes where sample traceability is lost or samples are lost during transportation.
Major equipment failure	This means major equipment failure which has, or could have, a significant impact on service delivery. This may include failure of storage units leading to the mortuary closing to admission of bodies, bodies being transferred to other premises, and, or deterioration in the condition of a body.
Post-mortem cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given	Although post-mortem cross-sectional imaging of a body is not a licensable activity, it is considered to be use of the body of a deceased person for a scheduled purpose. Appropriate consent or authorisation is required. Examples of incidents include injection of contrast or removal of samples from the body for analysis without appropriate consent or authorisation.
Post-mortem examination conducted was not in line with the consent given or the PM examination proceeded with inadequate consent	This includes any incident when a post-mortem examination is conducted: • not in line with consent or authorisation given; • with inadequate or no consent or authorisation. Examples of incidents include a full post-mortem examination being conducted when consent was for a limited post-mortem examination; or the family indicating that they were not fully informed about the post-mortem examination.
Post-mortem examination of the wrong body	This means any incident when the wrong body is prepared for post-mortem examination. This includes when the error is noticed during external examination and prior to evisceration.
Release of the wrong body	This means any incident where the wrong body is released from the mortuary. This includes when the error is noticed shortly after release of the body and the body is immediately returned to the mortuary.

Removal of tissue from a body without authorisation or consent	This means any incident where relevant material is removed from the body of a deceased person without appropriate authorisation or consent. This includes if a blood sample is removed from a body without appropriate consent for the purpose of testing to establish the presence of an infectious disease, so that post exposure prophylaxis can be administered to another person – *refer to* HTA Code of Practice B *(paragraph 123) for information on the consent requirements in such cases*.
Serious security breach	This means any serious incident where security procedures are breached, in areas covered by the HTA licence. This includes serious incidents of unauthorised access or interference with a body or samples.
Viewing of the wrong body	This means any incident where the wrong body is prepared for a viewing.

* The term 'family' is used to identify those who can give 'appropriate consent' under the Human Tissue Act 2004. This is broadly the deceased person's nominated representative or that of a person in a qualifying relationship to them immediately before they died. Further information is in HTA Code of Practice B.

** Wet trimmings and thin sections of processed tissue for microscope slides that are not suitable for microscopic examination can and should be disposed of as clinical waste. Tissue slides that are accidentally broken can also be disposed of. Breakages should be recorded to ensure the absence of slides can be accounted for in audits.

Incidents and near-miss incidents that do not fall within the HTARI classifications do not need to be reported to the HTA. Establishments should investigate and report all incidents, as appropriate, in line with their internal incident reporting procedures.

Part 2 – Notify the HTA of an incident or near-miss

Do not wait until your internal review or investigation is complete before notifying the HTA of a HTARI or near-miss incident. Establishments must notify the HTA of a HTARI or near-miss incident within the required timeframe of five working days of the incident occurring or being discovered.

HTA Portal

The DI or a Persons Designated (PD) on the licence should submit notification of an incident or near-miss incident to the HTA through the HTA Portal.

Access the HTA Portal at: https://portal.hta.gov.uk/

Set up your HTA Portal account, as soon as possible. DIs should ensure they and appropriate PDs have HTA Portal accounts. We advise having a PD in each area covered by the HTA licence, including at least one who works in the mortuary. This can help the DI to ensure appropriate oversight of all activities conducted under the licence, including reporting incidents.

Refer to Appendix 1 for guidance on registering for and using the HTA Portal.

Submit a notification

Complete the notification form as fully as you can, with detailed information about the incident, outcomes and initial corrective and preventative actions.

Please do not include any person identifiable details (such as names or photographs of patients or staff) in information submitted to the HTA.

Section 1 – General details

This section is automatically completed with your HTA Portal account details. Ensure the details are correct. See Appendix 1 for guidance on updating account details.

Section 2 – HTARI details

Licensed premises at which the HTARI occurred	Enter the name of the licensed premises. This should be the name of the hub or a satellite site covered by the HTA licence.
Date HTARI occurred	Enter the date the incident occurred, where this is known.
Date HTARI was discovered	Enter the date the incident was discovered.

Reason for delay between the incident occurring and being discovered, if applicable	If there was no delay between the incident occurring and being discovered, enter 'Not applicable'.
Reason for delay between the incident being discovered and being reported, if it is reported more than five working days after discovery	Establishments are required to notify the HTA of a HTARI or near-miss HTARI **within five working days** of the incident occurring or being discovered. If the notification is submitted within the required timeframe, enter 'Not applicable'.
Details of the person who reported the HTARI to you	Enter the person's initials and job title.
Body or relevant material involved	Select all options that apply: • Whole body • Whole organ(s) • Tissue blocks and/or slides • Fetus • Other • Not applicable
Type of post-mortem examination	Select all options that apply: • Adult forensic • Adult hospital • Adult routine Coroner's • Adult second/defence • Paediatric second/defence • Paediatric hospital • Paediatric routine Coroner's • Paediatric forensic • Not applicable
Where applicable, which Coronial district has/had jurisdiction over the body/bodies involved in the incident	Enter name of the Coronial district(s). Do not enter name(s) of Coroners.
Where did the HTARI occur?	Enter name of the department(s). If it is not clear where the incident occurred, provide details in the 'Any further comments' section of investigations that have been or will be completed to try to establish this.

Has the family been made aware?	Please confirm whether the family has been made aware of the incident. If the family has been made aware of the incident, enter details of when this took place and the outcome in the 'Any further comments' section.
If no, please explain	Provide the following information: • If a decision about whether to inform the family is pending, which team is responsible for making the decision and when you expect the decision to be made. • If the family are due to be made aware of the incident, which team or department is doing this and when it will happen. • If a decision has been made not to inform the family, what the reasons are for this decision.
Any further comments	Please provide any other additional information which may be useful to the HTA when reviewing the incident. In addition to the examples above, this may include: • whether the incident is thought to be a HTARI or near-miss HTARI; and • whether there is any actual or potential media interest in the incident, and details of this (for example, published articles or contact received from journalists).

Section 3 – HTARI classification

HTARI classification	Select all incident classifications that may apply. *Refer to the HTARI classifications section for guidance.*

Description of HTARI	Please include information of: • a detailed description of the incident; • how the incident was discovered; • any relevant events leading up to and following the incident; and • relevant dates, times and timeframes. *Where details are not known or are unclear, describe investigations that have been completed or are planned to try to establish the information.*

Section 4 – Further details

Staff groups involved in the incident	Select all groups that apply and specify any others.
To whom has the HTARI been reported	Provide details of who the incident has been reported to and the date it was reported. If an incident will be reported, but this has not been done at the time of the notification, describe the plans and timeframes in this section.
Has an internal investigation been initiated	Enter yes or no. If an internal investigation has not been initiated, explain why in the 'Actions taken in immediate response to the HTARI' section.
What is your internal reference for the HTARI (e.g. the incident number)	Enter internal investigation reference number.
What is the anticipated date of completion of the internal investigation	Enter the date when it is expected the internal investigation will be completed. Provide any further information in the next section.
Actions taken in immediate response to the HTARI	Describe: • Corrective actions taken to address the situation; and • Preventative actions taken to help to mitigate the risk of reoccurrence.
Initial findings on why the HTARI occurred	Describe preliminary information or findings of: • Root causes (why the incident occurred); and • Contributory factors for each root cause identified (why did it go wrong).

Part 3 – Investigation and follow-up reports

HTA initial review of notification

A HTA Regulation Manager will contact the DI and the incident notifier to confirm we have received the incident notification. We will usually do this within five working days of you submitting the incident notification. If the DI is not available, we may also contact the Corporate Licence Holder contact (CLHc).

Please call 020 7269 1900, if you need to speak with the team urgently.

We may request additional information to assess the incident. You will be advised of the information required and the timeframes to submit this. This may include:

- additional details of the incident and the initial response and actions;
- standard operating procedures and policies relevant to the incident;
- copies of staff training records and competency assessments; and
- updates on the investigation and implementation of actions whilst the investigation is ongoing.

We may also provide advice and guidance on the investigation and corrective and preventative actions.

Investigation follow-up reports

We require establishments to submit an investigation report to the HTA for review. This should be submitted **within two months** of the incident being reported.

If your establishment's internal investigation will not be completed within two months, discuss this with the Regulation Manager, as soon as possible. It may be appropriate to submit an interim or draft investigation report to the HTA and then submit the final investigation report when the investigation has been completed.

The investigation follow-up report must be submitted through the HTA Portal. See Appendix 1 for guidance on using the HTA Portal.

Report requirements

The investigation follow-up report should usually be the establishment's internal investigation report. As a minimum, the investigation report should include details of:

- how the investigation was undertaken (for example, the scope of the investigation and the evidence and information examined);
- summary timeline of events;

- root causes identified (what caused the incident – what went wrong);
- contributory factors for each root cause identified (why did it go wrong);
- corrective actions taken, or which will be taken, in response to the incident, including persons responsible and timeframes to complete these actions;
- preventative actions taken, or which will be taken, to help to prevent a similar incident occurring, including persons responsible and timeframes to complete these actions; and,
- where appropriate, information about whether the family have been informed of the incident and the outcome of this. If a decision has been made not to inform the family, describe the reasons for this decision.

You can also submit supporting documentation to the HTA. For example, this may include revised standard operating procedures and policies relevant to the incident.

Please do not include any person identifiable details (such as names or photographs of patients or staff) in information submitted to the HTA.

Outcome of HTA review

We will review the establishment's investigation and corrective and preventative actions taken in relation to matters within the HTA's regulatory remit.

We may:

- request additional information required for us to review the incident and corrective and preventative actions;
- advise of further steps the establishment can or should take to reduce the risk of a similar incident occurring in the future; and,
- monitor completion of corrective and preventative actions that are within the HTA's regulatory remit.

We will notify the establishment once we are satisfied that the incident can be closed on our system. If we determine the incident to be a HTARI, we will inform you of the incident classification and brief summary of the incident recorded for the incident.

We may determine that the incident is not a HTARI. In which case, we will advise the establishment of this and the incident will be closed on our system.

Part 4 – Further information

Support from the HTA

We recognise that incidents can be distressing for the families affected, as well as for the staff involved. When an incident occurs, we aim to support establishments in their review of the circumstances of the incident and the actions taken to help to mitigate the risk of an incident of a similar nature occurring in the future.

We review information received from HTARI notifications and investigation follow-up reports to identify and share lessons that can be learned about how things can go wrong and what can be done to help mitigate the risks of incidents occurring. We regularly publish learning and guidance reports on our website.

Disclosing information about incidents

Sharing information

Certain incidents reported to the HTA may be shared with the Care Quality Commission or other relevant bodies. Further information is available on our website.

HTA Publication Scheme

The Freedom of Information Act 2000 requires that each public authority maintains a Publication Scheme that describes the classes of information the organisation publishes or intends to publish. The HTA Publication Scheme is on our website.

Summary information of HTARIs is included in our quarterly reports. These reports are available on our website. Summary information is included only for cases determined by the HTA to be a HTARI and for which HTA review of the incident has been completed. The information included is: date the incident occurred (month and year only); establishment name and licence number; incident classification; and, brief summary of incident. You will be informed of this information at the conclusion of the HTA review of the case, before the information is included in a quarterly report.

Freedom of Information Act requests

We process requests for information about HTARIs in line with the provisions of the Freedom of Information Act 2000. Further information is available on our website.

Please contact the HTA if you require further information.

Appendix 1

Persons Designated

To add a PD to a licence, the DI (or Licence Holder, in the absence of the DI) should email licensing.enquiries@hta.gov.uk with details of the proposed PD – including name, job title and email address.

Applications to add PDs to a licence will be processed within 20 working days. PDs can then register for a HTA Portal account.

Managing your HTA Portal account

Create a new account

To create an account, click 'Create new account' on the HTA Portal homepage.

Enter your contact details, role and the establishment name. Please use the same information recorded in the licence record, to help us to link your account to the licence. Fields marked with a red asterisk (*) must be completed.

Once you have registered for an account, you will receive an email with a link to the HTA Portal to set your password. You can then login to the HTA Portal.

It can take up to one working day for your account to be verified and for you to be given access to your licence records.

Update your details

You can change your details and password in 'User Account' settings on the HTA Portal homepage. Click 'Edit' and update the details, as required.

Your licence information

You can view details of the licence your account is linked to. Licence numbers are on the blue banner on the HTA Portal homepage. Select 'Licence Details' to see information about the licensed premises, satellite sites, the DI and PDs.

Report an incident or near-miss

To submit an incident notification to the HTA:

1. Select the licence on the blue banner on the HTA Portal homepage.
2. Select 'HTA Reportable Incident'.

3. Select ‘Click here to submit a new: HTA Reportable Incident’. This loads the incident notification form. You can select ‘Save Draft’ to save the notification form to submit later. Click ‘submit’ to send the notification to the HTA. Please wait until the successful submission message is displayed, which confirms we have received the form, before logging out or navigating to another page.

Guidance on completing the incident notification is provided in this document.

You can download a PDF copy of the information you submitted on the ‘HTA Reportable Incident’ page.

Submit an investigation follow-up report

Investigation follow-up reports must be submitted through the HTA Portal.

4. Select the incident in the ‘Previous HTA Reportable Incident Submissions’ section and upload the follow-up report. Up to three documents can be submitted via the Portal (these must be submitted at the same time).

Email any additional documents to the HTA Regulation Manager. Please include the case reference in the email.