HTA
Human Tissue Authority

Archived

Guidance for reporting HTA Reportable Incidents (HTARIs) in the post mortem sector

Version 13/1, Issued March 2013 – updated June 2015

Overview

The HTA must be notified of all reportable incidents (HTARIs) that have occurred at licensed establishments in the post mortem sector since 1 May 2010.

From 1 April 2013, notifications must be made using the HTARI form on the HTA web Portal. This form can only be completed by a Designated Individual (DI) or Person Designated (PD) named on the licence who has a web Portal account. If you need to add a Person Designated- to your licence so they are able to report HTARIs, please email their name, job title, email address and postal address to licensing.enquiries@hta.gov.uk.

DIs can view and print all notifications which have been made by their establishment since 1 April 2013 within their respective web Portal accounts. PDs can view and print notifications they have submitted themselves since 1 April 2013.

For guidance on how to register for a web Portal account and manage your account details, please see our Guide to submitting HTARI notifications using the web Portal.

Notification of HTARIs must be submitted to the HTA **within five working days** of the incident occurring or being discovered. Establishments must not wait until any internal review or investigation is complete before notifying the HTA of a HTARI. This requirement is made in line with Standard Condition 4 (Annex B) of your HTA licence:

"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."

Types of incidents which must be notified to the HTA are outlined in Section 3 of this document. Near misses must also be reported so the HTA is aware and can work with establishments to reduce the likelihood of an incident occurring.

DIs are responsible for ensuring the HTA is notified of HTARIs, and systems must be in place at establishments to ensure staff know how to submit a notification to the HTA in the DI's absence.

If you have any queries that are not addressed in this document, please contact the HTA on 020 7269 1900 or email enquiries@hta.gov.uk.

Archived

How to complete the HTARI notification form

Page 1 – General details

These details are automatically populated from your account details. Please ensure they are correct and, if they are not, edit your account details by selecting 'User Account' under My Account and then the 'Edit' tab.

Section 2 – HTARI details

Please provide as much detail as possible about the incident when answering the questions asked. This will mean the Regulation Manager assigned to the case won't need to ask for the details at a later date.

Under the question 'Body or relevant material involved', please select all options which are applicable to the incident. For example, if fridge failure has occurred in a fridge where bodies and fetuses were being stored, please select 'whole body' and 'fetus'.

Under the question 'Type of post mortem examination', again please select all options which are applicable to the incident.

Section 3 – HTARI classification

The table below sets out incidents which must be notified to the HTA. When reporting an incident, please select all classifications which may apply. The Regulation Manager assigned to the case will then select the most appropriate classification when the incident has been reviewed.

HTARI classification	Further information
Accidental damage to a body	Incidents reported under this category include any damage to the body that occurred within the mortuary or under the care of mortuary staff, or those trained by mortuary staff, that has the potential to cause distress to the family or that means the deceased cannot be viewed. This includes damage that occurred during post mortem examination, for example during evisceration carried out by an inexperienced or trainee Anatomical Pathology Technologist or Pathologist, or poor reconstruction that prevents the viewing of a body. Only incidents which occur in the mortuary or other areas to which the licence has been extended (e.g. A&E or maternity wards), or occur when the deceased is in the care of mortuary staff or those other staff (such as porters) trained by mortuary staff, should be reported as HTARIs. Incidents of accidental damage to a body which occur outside the areas covered by the HTA licence and which do not involve mortuary staff should be raised as internal incidents, but need not be reported to the HTA, unless there is the possibility that they may fall under another HTARI category e.g. an incident that could result in adverse publicity.

Archived

	Incidents which need not be reported to the HTA include damage occasioned on the ward, while in the care of porters (except where the mortuary is responsible for the training of porters in duties relating to the transfer of the deceased), or funeral directors outside of the mortuary. These should, however, be raised as internal incidents and investigated.
Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	For example, a serious complaint against the mortuary service made by a family, which may generate media interest.
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 may include the discovery of an organ by a funeral director following release of the deceased.
Discovery of an organ or tissue following post-mortem examination and release of body	This means the organ or tissue should have been repatriated with the body, disposed of or released for burial / cremation.
Loss, disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family**	
Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family**	Although this is tissue from the living, it may be a potential indicator of wider systems problems and therefore warrants review by the HTA.
Inadvertent disposal or retention of an organ against the express wishes of the family**	
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	Such as a flood, fire, staffing issues (e.g. due to a pandemic).
Loss of an organ	This may include unintended disposal of an organ or other unexpected loss e.g. during transportation.
Major equipment failure	Such as a fridge or freezer malfunction which has caused decomposition of the deceased or which has, or could have, a significant impact on service delivery.
Post-mortem examination conducted was not in line with the consent given or the PM examination proceeded with inadequate consent	Such as the consent form indicating only a partial post-mortem examination should be undertaken, and a full examination being undertaken in error; or the family** indicating that they were not fully informed about the post-mortem examination.
Post-mortem examination of the wrong body	
Release of the wrong body	This includes all bodies, whether or not they have undergone post-mortem examination.

Archived

Removal of tissue from a body without authorisation or consent	
Serious security breach	Such as unauthorised access to the mortuary or interference with a body.
Viewing of the wrong body	Although the body may not be subject to a post mortem examination, this may be a potential indicator of wider systems problems and therefore warrants review by the HTA.

** For the purpose of this guidance document the term 'family' is used to identify those who can give 'appropriate consent' under the HT Act. This is broadly the deceased person's nominated representative or that of a person in a qualifying relationship to them immediately before they died.

Near miss definition	Further information
A near miss is an incident that was prevented from occurring by a factor external to the establishment's own procedures	Near misses should be reported under one of the HTARI classifications set out above, and will be managed by the HTA in line with the HTARI process. An incident that was prevented from occurring by the establishment's own procedures is not considered a near miss and does not need to be reported to the HTA.

Further information can be found in the HTA codes of practice.

Please provide as much detail as possible when writing a description of the incident, but do not include any person identifiable information, such as names of patients or staff or photographs of people. We will contact you should any additional information be required.

Page 4 – Further details

Provide as much detail as possible on any preliminary information and/or findings which may have contributed to the incident. Describe all actions that were taken immediately in response to the incident to address the situation and to mitigate the risk of reoccurrence while you are awaiting the conclusion of the internal incident reporting or investigation process.

Submission of the notification

Please check to ensure you have included all information required before you submit the notification, then click 'submit'. You may need to wait a moment for the next page to populate, but wait until you see the successful submission message which confirms we have received the form before you log out or navigate to another page.

Please take note of the reference number given on this page, which will be a series of letters and numbers, such as 'CAS-23289-BR8P'. This reference number should be quoted in all communication about the incident.

Once you have submitted the notification you will able to download a PDF copy for you to save and print as desired. You are able to view the HTARI notifications you have made by clicking on the 'HTA Reportable Incident' tab under the Self Service menu. The DI of the licensed establishment

Archived

will be able to view all notifications the establishment have submitted since 1 April 2013 in their web Portal account.

What happens next?

A Regulation Manager will be assigned to review the incident and will contact the DI and notifier (if the DI did not submit the notification) for further details once the information provided on the notification form has been reviewed. In the DI's absence, the Regulation Manager will also contact the Licence Holder or named contact for the Corporate Licence Holder.

The DI must ensure a follow up report is submitted to the HTA within two months of reporting the incident.

Certain incidents reported to the HTA, which may have reputational risk for the reporting establishment or create media interest, will be shared with the CQC under the terms of the Memorandum of Understanding between the HTA and the CQC.

Follow up reports

Follow up reports must be submitted via the HTA web Portal, by clicking into the 'HTA Reportable Incident' tab under the Self Service menu and then selecting the relevant report under 'Previous HTA Reportable Incident Submissions'.

You can submit up to three documents via the web Portal but these must be submitted at the same time. Should you need to submit further documents at a later date, please send these by email to HTARI@hta.gov.uk, referring to the HTARI reference number provided when the notification was initially acknowledged.

DIs must ensure a follow up report is submitted within two months of notification of the incident. The follow up report should be the internal investigation report on completion of the establishment's internal investigation of the incident. In particular, we would expect the final report to contain:

- Root causes identified (what went wrong)
- Contributory factors for each root cause identified (why did it go wrong)
- Corrective actions taken in response to the incident, including persons responsible and deadlines/timeframes for completion
- Preventative actions taken, or which will be taken, to ensure the incident does not happen again, including persons responsible and deadlines/timeframes for completion
- Where appropriate, actions taken with families/loved ones

Further guidance will be provided by the Regulation Manager assigned to the incident.

The report will be reviewed by the Regulation Manager, who will contact the DI should we require any further information to assess the incident. We will monitor Corrective and Preventative Action (CAPA) plans where actions have been identified but not yet implemented. We may also provide advice on further steps establishments can or should take to further mitigate the risk of reoccurrence.

Archived

Freedom of Information requests

We occasionally receive requests for information about reportable incidents. We process these requests in line with the provisions of the Freedom of Information Act 2000. Therefore please bear in mind that we sometimes have to release information about HTARIs in response to a request under the Freedom of Information Act.

In response to requests in the past we have relied on exemptions outlined in the Freedom of Information Act and have not released any reports in full. Instead, we have released the date the notification was received, the name of the establishment involved, whether the notification was determined an ‘incident’ or ‘near miss’ and the incident classification.

We always inform establishments involved of requests we receive with details of the response we intend to provide, giving them the opportunity to comment beforehand.

Further information

If you have any queries that are not addressed in this guidance document, please contact the HTA by telephoning 020 7269 1900 or emailing enquiries@hta.gov.uk.

Archived