HTA
Human Tissue Authority

Guidance on HTA Reportable Incidents (HTARIs) in the Anatomy sector

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Contents

Overview

Establishments licensed in the HTA's Anatomy sector are required to notify the HTA of serious incidents and near-miss incidents that may affect the dignity and care of the deceased people. 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 has 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.

We welcome early discussions about adverse events and reporting.

Part 1 – Reporting requirements

Establishments licensed in the Anatomy 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 and care of deceased people. Please refer to the HTARI categories section for more information on the types of reportable incident.

The HTA may take the decision to share information relating to incidents with other organisations (such as regulators) or key stakeholders.

HTARIs can be considered as largely preventable incidents that should not occur if establishments and their staff are compliant with HTA standards and guidance where applicable and available preventative measures are in place to mitigate the risk of incidents.

The HTA may take additional action in response to a reportable incident, including an inspection or Police referral.

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.

[1] The requirement to notify the HTA of HTARIs is made in line with Standard Condition 3 (Annex B) of Anatomy 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 general guidance

Designated Individuals are responsible for ensuring the HTA is notified of HTARIs and near-miss HTARIs. The HTA will copy the Corporate Licence Holder contact into the initial correspondence and HTARI closure notices for their awareness and oversight.

Staff should know how to identify and report incidents, both internally and to the HTA.

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

HTARI categories

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

HTARI category	Further information
Acceptance or release of the wrong body or other human material	Any incident where the wrong person's body (or other human material) has been accepted or released.

Damage to a body or other human material	Any incident where avoidable or preventable damage has been caused to a body or other material from a deceased person. Damage may be accidental or deliberate. Please note that we do not necessarily expect reporting of deterioration that can reasonably be attributed to typical preservation, storage and use. Examples of this could include: • Gradual deterioration due to repeated handling by authorised students • Authorised dissection • Incisions and chemically-induced alterations expected as the result of the embalming process.
Equipment failure that has a negative impact on a body or other human material	Any incident where the integrity of a body or other material from a deceased person - or the dignity of a deceased person - is compromised by equipment failure. The term ‘equipment’ should be applied in its broadest meaning, and includes any equipment used in the movement, preservation, handling, storage or use of bodies or other material from deceased people.

Incomplete or missing records	Any incident where records required to evidence lawful possession are incomplete or missing. Examples could include: • Storage records • Records to evidence valid and appropriate consent • Records to evidence that certification of the cause of death has been completed as required
Incorrect disposal or retention of a body or other human material	Any incident involving incorrect disposal or retention of a body or other material from a deceased person. Examples could include: • Disposal not in accordance with expectations • Retention for longer than authorised
Loss of a body or other human material	Any incident where a body or material from a deceased person cannot be found even though records indicate it should be present.

Loss of traceability	Any incident where the auditable link between a body or other material from a deceased person and the associated records has broken down. Please note that we do not necessarily expect trivial and temporary instances to be reported; for example, temporary dislodgement of tags or labels, or when there is a delay in updating records which does not impact traceability.
Security compromise or breach	Any incident where security arrangements are compromised or breached. Examples could include: • Unauthorised access, whether by unauthorised individuals or by authorised individuals for an unauthorised purpose. • Serious failure of security systems • Lapse of security or access controls Please note that we do not necessarily expect trivial incidents, such as false alarms and authorised students mistakenly attending the wrong class, to be routinely reported.

Unauthorised activity involving a body or other human material	Any incident where an unauthorised activity involving the body or material of a deceased person takes place. The term ‘unauthorised’ should be applied in its broadest meaning, and can include activities that are not in line with the consent of the donor as well as those that breach the licensing requirements of the Human Tissue Act 2004. Examples could include the unauthorised loan of human material
Unplanned disruption of services	Any incident that leads to unplanned service delivery disruptions and has, or could have, a significant impact on the dignity and care of the deceased. Serious service disruption may occur as a result of staffing issues (including due to sickness absence), flooding or fire.

Any other reportable incident	Any other incident outside of the other specific HTARI categories relating to dignity and care of deceased people Examples could include: • A serious complaint or adverse publicity • A matter involving the police • A matter involving the Health & Safety Executive • Legal action or compensation claims made against the establishment • A serious deviation from expected practices and documented processes • Inappropriate behaviours by staff or visitors, including students

Incidents and near-miss incidents that do not fall within the HTARI classifications do not need to be reported to the HTA.

We welcome early discussions about adverse events and reporting.

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.

We welcome early discussions about adverse events and reporting.

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/

We advise you set up your HTA Portal account/s as soon as possible.

DIs should ensure they and appropriate PDs have HTA Portal accounts.

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. The information you provide should be sufficient to enable the HTA reviewer to understand what has happened, including details of initial findings and immediate corrective and preventative actions taken.

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 • Body part / prosection • Bone / skeleton • Potted specimen • Other • Not applicable
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.

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 categories

HTARI category	Please select all incident categories that may apply. *Please refer to the* HTARI categories 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.

Details of other parties informed	Provide details of other parties who have been informed of the incident (e.g. Executive team, Corporate Licence Holder contact, professional body, Police, relative of donor) If other parties are to be informed 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, please 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: • Details of and findings from any initial investigation undertaken on discovery of the incident. • 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 Designated Individual, the incident notifier (if not the Designated Individual) and the Corporate Licence Holder contact to

confirm we have received the incident notification. We will usually do this by email within five working days of you submitting the incident notification.

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

We may request additional information to assess the incident and monitor your response to it.

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, please 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, including the scope of the investigation and the information examined
- summary timeline of events
- root causes identified
- contributory factors for each root cause identified
- corrective actions taken, or which will be taken, in response to the incident, including the individuals responsible and timeframes to complete these actions
- preventative actions taken, or which will be taken, to help to prevent a similar incident occurring, including individuals responsible and timeframes to complete these actions

- where appropriate, information about whether anyone related to the deceased have been informed of the incident and the outcomes. If a decision has been made not to inform anyone related to the deceased, please describe the reasons for this decision and the decision-making process.

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.

Reporting of incidents to the HTA is not considered to be a corrective or preventative action.

We may:

- request additional information
- advise of further steps the establishment can or should take to reduce the risk of a similar incident occurring in the future
- monitor completion of corrective and preventative actions

We will notify you after we are satisfied that the incident can be closed in our systems. If we determine the incident to be a HTARI, we will inform you of the incident category and the brief summary we have recorded.

If we determine that the incident is not a HTARI, we will notify you and close the incident. We may still provide advice and guidance in response to non-HTARIs.

Part 4 – Further information

Support from the HTA

We recognise that incidents can cause distress, and 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.

Disclosing information about incidents

Sharing information

Certain incidents reported to the HTA may be shared with the other organisations, including other regulators.

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 category; 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.

Requests made under the Freedom of Information Act 2000

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 Person Designated to a licence, the Designated Individual (or - in the absence of a Designated Individual - a Licence Holder representative, such as a Corporate Licence Holder contact) should email licensing@hta.gov.uk with details of the proposed Person Designated, including title, name, job role, telephone number and email address.

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

Managing your HTA Portal account

Create a new account

To create an account, click ‘Sign up now’ 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 linked to your account. Licence numbers are found by selecting the green tile (marked ‘Licences’) 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 your licence after clicking on the green tile on the HTA Portal homepage (marked ‘Licences’).
2. Select ‘Anatomy HTA Reportable Incident’.
3. Select ‘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.
4. You can monitor progress of your submitted report in Anatomy HTA Reportable incident in Progress section
5. You can view all previously submitted reports in the ‘Previous Anatomy HTA Reportable Incident Submissions’ section

Submit an investigation follow-up report

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

6. 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 dealing with your case. Please include the case reference in the email.