Human Tissue Authority
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Web www.hta.gov.uk
Email enquiries@hta.gov.uk
Date 17 February 2020

[redacted]

By email to [redacted]

Dear [redacted],

Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOIA), which was received by the Human Tissue Authority (HTA) on 22 January 2020. Your email outlined the following request:

> Please can I request, under the Freedom of Information Act, details of all HTA Reportable Incidents which occurred in the calendar year 2019, to include:
>
> - The month when incident took place
> - The establishment where incident took place
> - Incident classification
> - As full a summary of the incident as possible (please can this be more detailed than simply stating 'Human error led to accidental damage of body' or similar).
> - Outcome of incident (e.g. any corrective actions taken in response to the incident, or actions taken with the family)
>
> Further to this request, I note that the HTA has released similar information for the years 2014-2018 in response to Freedom of Information requests.
>
> If any HTARIs have come to light for the years 2014-18 which were not published in these previous FOI releases, please can the details of these too be supplied.
>
> If the following request cannot be met within cost limits, please advise how I may refine my request.

Response

The HTA does hold information about incidents and incident outcomes for HTA Reportable Incidents (HTARIs) reported to the HTA to have occurred in 2014 to 2019. In considering your request for this information, we have concluded that some of the information we hold is exempt from disclosure by virtue of the exemptions at sections 31 and 21 of the FOIA, for the reasons set out below.

Section 31

We have considered your request for information of: detailed incident summaries; and, outcomes of incidents (e.g. corrective and preventative actions, and actions taken with the family).

Section 31(1)(g) provides a qualified exemption for information, the disclosure of which would, or would be likely to prejudice "the exercise by any public authority of its functions for any of certain specified purposes". Those specified purposes include the purpose of "ascertaining whether circumstances which would justify regulatory action in pursuance of any enactment exist or may arise". The HTA has statutory functions under the Human Tissue Act 2004 (the HT Act) in respect of various regulated activities. The HTA's functions, which are set out in general terms at section 15 of the HT Act, include superintending compliance with requirements under Part 1 of the Act and with Codes of Practice made under the Act.

Detailed incident summaries

It is very important that establishments have confidence to provide information and discuss sensitive matters with the HTA without fear of disclosure. We consider it likely that establishments would be less likely to provide full and frank information to the HTA if they thought such information may be disclosed into the public domain. This, in turn, would prejudice the HTA's ability to superintend compliance with requirements under the HT Act and with the HTA Codes of Practice, undertake investigations appropriately in the future, and to take such regulatory action as may be required in accordance with our regulatory functions. Disclosing detailed information about these incidents would prejudice the exercise by the HTA of our functions for certain specified purposes. Those specified purposes include the purpose of "ascertaining whether circumstances which would justify regulatory action in pursuance of any enactment exist or may arise".

The section 31(1)(g) exemption is subject to the public interest test. We have considered the public interest in disclosure of detailed incident summaries against the public interest in avoiding the prejudicial effects set out above, for this case. We recognise that there is a public interest in transparency about the incidents.

We consider that there is a strong countervailing public interest in ensuring that we can continue to carry out our regulatory activities and to receive full and frank information from establishments without them fearing disclosure of the information. We believe there is a risk that providing detailed information for these incidents could lead to groups of staff/staff members at establishments being identified. We conclude that in this case there is a stronger public interest in ensuring that the HTA can carry out its investigative functions without the harm identified.

We therefore conclude that information of detailed incident summaries for these incidents is exempt from disclosure by virtue of the exemption under section 31(1)(g) of the FOIA. We have provided brief summary of information for the incidents in the table below.

Outcomes of incidents (e.g. corrective and preventative actions, or actions with the family)

As set out above, it is very important that establishments have confidence to provide information and discuss sensitive matters with the HTA without fear of disclosure. We consider it likely that establishments would be less likely to provide full and frank information to the HTA if they thought such information may be disclosed into the public domain. This, in turn, would prejudice the HTA's ability to superintend compliance with requirements under the HT Act and with the HTA Codes of Practice, undertake investigations appropriately in the future, and to take such regulatory action as may be required in accordance with our regulatory functions. Disclosing detailed information about the outcomes of these incidents would prejudice the exercise by the HTA of our functions for certain specified purposes. Those specified purposes include the purpose of “ascertaining whether circumstances which would justify regulatory action in pursuance of any enactment exist or may arise”.

The section 31(1)(g) exemption is subject to the public interest test. We have considered the public interest in disclosure against the public interest in avoiding the prejudicial effects set out above, for this case. We recognise that there is a public interest in transparency about the outcomes of the incidents, including corrective and preventative actions and actions taken by establishments with the family. We also recognise that there is a public interest in transparency about our work and that our investigations into incidents and actions taken by establishments are carried out appropriately. We have procedures to review investigations undertaken by establishments in response to incidents, including the corrective and preventative actions that they take. We consider that there is a strong countervailing public interest in ensuring that we can continue to carry out our regulatory activities and to receive full and frank information from establishments without them fearing disclosure of the information.

We conclude that in this case there is a stronger public interest in ensuring that the HTA can carry out its investigative functions without the harm identified. We therefore conclude that information of outcomes of these incidents is exempt from disclosure by virtue of the exemption under section 31(1)(g) of the FOIA.

Section 21

Information of HTARIs published by the HTA in response to previous FOIA requests is exempt from disclosure by virtue of the absolute exemption under 21 of the FOIA. This is because this information is easily accessible by other means.

We publish responses to FOIA requests on our website at: https://www.hta.gov.uk/about-us/freedom-information-and-data-protection/freedom-information-responses

Please note that we published information about HTARIs in 2019, in response to a recent FOIA request. This is available on our website at: https://www.hta.gov.uk/sites/default/files/2019%20HTARI%20reports%20FOI%20response.pdf

Information is provided in the table below for incidents in 2014 to 2019. This is for incidents determined to be HTARIs and which have been closed on our systems.

Date incident occurred	Establishment (hub site)	Licence number	Incident classification	Summary of incident
Aug-14	Frimley Park Hospital	30014	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Breach of mortuary procedures.
Oct-14	James Cook University Hospital	12089	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Administrative error led to retention of tissue blocks and slides.
Feb-15	Royal Glamorgan Hospital	12338	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to retention of tissue.

Feb-15	King's College Hospital	12377	Removal of tissue from a body without authorisation or consent	Human error led to use of incorrect consent form.
Apr-15	Darent Valley Hospital	12226	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Communication errors meant the family's wishes were not followed.
Apr-15	Torbay Hospital	12181	Serious security breach	Procedural error led to unauthorised access to the mortuary.
Oct-15	John Radcliffe Hospital	12052	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to retention of tissue.
Mar-16	Leicester Royal Infirmary	12337	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error meant that testing of samples was not completed.
Apr-16	University Hospitals Coventry and Warwickshire	30018	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to repatriation of tissue not in line with the family's wishes.
May-16	George Eliot Hospital	12171	Accidental damage to a body	Human error led to accidental damage to a body.
Jun-16	Royal Stoke University Hospital	12224	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Staffing issues resulted in delays to post-mortem examinations.
Jul-16	North Middlesex University Hospital NHS Trust	12562	Serious security breach	Unauthorised access to the mortuary premises.

Jul-16	Wycombe Hospital	12245	Discovery of an organ or tissue following post-mortem examination and release of body	Administrative error led to delayed return of tissue.
Sep-16	Queen's Medical Centre	12258	Loss of an organ	Human error led to loss of part of an organ.
Oct-16	St George's Hospital	12387	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to retention of tissue.
Oct-16	Derriford Hospital	12034	Accidental damage to a body	Procedural error led to accidental damage to a body.
Oct-16	Leicester Royal Infirmary	12337	Loss of an organ	Human error led to loss of tissue traceability.
Nov-16	Addenbrooke's Hospital	12318	Accidental damage to a body	Human error led to accidental damage to a body.
Nov-16	Hull Royal Infirmary	12170	Release of the wrong body	Human error led to short-term release of the wrong body.
Nov-16	Luton and Dunstable University Hospital	12348	Removal of tissue from a body without authorisation or consent	Human error led to unauthorised removal of tissue during PM examination.
Nov-16	Leicester Royal Infirmary	12337	Discovery of an organ or tissue following post-mortem examination and release of body	Human error led to delayed disposal of tissue.
Nov-16	The Royal London Hospital	12187	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Administrative error led to delayed disposal of tissue.
Dec-16	University Hospitals Coventry and Warwickshire	30018	Accidental damage to a body	Human error led to accidental damage to a body.

Dec-16	Calderdale Royal Hospital	12108	Accidental damage to a body	Human error led to accidental damage to a body.
Dec-16	Colchester General Hospital	11104	Viewing of the wrong body	Human error led to viewing of the wrong body.
Dec-16	Royal Bolton Hospital	12035	Loss of an organ	Human error led to loss of tissue during a post-mortem examination.
Dec-16	Leicester Royal Infirmary	12337	Release of the wrong body	Human error led to release of the wrong body from the mortuary to another department.
Mar-17	Queen Alexandra Hospital	12237	Discovery of an organ or tissue following post-mortem examination and release of body	Human error led to retention of tissue.
Oct-17	Royal Glamorgan Hospital	12338	Discovery of an organ or tissue following post-mortem examination and release of body	Administrative error led to retention of blocks and slides.
Dec-17	Leeds General Infirmary	12231	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Procedural error led to retention of tissue.
Dec-17	Royal Liverpool University Hospital	30002	Serious security breach	Procedural error led to unauthorised access to the mortuary.
Dec-17	Great Ormond Street Hospital for Children NHS Foundation Trust	30001	Major equipment failure	Fridge failure required transfer of bodies to alternative storage facilities.
Jan-18	Salisbury District Hospital	12047	Accidental damage to a body	Human error led to accidental damage to a body.

Jan-18	Royal Glamorgan Hospital	12338	Disposal or retention of an organ or tissue against the express wishes of the family	Administrative error led to loss of traceability of tissue.
Jan-18	Leeds General Infirmary	12231	Accidental damage to a body	Human error led to accidental damage to a body.
Jan-18	Kingston Hospital	12023	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of valuables from the mortuary premises.
Jan-18	Leicester Royal Infirmary	12337	Serious security breach	Unauthorised access to the mortuary premises.
Feb-18	Royal Glamorgan Hospital	12338	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to delayed disposal of tissue.
Feb-18	Kingston Hospital	12023	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of valuables from the mortuary premises.
Feb-18	Kingston Hospital	12023	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of valuables from the mortuary premises.
Mar-18	Royal Glamorgan Hospital	12338	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Failure of staff to follow the establishment's procedure for transfer of bodies.
Mar-18	Royal Glamorgan Hospital	12338	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to disposal of tissue against the wishes of the family.

Mar-18	Royal Glamorgan Hospital	12338	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to loss of traceability of tissue.
Apr-18	Calderdale Royal Hospital	12108	Release of the wrong body	Human error led to short-term release of the wrong body.
Apr-18	King's College Hospital	12377	Loss of an organ	Procedural error led to loss of tissue.
Apr-18	Royal Free Hospital	12013	Discovery of an organ or tissue following post-mortem examination and release of body	Procedural error led to retention of tissue.
May-18	Queen's Medical Centre	12258	Discovery of an organ or tissue following post-mortem examination and release of body	Procedural errors led to discovery of tissue following release of a body.
May-18	Darent Valley Hospital	12226	Accidental damage to a body	Human error led to accidental damage to a body.
May-18	Royal Bolton Hospital	12035	Accidental damage to a body	Human error led to accidental damage to a body.
Jun-18	Salisbury District Hospital	12047	Accidental damage to a body	Human error led to accidental damage to a body.
Jun-18	Royal Surrey County Hospital	12222	Accidental damage to a body	Human error led to accidental damage to a body.
Jul-18	Royal Glamorgan Hospital	12338	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Adverse publicity resulted from alleged theft of valuables.
Jul-18	Sandwell General Hospital	12131	Release of the wrong body	Human error led to the short-term release of the wrong body.

Jul-18	Leicester Royal Infirmary	12337	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to loss of tissue.
Jul-18	Leicester Royal Infirmary	12337	Accidental damage to a body	Human error led to accidental damage to a body.
Aug-18	Royal Glamorgan Hospital	12338	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Administrative error led to delayed disposal of tissue.
Sep-18	Royal Hampshire County Hospital	12014	Discovery of an organ or tissue following post-mortem examination and release of body	Human error led to inadvertent retention of tissue.
Sep-18	Leighton Hospital	12145	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Communication error led to disposal of tissue against the family's wishes.
Sep-18	University Hospital of North Durham	12461	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Procedural error led to retention of tissue.
Sep-18	Broomfield Hospital	12441	Major equipment failure	Freezer failure led to transfer of bodies to a temporary freezer unit.
Sep-18	University Hospital of Wales	12163	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Procedural error led to delayed disposal of tissue.
Oct-18	The Royal Oldham Hospital	12342	Accidental damage to a body	Human error led to accidental damage to a body.

Oct-18	Pinderfields Hospital	12086	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Communication errors led to delayed disposal of tissue.
Oct-18	University Hospital of North Tees	12446	Disposal or retention of an organ or tissue against the express wishes of the family	Human error led to inadvertent disposal of tissue.
Oct-18	Royal Stoke University Hospital	12224	Discovery of an organ or tissue following post-mortem examination and release of body	Procedural error led to inadvertent retention of tissue.
Oct-18	Broomfield Hospital	12441	Major equipment failure	Major equipment failure led to temporary impact on establishment to store bodies.
Oct-18	Basildon University Hospital	12051	Major equipment failure	Equipment failure led to temporary transfer of bodies to alternative storage.
Nov-18	Stepping Hill Hospital	12031	Accidental damage to a body	Human error led to accidental damage to a body.
Nov-18	Royal Glamorgan Hospital	12338	Accidental damage to a body	Human error led to accidental damage to a body.
Nov-18	Luton and Dunstable University Hospital	12348	Loss of an organ	Procedural error led to loss of tissue.
Nov-18	Luton and Dunstable University Hospital	12348	Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	Failure of mortuary heating system resulted in delayed post-mortem examinations.
Nov-18	Northampton General Hospital	12253	Accidental damage to a body	Human error led to accidental damage to a body.

Nov-18	Manchester University NHS Foundation Trust	12554	Disposal or retention of an organ or tissue against the express wishes of the family	Human error led to disposal of tissue against the wishes of the family.
Dec-18	Victoria Hospital	30031	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to inadvertent disposal of tissue.
Dec-18	Heartlands Hospital	12366	Accidental damage to a body	Human error led to accidental damage to a body.
Dec-18	Royal Glamorgan Hospital	12338	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to disposal of tissue not in line with the family's wishes.
Dec-18	The Public Mortuary at Flax Bourton	12536	Accidental damage to a body	Human error led to accidental damage to a body.
Dec-18	Lister Hospital	12110	Release of the wrong body	Human error led to short-term release of the wrong body.
Dec-18	Wythenshawe Hospital	12203	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Complaint about the condition of a body.
Dec-18	Alder Hey Children's NHS Foundation Trust	12213	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Communication errors led to release of a body against the family's wishes
Jul-19	Royal Brompton Hospital	12262	Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	Unplanned closure of a mortuary facility due to failed environmental cooling system.

Jul-19	Southampton General Hospital	12214	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Examination of fetal remains was conducted without appropriate consent.
Sep-19	Leeds General Infirmary	12231	Accidental damage to a body	Human error led to accidental damage to a body.
Sep-19	Leeds General Infirmary	12231	Accidental damage to a body	Human error led to accidental damage to a body.
Sep-19	Manchester University NHS Foundation Trust	12554	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Communication errors contributed to the release of a wrong body.
Nov-19	St Mary's Hospital	12553	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to a body not being refrigerated.

Further information

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below. There is no charge for making an appeal.

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Telephone: 08456 30 60 60 or 01625 54 57 45
Website: www.ico.gov.uk

Yours sincerely,

[redacted]