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Date 26 February 2015

[redacted]

By email to [redacted]

Dear [redacted]

Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOI Act), which was received by the Human Tissue Authority (HTA) on 28 January 2015. Your email outlined the following request:

"Please accept this as a request for information under the FOI Act.

Could you please provide:

i) The number of SAEARs in the human application sector reported to the HTA during 2013 and 2014;

ii) The number of SAEARs in the organ donation and transplantation sector reported to the HTA during 2013 and 2014;

iii) Please also provide a description of each incident and the classification given to each incident.

I look forward to receiving a response within 20 working days."

Response

We can confirm we have treated your email as a request under the Freedom of Information Act.

i) Serious adverse events and reactions (SAEARs) in the Human Application sector reported to the HTA during 2013 and 2014

The European Union Tissue and Cells Directive (EUTCD) states that the HTA must set up a system for tissue establishments to report serious adverse events and reactions. The EUTCD sets out definitions of serious adverse events and reactions as follows:

a) a ‘serious adverse event’ (SAE) is any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

b) ‘serious adverse reaction’ (SAR) is an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Serious adverse events (SAEs) are reported against the process they are linked to, such as ‘storage’ in the case of freezer failure. Serious adverse reactions (SARs) are reported as donor or recipient reactions, depending on whom the reaction has occurred in.

We have performed a search of our licensing system and 181 SAEARs were reported to the HTA by licensed establishments in the Human Application sector during 2013 and 2014.

The classification and description of each of the SAEs in the Human Application sector is in the table below:

Ref no	Process event linked to	Description of Human Application SAE
1	Distribution	Bone labelled with incorrect barcode label. Was recalled and disposed of.
2	Procurement	Failure of a stem cell collection set led to loss of some cells.
3	Storage	One bag of autologous stem cells disposed of in error.
4	Procurement	Contamination of peripheral blood stem cell product with microorganism usually found on skin.
5	Processing	Bacterial contaminant detected on gloves of technician who packaged chondral tissue for distribution.
6	Procurement	A midwife procured cord blood as the trained procurer who was working under a third party agreement was delayed and unable to be present at the birth.
7	Distribution	Eye bank staff issued cornea which was not suitable for endothelial keratoplasty (EK) procedure and surgeon had to cancel operation.
8	Materials	Leak in cord blood cryobag, small quantity of cells lost.
9	Other	Donor issued with out of date medication (Lenograstim) used to mobilise stem cells; did not affect collection of cells.
10	Storage	Two overwrap bags surrounding inner bags which contained cryopreserved cells were damaged; inner bags undamaged.
11	Procurement	Procurer of cord blood did not have a Third Party Agreement, but was collecting under the supervision of a trained person who was acting under Third Party Agreement.
12	Other	Cells infused one hour beyond supplier’s indicated expiry time of 48 hours. Decision made to infuse as cells showed 99% viability.

Ref no	Process event linked to	Description of Human Application SAE
13	Processing	A low volume harvest was partially frozen instead of cooled as the procedure applied to larger volumes.
14	Procurement	Failure of a collection set led to cell spillage in machine during apheresis. Sufficient amount of cells collected.
15	Preservation	Incorrect controlled rate freezing protocol used to cryopreserve autologous stem cell donation.
16	Procurement	One laboratory detected microbial contamination in stem cell harvest, but this could not be verified.
17	Procurement	Tissue bank disposed of femoral head as consent for human application was not in place.
18	Procurement	Retrieved femoral head was discarded as it was placed in fridge rather than in freezer.
19	Procurement	Patient was given alternative stem cell mobilising agent instead of the prescribed one, but collection was successful.
20	Other	Incorrect weight used to calculate cell dose for infusion.
21	Procurement	Retrieval of heart valves undertaken without training or any agreements being in place.
22	Distribution	Wrong type of heart valve issued in error to end user. Suitable valve sourced at short notice.
23	Other	One bag of stem cells dropped and damaged. Sufficient dose of cells in other bags.
24	Processing	Delayed cryopreservation of cells resulted in lower than expected cell viability.
25	Storage	Several cell harvests labelled with incomplete patient details.
26	Other	Leak in one bag of stem cells Sufficient dose of cells in other bags.
27	Storage	Vessels for liver transplantation sent by tissue bank were too short. Consultant decided to use out of date (2 days) vessels instead.
28	Procurement	A potentially high risk donor was not identified. Additional staff training to ensure more rigorous checks take place implemented.
29	Procurement	Donor did not commence injections of mobilization agent on the correct day which led to delays in apheresis collection and infusion into the recipient.
30	Storage	Bag containing cryopreserved stem cells was damaged. Bag placed in overwrap bag and stored.
31	Processing	Labelling errors detected on several stem cell bags stored for transplantation.
32	Procurement	Contamination was detected in a bone marrow harvest.
33	Procurement	A trained procurer who was working under a third party agreement was delayed and a lower than expected volume of cord blood collected.
34	Preservation	Incorrect controlled rate freezing protocol used to cryopreserve cord blood donation. Cells were banked, and error clearly highlighted in records.
35	Transportation	Unexplained interruption in data collected by temperature logging device during transportation of cryopreserved cord blood to end user.

Ref no	Process event linked to	Description of Human Application SAE
36	Storage	Lack of communication between maintenance staff and stem cell laboratory resulted in power outage for four hours during maintenance. No impact on stem cell harvests stored in liquid nitrogen as temperature was maintained.
37	Procurement	Trained midwife who was not working under a third party agreement, procured cord blood, following emergency Caesarean section. Phlebotomist attended shortly after the birth and procured cord tissue, reviewed and was satisfied with procedures followed by midwife.
38	Processing	Concentration of white blood cells in imported stem cell harvest exceeded the internationally recognised limit. Patient engrafted but suffered a late graft failure.
39	Storage	Human error resulted in kits used to procure cartilage being placed in fridge rather than being stored at recommended temperature.
40	Procurement	Unexpected clotting during bone marrow collection due to using non-heparinized syringe. Collection stopped and cells discarded.
41	Materials	Stem cell bag damaged when dropped in cryo-cart. Contents of bag compromised.
42	Preservation	The use of a substitute for the starch solution used when freezing stem cells resulted in clots forming when the product was thawed. A new cryopreservation method was validated.
43	Transportation	Four corneas delivered at wrong hospital. Had to be re-routed to the correct hospital.
44	Testing	Computer error when creating reports for bacteriology test results.
45	Storage	Inner packaging containing heart valve was damaged when outer cardboard package was opened. Alternative heart valve obtained and operation proceeded.
46	Processing	Air flow failure in clean room compromised air quality in area where tissues are processed area. No tissue was being processed at the time.
47	Preservation	Evidence of bacterial contamination in stem cell harvest. The patient's central line was the source of contamination. Cells discarded.
48	Procurement	Leak in apheresis kit noted during collection. Cause identified and rectified.
49	Procurement	Clots formed during collection/processing of PBSCs. Harvest discarded as a precaution.
50	Testing	Bacterial contamination detected in corneal transplant.
51	Storage	Faulty controlled rate freezer resulted in required temperature not being achieved, but did not appear to compromise quality of stem cells.
52	Preservation	Staff forgot to remove frozen cells from the controlled rate freezer and place them in storage.
53	Preservation	Control rate freezer failed during cryopreservation. Product assessed as suitable for transplantation.
54	Storage	Failure of heat-sealer compromised the seal of stem cell storage bag.

Ref no	Process event linked to	Description of Human Application SAE
55	Materials	Leak in stem cell cryobag and cells transferred to another bag.
56	Other	Stem cell stimulating factor administered to donor was not the one which was prescribed.
57	Procurement	One of three bags of bone marrow discarded due to contamination, possibly caused during collection.
58	Procurement	Microbial contamination detected in stem cells collected using a contaminated apheresis line.
59	Materials	Microbial contamination identified in two batches of media. None of the recipients reported any problems but as a precaution, all recalled early for review by consultant.
60	Procurement	Contamination of bone marrow harvest, thought to have arisen from poor aseptic technique during procurement.
61	Procurement	Microbial contamination in bone marrow harvest, probably occurred during procurement.
62	Preservation	Liquid nitrogen ran out during cryopreservation of stem cells, Cells deemed unsuitable.
63	Materials	Leak noted in cryobag containing stem cells and small amount of cells lost.
64	Other	Loss of traceability of acellular materials delivered to end user as ineffective systems in place.
65	Procurement	Infection from central line resulted in contamination and loss of autologous stem cells.
66	Storage	Due to failure of freezer, stored femoral heads were disposed and freezer replaced.
67	Preservation	Increase in delay to engraftment where cryopreserved cells prompted investigation and change in cryopreservation process.
68	Distribution	Delay in delivery of urgent allograft, resulted in surgeon using autograft as well as allograft.
69	Procurement	Contamination of bone marrow harvest. Likely cause skin contamination from donor.
70	Procurement	Contamination of bone marrow harvest.
71	Other	End-user did not follow documented procedure- swabbing bone strut before implantation to identify contamination.
72	Transportation	Cord blood for transplant irradiated at airport; cell viability did not appear to be affected and patient successfully engrafted.
73	Procurement	Faulty assembly in apheresis machine resulted in harvest with high red blood cell levels.
74	Processing	Contamination detected in two cell cultures from thymus which were discarded.
75	Distribution	Sub-optimal cell count and viability in cord blood units supplied via a registry.
76	Processing	Leak observed in port on one bag of stem cells; cells discarded.
77	Testing	Sign off procedures to ensure donor testing for HTLV 1 was in place for tissue imported from the US was not followed.

Ref no	Process event linked to	Description of Human Application SAE
78	Processing	Errors in initial count lead to overloading of columns resulting in unsuccessful T cell depletion; product not infused.
79	Procurement	Bacterial contamination detected in bone marrow harvest, received via a registry.
80	Procurement	Contamination detected in bone marrow harvest, most probably occurred during procurement.
81	Procurement	High level of incompatible red cells in stem cell product received through a registry.
82	Other	Post mortem identified high likelihood of sporadic CJD in donor of femoral head donor 8 years after donation.
83	Processing	Microbial growth observed in medium used to de-swell cornea.
84	Procurement	Three contaminated bone marrow procurements detected.
85	Testing	Swab of bone taken just before bone was implanted was not labelled and so not tested for microbial contamination.
86	Transportation	Traceability of cord blood unit en-route from overseas was lost for short period of time and arrived late.
87	Procurement	Clotting during apheresis collection, not due to equipment failure; cells could not be used.
88	Other	Cells clotted during infusion into recipient.
89	Procurement	Bacterial contamination of bone marrow harvest detected- by skin commensals.
90	Distribution	Quality checks on epithelial surface of cornea prior to release for end use failed to detect evidence of previous surgery.
91	Distribution	Two corneas which did not meet release criteria were released for distribution and transplanted.
92	Storage	Cord blood cells leaked from cryobag during transport to end; caused by defective heat sealer.
93	Preservation	Fault in controlled rate freezer affected freezing protocol for ovarian tissue. Tissues will be issued under concessionary release.
94	Preservation	Controlled rate freezer failure resulted in loss of cell viability. Collection repeated and successful transplant and engraftment took place.
95	Materials	Cryobag leaked during thawing, however transplant proceeded and patient engrafted with no adverse effects.
96	Procurement	Bacterial contamination of a bone marrow harvest, attributed to a skin commensal.
97	Distribution	Cornea incorrectly released, as it did not meet the specifications required by surgeon.
98	Other	Clumps of white cells observed during infusion of stem cells.
99	Storage	Cells were in contact with cryo-preservative for extended period of time as heat sealer was not used correctly; stem cell quality compromised.
100	Other	End user mistakenly transplanted Rh+ femoral head into patient.
101	Materials	Damaged seal on cryobag; leaking of cells observed during infusion of stem cells into recipient.

Ref no	Process event linked to	Description of Human Application SAE
102	Materials	Inlet seal of cryobag snapped after cryopreservation exposing cells to atmosphere.
103	Procurement	End user detected microbial contamination (skin commensal) in bone marrow collection.
104	Materials	Cryobag leaked when thawed before infusing into recipient. Small amount of stem cells lost but infusion continued successfully.
105	Procurement	Contamination of bone marrow harvests detected at the end user site, but not at the procurement site.
106	Distribution	Incorrect weight used to calculate dosage of stem cells sourced using a registry.
107	Distribution	Stem cell collection was stored in insulated box left in laboratory overnight and not placed in fridge.
108	Procurement	Bacterial contamination of one bag of stem cells, probably due to a skin commensal from the donor.
109	Processing	Faulty incubator used to process cells for patient treatment.
110	Storage	Bag of stem cells dropped when it was from a liquid nitrogen storage tank.
111	Procurement	Faulty assembly in apheresis machine resulted in harvest with high level of red cells.
112	Storage	Power failure resulted in the failure of the bone bank freezer and data logger.
113	Distribution	Borderline cornea released for transplantation; should not have been released
114	Procurement	Stem cells were procured through contaminated line attached to donor.
115	Storage	Heat seal failure resulted in cells leaking from cryobags.
116	Other	Clumping observed in bag of stem cells during infusion.
117	Testing	Low levels of Hepatitis B viral DNA detected in stem cell donor after donation. Pre donation result was negative. Probably due to rare reactivation of dormant virus during mobilisation.
118	Procurement	Fibrin type clots/clumps observed during apheresis (stem cell collection).
119	Procurement	Staff inexperience led to some loss of stem cells during collection.
120	Procurement	Untrained nurse procured cord blood after following phlebotomist's instructions over the phone. Phlebotomist worked under a third party agreement, but could not attend the labour ward in time.
121	Distribution	Stem cell collections from two donors reserved for one patient. Clinician requested collection from one donor, but tissue bank release collection from the other donor.
122	Storage	Cryo-storage tank left open and room left unsecure and unsupervised by engineers during routine maintenance.
123	Testing	Incorrect parameters used to calculate cell collection and patient received unnecessary pre-collection component support.
124	Transportation	Battery failure in data logger during transportation; no reason to believe the cord unit has been affected.

Ref no	Process event linked to	Description of Human Application SAE
125	Procurement	'Break seal' failure of inline tubing resulted in product loss during collection of stem cells.
126	Preservation	Poor quality of donor lymphocytes obtained following cryopreservation; cells discarded.
127	Transportation	Damage caused to three cryobags most probably due to mishandling during transport.
128	Other	The donor was incorrectly (verbally) identified as a match for their sibling; was followed up and corrected.
129	Testing	Microbiology department detected bacteria on swabs from several femoral heads; most likely due to cross contamination in the microbiology laboratory.
130	Procurement	Procurement of cord tissue using staff who were not working under a third party agreement.
131	Procurement	Yeast contamination of stem cells collected by apheresis using haemodialysis line. Cells discarded and patient successfully remobilised.
132	Transportation	Cord blood thawed during transportation. Cells unusable for transplant.
133	Transportation	Stem cells accidentally passed through airport x-ray machine. Follow up testing indicated no impact on cells, or recipient.
134	Materials	Leak in cryobag containing stem cells observed during thawing of cells.
135	Distribution	Incorrect cord blood unit handed to courier for distribution.
136	Processing	Media used when processing skin found to be contaminated.
137	Other	During preparation of a cornea the graft tore and could not be used.
138	Storage	Hepatitis C positive stem cells harvested in 1997 were not being stored high risk quarantine tank.
139	Processing	Clean room failure; No processing was taking place in the clean room suite at the time and none was planned.
140	Transportation	Discrepancies observed between temperature unit and manual temperature checks when monitoring temperature of stem cell units during transport.
141	Procurement	Contamination (microbial skin contaminant) detected in stem cells collected by apheresis.
142	Materials	Outer packaging did not meet acceptable quality to act as an effective sterile barrier. Product recall carried out.
143	Preservation	Programmable freezer failure during cryopreservation of therapeutic T cells.
144	Testing	Sibling donor assessment did not detect borderline neutropenia.
145	Storage	During retrieval from cryo-storage one cryobag containing stem cells was dropped and damaged.
146	Procurement	Microbial contamination detected in stem cells collected using a contaminated line.
147	Storage	Control valve failure during filling of liquid nitrogen storage tank resulted in cryobags being immersed in liquid nitrogen.

Ref no	Process event linked to	Description of Human Application SAE
148	Procurement	Apheresis machine failed during harvesting.
149	Storage	Incorrect stem cells retrieved from storage. Patient infusion delayed until correct bag of stem cells located. Incident due to transcription error. Processes being reviewed.
150	Procurement	Contamination of stem cells harvest detected.
151	Procurement	Bone marrow collected from sibling donor found to be contaminated.
152	Storage	Out of date strut graft issued to end user; not used.

The classification and description of each of the SARs in Human Application sector is in the table below:

Ref No	Patient reaction occurred in	Description of Human Application SAR
1	Recipient	Neurological symptoms following reinfusion of stem cells collected by apheresis.
2	Donor	Donor had an allergic reaction, probably to citrate, during apheresis.
3	Recipient	Reaction due to the large volume of stem cells infused into paediatric patient.
4	Recipient	Recipient reaction due to high Anti-A in the bone marrow transfusion product following clinical decision to infuse an unwashed ABO incompatible bone marrow product.
5	Recipient	Mild reaction following allogeneic bone marrow transplant in recipient.
6	Recipient	Reaction following infusion of cord blood into recipient. Decision made to wash any further donations before infusion into patient.
7	Recipient	Reaction in recipient following cord blood infusion most probably due to the presence of red blood cells.
8	Recipient	Recipient suffered from endophthalmitis and loss of vision, caused by slow growing Mycobacterium species. Contamination could be of donor origin, but no evidence to confirm.
9	Donor	Donor reaction, during apheresis due to citrate toxicity.
10	Recipient	Low cell viability and cell counts in cryopreserved cord blood unit used for infusion into recipient.
11	Donor	Donor reaction during apheresis, due to citrate toxicity.
12	Recipient	Haematuria following infusion of cord blood obtained via a registry; most probably due to the presence of red blood cells.
13	Recipient	Infection following implantation of irradiated tendons. Not able to link reaction to the implant.
14	Recipient	Recipient received and reacted to contaminated bone marrow donation.
15	Recipient	Recipient developed reaction to cryopreservative used to preserve stem cells.

Ref No	Patient reaction occurred in	Description of Human Application SAR
16	Recipient	Recipient developed Endopthalmitis following corneal transplant. Two eye banks were involved but so far no clear evidence to implicate cornea, as tests were negative.
17	Recipient	Transplant recipient undergoing double red cell depleted cord transplant developed; may be due to lysed red cells in cord blood.
18	Recipient	Clinical decision made to infuse E.coli positive autologous cord blood resulted in infection in recipient.
19	Recipient	Primary graft failure due to an infection. Cornea released in accordance with eye bank's quality procedures, unable to confirm if the infection was transmitted from the donor or related to the quality of the cornea.
20	Recipient	Failure of stem cell engraftment. Patient died shortly afterwards. Unable to confirm that it was related to quality and safety of cells.
21	Recipient	The recipient had a bacterial infection following use of pericardium during eye surgery. Surgeon stated that it is unlikely that the reaction was linked to the quality of the graft.
22	Donor	Donor fainted after donating stem cells.
23	Donor	Donor reaction could be due to citrate toxicity; however donor has a history of palpitations.
24	Recipient	Post-operative dilation of transplanted pulmonary valve; graft removed.
25	Donor	Patient fainted after donating stem cells.
26	Donor	Donor reaction possibly to medications used to prime donor for stem cell collection by apheresis.
27	Donor	Cardiac event in an anxious patient at time of attempted stem cell collection.
28	Donor	Sibling stem cell donor was hospitalized following administration of stem cell mobilising agent which resulted in side effects.
29	Recipient	Following cord blood transfusion, patient had reduced pulse rate. Possible reaction to preservation component in cord blood. Patient recovered.

ii) SAEARs in the organ donation and transplantation (ODT) sector reported to the HTA during 2013 and 2014

SAEARs in the ODT sector must be reported under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the 2012 Regulations).

The 2012 Regulations define SAEARs in the ODT sector as follows:

a) a serious adverse event (SAE) is ‘any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity’.

SAEs that may influence the quality and safety of an organ and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs must be reported and investigated.

The HTA also requires that any SAEs which occur at a transplant centre which may influence the quality and safety of an organ must be reported and investigated.

b) A serious adverse reaction (SAR) is 'an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity'.

SARs observed during or after transplantation which may be connected to the testing, characterisation, procurement, preservation and transport of organs must be reported and investigated.

NHS Blood and Transplant (NHSBT) manage the system for reporting and managing ODT SAEARs on behalf of the HTA as one of a series of assisted functions. Reports of ODT SAEs and SARs are made to NHSBT as part of their wider clinical incident reporting system, which is a continuation of the practice NHS establishments undertook prior to the introduction of the 2012 Regulations.

NHSBT investigate the reports they receive and report incidents which meet the definition of a SAE or SAR under the 2012 Regulations to the HTA. NHSBT notify the HTA of the steps being taken to manage the SAEAR and provide confirmation that all actions associated with the SAEAR have been concluded.

We have performed a search of our licensing system and 77 ODT SAEARs were reported to the HTA, via NHSBT, by licensed establishments in the ODT sector during 2013 and 2014.

The classification and description of each of the ODT SAEARs is in the table below:

Ref no	ODT SAE or SAR	Patient reaction occurred in	Brief Description
1	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
2	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
3	ODT SAE	N/A	Malignancy in donor organ; lesion removed.
4	ODT SAR	Recipient	Incorrect packaging/ preservation fluid.
5	ODT SAE	N/A	Incorrect virology recorded - organs accepted for transplant and recipient centre immediately informed.
6	ODT SAE	N/A	Tumour in organ identified post transplantation.
7	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
8	ODT SAE	N/A	Potential tumour in organ detected post-transplant.

Ref no	ODT SAE or SAR	Patient reaction occurred in	Brief Description
9	ODT SAE	N/A	Damage during organ retrieval – organ had been accepted for transplant but was later deemed to be unsuitable.
10	ODT SAE	N/A	Blood group error - identified when potential organ transplant recipient was admitted for transplant.
11	ODT SAR	Recipient	Poorly packaged organ.
12	ODT SAR	Recipient	Organ recipient acquired metabolic disease from donor.
13	ODT SAE	N/A	Retrieval damage to organ during operation on live donor.
14	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
15	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
16	ODT SAR	Donor	Retrieval damage to organ during operation on live donor.
17	ODT SAE	N/A	Loss of organs - not appropriately perfused at retrieval.
18	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted
19	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
20	ODT SAE	N/A	Discrepancy in virology results- laboratory transcription error.
21	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
22	ODT SAR	Recipient	Incorrect perfusion fluid used by transplant centre. Organ transplanted and subsequently removed.
23	ODT SAR	Recipient	Damage during retrieval, organ transplanted, and subsequently removed.
24	ODT SAE	N/A	Incorrect type of perfusion fluid used to perfuse organ – organ not transplantable.
25	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
26	ODT SAR	Recipient	Incorrect Donor HLA reported for organ recipient.
27	ODT SAE	N/A	Following transplantation of an organ, a non-malignant tumour was detected in another organ.
28	ODT SAE	N/A	Loss of organ for transplant due to considerable blood loss during retrieval.
29	ODT SAE	N/A	Donor malignancy discovered during post mortem - after organs were transplanted.
30	ODT SAE	N/A	Super urgent patient (recipient) removed from waiting list in error.
31	ODT SAR	Recipient	Damage during retrieval; organ transplanted and subsequently removed.
32	ODT SAE	N/A	Donor infection detected after organs were transplanted.
33	ODT SAR	Recipient	Infection in recipient; most likely donor derived infection.
34	ODT SAE	N/A	Unlabelled organ box caused delay and contributed to organs not transplanted
35	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.

Ref no	ODT SAE or SAR	Patient reaction occurred in	Brief Description
36	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
37	ODT SAR	Recipient	Transmission of infection from donor to recipient, transcription error.
38	ODT SAE	N/A	Malignancy discovered during post mortem on donor.
39	ODT SAE	N/A	Delay in test results; incorrect processing of sample in laboratory.
40	ODT SAR	Recipient	Possible transmission of infection from donor to organ recipient.
41*	ODT SAR	Recipient	Aborted transplantation procedure - potential donor malignancy identified at time of transplantation.
42*	ODT SAE	N/A	Potential donor malignancy not recorded on EOS (Electronic Offering System) at time of offer – organ transplanted.
43	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
44	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
45	ODT SAR	Recipient	Recipient underwent unnecessary general anaesthetic; donor malignancy discovered and organ not transplanted.
46	ODT SAE	N/A	Potential for transmission of infection from donor to organ recipient.
47	ODT SAR	Recipient	Transmission of infection from donor to two organ recipients.
48	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
49	ODT SAE	N/A	Delays in transport of organs – one organ not transplanted.
50	ODT SAE	N/A	Recipient centre detected malignancy in one organ; other organ already transplanted.
51*	ODT SAE	N/A	Donor malignancy discovered after one organ was transplanted. Other organ transplanted based on clinical risk assessment.
52*	ODT SAR	Recipient	Donor malignancy discovered during retrieval. Two organs were transplanted, but one potential recipient for another organ was anaesthetized unnecessarily as transplant of that organ was aborted.
53	ODT SAR	Recipient	Organ found unsuitable for transplant at back bench at recipient centre - recipient had already been anaesthetized.
54	ODT SAE	N/A	Poor perfusion of organs. Organs not transplanted.
55	ODT SAE	N/A	Biopsy not taken appropriately; organ disposed of.
56	ODT SAE	N/A	Organ not retrieved as the amount of perfusion fluid available in the theatre was not sufficient.
57	ODT SAE	N/A	Organ found unsuitable for transplant due to damage - recipient already anaesthetized.

Ref no	ODT SAE or SAR	Patient reaction occurred in	Brief Description
58	ODT SAE	N/A	Damage during retrieval of organ; damage repaired and organ transplanted.
59	ODT SAE	N/A	Laboratory tissue typing transcription error; impact on organ allocation.
60	ODT SAE	N/A	Organ incorrectly packaged; not transplanted.
61	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
62	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
63	ODT SAR	Recipient	Recipient anaesthetized unnecessarily; organ could not be transplanted.
64	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
65	ODT SAR	Donor	Living donor was hospitalized for a prolonged period following donation.
66	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
67	ODT SAR	Recipient	Post-transplant complication in organ recipient.
68	ODT SAR	Recipient	Transmission of viral infection from donor to recipient five years post-transplant.
69	ODT SAR	Recipient	Transmission of infection from donor to recipient.
70	ODT SAE	N/A	Recipient centre detected a thrombus in organ. Organ not transplanted.
71	ODT SAE	N/A	Damage during organ retrieval - organ not transplanted.
72	ODT SAE	N/A	Malignancy detected in organ, post transplantation.
73**	ODT SAE	N/A	Perfusion protocol not followed.
74**	ODT SAR	Recipient	Post-transplant complications in recipient. Recipient required re-graft.
75	ODT SAR	Recipient	Organ size not communicated, also poor perfusion and packaging - organ transplanted, recipient suffered early graft dysfunction and died.
76	ODT SAE	N/A	Organ inadequately perfused and sent to the wrong destination - organ not transplanted.
77	ODT SAE	N/A	Miscommunication of information from retrieval centre to implanting centre – organ could not be used as recipient not ready for transplant.

* same incident resulted in SAE and SAR

** same incident resulted in SAE and SAR

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

There is no charge for making an appeal.

Yours sincerely

[redacted]

[redacted]