

Human Tissue Authority
151 Buckingham Palace Road
London
SW1W 9SZ

██████████

By email to ██████████

Tel 020 7269 1900
Web www.hta.gov.uk
Web www.hta.gov.uk
Email enquiries@hta.gov.uk
Date 10 February 2017

Dear ██████████

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 14 January 2017. Your email outlined the following request:

Please can the HTA provide the following under the FOI Act:

*information on each of the serious adverse events and adverse reactions (SAEARs) in the organ donation and transplantation sector reported to the HTA during the year 2016.

*information on the number and nature of serious incidents in mortuaries (HTARIs) reported to the HTA during the year 2016.

Response

With regard to part one of your request: **information on each of the serious adverse events and adverse reactions (SAEARs) in the organ donation and transplantation sector reported to the HTA during the year 2016.*

The information that you requested is provided in the table below. For additional context to your request, SAEARs are recorded by NHS Blood and Transplant under a service level agreement with the HTA.

Below is a table of the 50 incidents that were reported in 2016; some of which, are still under investigation. Reported incidents comprise a very small proportion of activity in this sector. In 2016, 4688 organs were successfully transplanted.

Case Number	Classification	Description of SAEARS
CAS-33933-K8C5	ODT Reaction	Transcription error at time of donation, recipient given prophylaxis.
CAS-33829-Q0N0	ODT Reaction	Miscommunication of details on Human Leukocyte Antigen (HLA) request form. Delay to transplantation of organ.
CAS-34099-L5L3	ODT Reaction	Haematuria in organ - potential retrieval damage.
CAS-33656-D3P6	ODT Event	Retrieval damage – loss of organ.
CAS-33595-M9N1	ODT Reaction	Prolonged surgery following organ repair.
CAS-33589-X5K7	ODT Event	Retrieval damage – loss of organ.
CAS-34325-M0Y2	ODT Event	Malignancy detected in donor. Donor referred for follow-up treatment and recipient contacted.
CAS-34502-L7C5	ODT Event	Poor packaging – kidney unsuitable for transplantation.
CAS-34564-C5L1	ODT Event	Retrieval damage - organ unsuitable for transplantation.
CAS-34569-W9L5	ODT Event	Kidney not transplantable due to haematoma - placed for research.
CAS-34571-S8S9	ODT Event	Retrieval damage led to loss of organ but hepatocytes were used.
CAS-34628-B5V6	ODT Event	Retrieval damage (pancreas) - placed for research.
CAS-34672-X7Q5	ODT Event	Kidney not transplantable due to ischemia.
CAS-34688-N2V7	ODT Event	Retrieval damage – loss of organ.
CAS-34812-F5V4	ODT Event	Retrieval damage (kidney) - placed for research.
CAS-34813-B9V3	ODT Event	Poor perfusion (kidney) - placed for research.
CAS-34504-Z9D6	ODT Reaction	Kidney not transplanted as further biopsy results required - recipient had been anaesthetised.
CAS-34506-Y6J6	ODT Reaction	Retrieval damage (lungs) - lungs transplanted but prolonged surgical time.
CAS-34605-R1J9	ODT Reaction	Malignancy detected in transplanted kidney - recipient nephrectomy.
CAS-34660-Q1J4	ODT Reaction	Kidney not transplanted due to ischaemia - recipient had been anaesthetised.
CAS-34670-T4G9	ODT Reaction	Damage to kidney - was offered on and transplanted.
CAS-34732-R8D9	ODT Reaction	Potential infection in transport fluid. Three recipients treated prophylactically.
CAS-35104-B1H3	ODT Event	Retrieval damage – loss of organ.
CAS-35373-B6G3	ODT Event	Histopathology delay – loss of organ.
CAS-35551-V6V5	ODT Event	Organ transplanted – pre-existing HLA specificities identified.

CAS-35863-Q8H6	ODT Event	Malignancy detected post-donation.
CAS-35180-Q2R1	ODT Reaction	Surgical repair of organ post-transplant.
CAS-35594-J4D7	ODT Reaction	Surgical damage – organ removed following implantation.
CAS-35596-L9Z4	ODT Reaction	Surgical repair of organ – organ transplanted.
CAS-35941-K7X1	ODT Reaction	Incorrect laboratory result – organs transplanted.
CAS-37447-N8V0	ODT Event	Retrieval damage to pancreas - pancreas not transplanted.
CAS-37421-G0Z4	ODT Reaction	Retrieval damage to kidney - kidney transplanted.
CAS-37417-N3Y2	ODT Event	Retrieval damage to liver - liver not transplanted.
CAS-37263-B3H7	ODT Event	Malignancy detected post-donation.
CAS-37111-V1V8	ODT Event	Incorrect laboratory result detected post-donation.
CAS-37014-L2R8	ODT Event	Retrieval damage to kidneys - not transplanted.
CAS-36778-G8D6	ODT Reaction	Kidney recipient underwent nephrectomy following new clinical information.
CAS-36697-Q0J9	ODT Event	Organ offered on negative CMV result when donor was positive.
CAS-36590-D7C9	ODT Event	Retrieval damage to pancreas - not transplanted.
CAS-36557-J1F0	ODT Reaction	Miscommunication of information over liver reconstruction - recipient affected.
CAS-36544-S1B4	ODT Reaction	Prolonged retrieval time - recipient primary graft non-function.
CAS-36488-Q8Z3	ODT Event	Prolonged retrieval time - liver not accepted for transplantation.
CAS-36479-F1M9	ODT Reaction	Poor perfusion (lungs) - prolonged hospitalisation of recipient.
CAS-36348-B4L6	ODT Event	Poor perfusion (abdominal organs).
CAS-36338-C9C0	ODT Event	Poor perfusion (kidneys) – organ discarded.
CAS-36304-X2K5	ODT Event	Retrieval damage (liver) - not transplanted.
CAS-36241-N8Y9	ODT Event	Poor perfusion of organ.
CAS-36236-N3H7	ODT Event	Infection not queried at the time of donation.
CAS-34901-Z8F9	ODT Reaction	Retrieval damage (kidney).
CAS-34898-T0V0	ODT Event	Malignancy detected post-transplant.

Concerning part two of your request: **information on the number and nature of serious incidents in mortuaries (HTARIs) reported to the HTA during the year 2016.*

I can confirm that 83 post-mortem HTARIs were reported during 2016. A breakdown of the nature of these incidents is set out in the table below. In 2014-15, mortuaries licensed by the HTA admitted around 330,000 bodies, and performed over 100,000 post-mortem examinations.

Case Number	HTARI Classification	Description of Incident
CAS-33527-Z1T4	Accidental damage to a body	Mechanical trolley failure resulted in accidental damage to a body.
CAS-33639-M3B7	Release of the wrong body	Due to human error, the wrong body was released to the funeral director.
CAS-33640-S4T8	Major equipment failure	Temporary failure of the fridges in the mortuary. No damage to bodies occurred.
CAS-33689-H6G0	Serious security breach	Human error resulted in serious security breach.
CAS-33695-M9C5	Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	Delay of Post Mortem (PM) examinations due to flooding and loss of hot water supply in the mortuary.
CAS-33721-S9T8	Accidental damage to a body	Human error resulted in accidental damage to a body.
CAS-33746-B8M3	Discovery of an organ or tissue following post-mortem examination and release of body	Human error resulted in retention of blocks and slides following PM and release of body.
CAS-33753-T8G1	Post-mortem examination of the wrong body	Human error resulted in a post-mortem examination being carried out on the wrong body where two individuals had similar names.
CAS-33889-R8P8	Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	Human error led to a delay in the funeral arrangements of a fetus.
CAS-33937-Q4Q2	Viewing of the wrong body	Human error resulted in viewing of the wrong body.
CAS-33983-S6Q7	Release of the wrong body	A bank of fridges failed in the mortuary. Bodies were moved while the fridge was repaired. No damage to bodies occurred.
CAS-34041-N7J3	Discovery of an organ or tissue following post-mortem examination and release of body	Human error resulted in body release prior to return of an organ.

CAS-34049-H6V7	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error resulted in release of body without PM examination.
CAS-34075-G7Y5	Accidental damage to a body	Human error resulted in accidental damage to a body.
CAS-34110-K6V5	Viewing of the wrong body	Human error resulted in viewing of the wrong body.
CAS-34137-Y1J2	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Fetus (14 Week gestation), could not be found following delivery.
CAS-34190-S7C6	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 resulted in disposal of pregnancy remains.
CAS-34198-Q2H7	Accidental damage to a body	Human error resulted in accidental damage to a body.
CAS-34266-B1Z6	Major equipment failure	A bank of fridges failed in the mortuary. Bodies were moved while the fridge was repaired. No damage to bodies occurred.
CAS-34312-M6L4	Accidental damage to a body	Minor accidental damage caused during PM examination.
CAS-34370-Z1T3	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error resulted in chest clamp not being removed before release for burial.
CAS-34409-Z3K9	Release of the wrong body	Human error resulted in the release of the wrong body.
CAS-34451-R8X6	Accidental damage to a body	Accidental damage to a body occurred following a post mortem examination.
CAS-34458-H0P2	Release of the wrong body	Wrong body released and cremated.
CAS-34475-P5B2	Major equipment failure	Failure of fridges led to accidental damage to a body.
CAS-34509-L6P4	Discovery of an organ or tissue following post-mortem examination and release of body	Failure to follow documented procedure resulted in discovery of additional tissue.
CAS-34555-Y9F1	Accidental damage to a body	Minor damage found on the arm of a deceased individual, investigation underway to try to establish where and how the incident happened.
CAS-34563-J2N6	Viewing of the wrong body	Due to human error, the wrong body was viewed by the family.

CAS-34618-X5W4	Major equipment failure	Fridge alarm did not alarm as expected following a failure of the fridge. No adverse consequences on bodies but reported as equipment failure.
CAS-34654-Y2N1	Post-mortem examination of the wrong body	Due to human error, a PM examination was performed on the wrong body.
CAS-34703-Z7K0	Accidental damage to a body	Human error led to accidental damage.
CAS-34721-G4L4	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 resulted in inadvertent retention of fetus.
CAS-34825-J4M6	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Staff action resulted in unauthorised access to the body store area.
CAS-34874-S1C6	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-34918-Q5H8	Accidental damage to a body	Human error resulted in accidental damage to a body.
CAS-34970-D1D2	Removal of tissue from a body without authorisation or consent	One block of retained tissue discovered during an audit, without appropriate consent.
CAS-34972-F3B9	Viewing of the wrong body	Human error led to the viewing of the wrong body.
CAS-35011-M3K6	Accidental damage to a body	Minor damage to a deceased person noted prior to post mortem examination.
CAS-35083-S5N3	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Fetus misplaced.
CAS-35094-M5J0	Accidental damage to a body	Ineffective systems lead to accidental damage of a deceased individual.
CAS-35105-W5X3	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Memory stick containing unencrypted images from two post mortem examinations, left on public transport.
CAS-35121-N9V2	Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent	Due to error in paperwork, the post-mortem examination was not in line with the consent given.

CAS-35279-W8Y7	Disposal or retention of an organ against the express wishes of the family	Brain kept/disposed of, contrary to the wishes of the family.
CAS-35297-B2R2	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Brakes on trolley were not applied and tray moved when touched by family member.
CAS-35298-G6T1	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error resulted in mix-up of brains.
CAS-35344-Y6N7	Accidental damage to a body	Human error led to accidental damage.
CAS-35393-J5K6	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Inadvertent disposal of fetal remains against family wishes.
CAS-35402-G0T9	Accidental damage to a body	Human error led to accidental damage.
CAS-35417-C3K8	Accidental damage to a body	Incorrect hoist used while admitting a body and accidental damage was caused to the body.
CAS-35418-G4C9	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Missing pregnancy remains, presumed to have been disposed of in error.
CAS-35507-N6B5	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Release for burial of container believed to contain fetus as well as placenta. Subsequent to burial fetus confirmed to be present in mortuary. Later confirmed that casket buried contained placenta only. Further funeral undertaken to rebury fetus.
CAS-35512-K0X5	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Body positioned incorrectly on the refrigerator tray causing discolouration to the face of the deceased.
CAS-35543-M1R9	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	A fetal brain used by a medical student in a research project, despite no consent for use for research being in place. Consent was given for use for education, medical record and genetics.
CAS-35563-V4H8	Viewing of the wrong body	Due to human error, the wrong body was viewed by the family.

CAS-35578-X3K0	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Delay in informing the family of baby's return from consented PM at another Mortuary resulting in delays to the release and funeral of the infant.
CAS-35592-Q0J6	Accidental damage to a body	Human error led to accidental damage.
CAS-35610-F2K9	Removal of tissue from a body without authorisation or consent	Human error resulted in removal of tissue without consent.
CAS-35652-Y3F6	Viewing of the wrong body	Due to human error, the wrong body was viewed by the family.
CAS-35675-S6D8	Release of the wrong body	Human error resulted in the release of the wrong body.
CAS-35681-H4K2	Discovery of an organ or tissue following post-mortem examination and release of body	Due to an administrative error, the body was released to funeral directors without histology samples being repatriated.
CAS-35703-N1K1	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	The deceased was released with devices still in place. Staff did not note their presence so the funeral director was not offered the option of removal.
CAS-35818-Z1L3	Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent	Due to a transcription error, the post-mortem examination was not in line with the consent given.
CAS-35819-D8C4	Accidental damage to a body	Human error led to accidental damage
CAS-35982-W4V4	Accidental damage to a body	Human error led to accidental damage
CAS-36021-K9G3	Accidental damage to a body	Human error led to accidental damage
CAS-36047-C6X5	Accidental damage to a body	Human error led to accidental damage
CAS-36053-B8Q7	Major equipment failure	Failure of the bariatric fridges but no signs of any detrimental effects or deterioration of bodies as a result.
CAS-36287-L7X5	Accidental damage to a body	Accidental skin tear damage during dissection.
CAS-36314-C6V5	Accidental damage to a body	Accidental damage to body when admitting into fridge.
CAS-36498-T3R9	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Unintentional retention of tissue slides and blocks.

CAS-36507-S5M3	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	HTA conducted a non-routine inspection of an establishment licensed in the post mortem sector, in order to review the premises following a CQC inspection.
CAS-36530-L8P4	Release of the wrong body	Due to human error, the wrong body was released to funeral directors.
CAS-36621-Y1S2	Discovery of an organ or tissue following post-mortem examination and release of body	Tissue taken from a post mortem was discovered after the release of a body.
CAS-36722-H1B4	Accidental damage to a body	Accidental damage to body.
CAS-36826-S4S5	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of a specimen following post mortem examination.
CAS-36906-D5S3	Accidental damage to a body	Accidental damage to a body due to staff training.
CAS-36918-N9R1	Release of the wrong body	Due to human error, the wrong body was released to funeral directors.
CAS-36947-Q3F8	Serious security breach	Mortuary closure procedure not followed correctly.
CAS-37146-N5K2	Accidental damage to a body	Minor damage to body during routine procedure.
CAS-37207-V5N0	Accidental damage to a body	Inappropriate storage of body.
CAS-37264-T4J1	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Retention of tissue in error.
CAS-37294-Z8V2	Accidental damage to a body	Accidental damage to body when admitting into fridge.
CAS-37295-T7T4	Accidental damage to a body	Damage to deceased on admission to body store.

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

