Human Tissue Authority

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Date: 29 March 2022

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 4 March 2022. Your email outlined the following request:

"For (i) 2019, (ii) 2020 and (iii) 2021 please provide me with a table of Serious Adverse Events and Adverse Reactions in the organ donation and transplantation sector. Please could this table be provided in the same level of detail as that provided in a previous FoI response [Ref: 26 February 2015]. However, if there was an infection or disease transmitted to the recipient then please state what this disease or infection was."

Response

The HTA holds information about Serious Adverse Events and Adverse Reactions (SAEARs) in the Organ Donation and Transplantation (ODT) sector.

Serious Adverse Events and Adverse Reactions (SAEARs) in the organ donation and transplantation (ODT) sector must be reported under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended), referred to as the 'Regulations'.

The 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.

The Regulations set out a number of functions that the HTA must undertake and allows the HTA to make arrangements for other organisations to assist us in carrying out these functions. 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.

NHSBT oversee the reports they receive and report all incidents that meet the definition of a SAE or SAR 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.

The HTA routinely publishes quarterly reports, detailing the nature and volume of incidents reported, on its website.

In reviewing the information you have requested, we have noted that some of the information we hold is exempt from disclosure by virtue of the following exemptions:

Section 21

Information is absolutely exempt under Section 21 if it is accessible to the applicant by other means. Information in relation to SAEARs covering the period April 2020 to December 2021 can be found on the disclosing information on incidents page on the HTA website: https://www.hta.gov.uk/about-hta/transparency/disclosing-information-incidents If you have any difficulties in accessing this information at the source which I have provided, please contact me again.

Information that is not currently published on the HTA website covering the period from January 2019 to March 2020 has been provided in the Appendix.

Section 31

Section 31(1)(g) of the FOIA provides an exemption for "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".

We have set out below the matters we have taken into account in considering where the balance of public interest lies concerning the release of information about SAEARs in the ODT sector.

- We acknowledge that there is a public interest in the HTA and how we fulfil our regulatory function, which includes the reporting and investigation of SAEARs in the ODT sector. We also acknowledge that there is public interest in having information about SAEARs in the ODT sector. We have therefore concluded that the public interest in disclosing that information outweighs the public interest in not disclosing that information.

- We have also considered where the balance of public interest lies in disclosing the information you have requested for individual incidents, including specific details of any potential disease or infection transmission.

- We have concluded that releasing all the information you have requested could have an adverse impact on the quality of reports supplied. The prospect of disclosure under FOIA is likely to result in a cautious and restrictive approach to SAEARs reporting, which could in turn be a risk to public safety.

- Establishments being deterred from providing detailed and frank reports by the prospect of disclosure would clearly prejudice our supervisory functions in relation to licensed establishments and would make it more difficult for us to establish whether formal regulatory action is required in specific cases.

Having reviewed the potential information we could release in response to your request for further details, we are satisfied that full disclosure of the detail in the reports is information which, if disclosed, would prejudice our ability to exercise our regulatory functions in supervising licensed establishments and investigating SAEARs.

We have therefore concluded that we will not disclose all of the information you requested; we believe that the public interest in disclosing some of that information does not outweigh the public interest in not disclosing that information.

The information for which we believe the balance of public interest in not disclosing outweighs the public interest in disclosing is as follows:

- precise detail of each individual SAEAR, including the identification of any disease or infection potentially transmitted.

We have therefore not disclosed this information in our response.

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, 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.org.uk

Yours sincerely

Appendix

ODT sector SAEARs, January – December 2019 and January – March 2020

We have performed a search of our system and a breakdown of the number of ODT SAEARs reported to the HTA, through NHSBT, by licensed establishments in the ODT sector:

- January – December 2019: 110 ODT SAEARs were reported.
- January 2020 – March 2020: 18 ODT SAEARs were reported.

The classification and description of each of the ODT SAEARs for these periods can be found in the tables below:

January – December 2019 110 incidents:

Number	Subject	Description of incident
1	ODT SAE	Damage to pancreas - not transplanted
2	ODT SAE	Damage to kidney - not transplanted
3	ODT SAE	Damage to pancreas - not transplanted
4	ODT SAE	Findings post-transplant
5	ODT SAE	Damage to kidney - not transplanted
6	ODT SAE	Probable donor derived infection
7	ODT SAR	Probable donor transmitted infection
8	ODT SAR	Probable donor derived infection
9	ODT SAE	Probable donor derived infection
10	ODT SAE	Probable donor derived infection
11	ODT SAE	Probable donor derived infection

12	ODT SAR	Biopsy site bleed
13	ODT SAR	Damage to kidney - recipient impacted
14	ODT SAR	Possible donor transmitted infection
15	ODT SAR	Biopsy site bleed
16	ODT SAE	Damage to liver - not transplanted
17	ODT SAE	Damage to liver - not transplanted
18	ODT SAR	Probable donor transmitted infection
19	ODT SAE	Probable donor transmitted infection
20	ODT SAE	Damage to pancreas - not transplantable
21	ODT SAR	Biopsy site bleed
22	ODT SAE	Damage to pancreas - not transplanted
23	ODT SAR	Possible donor derived disease
24	ODT SAR	Possible donor derived disease
25	ODT SAR	Probable donor derived disease
26	ODT SAE	Probable donor derived disease
27	ODT SAR	Probable donor derived disease
28	ODT SAR	Biopsy site bleed
29	ODT SAR	Recipient anaesthetised - transplant did not proceed

30	ODT SAR	Damage to liver
31	ODT SAE	Potential for donor derived disease
32	ODT SAR	Potential for donor derived disease
33	ODT SAE	Unexpected finding post-transplant
34	ODT SAR	Recipient anaesthetised - did not receive a transplant
35	ODT SAR	Recipient anaesthetised - transplant did not proceed
36	ODT SAR	Transplantation did not proceed
37	ODT SAE	Damage to kidney - not transplanted
38	ODT SAE	Damage to kidney - not transplanted
39	ODT SAR	Increased recipient anaesthetic
40	ODT SAE	Finding post-transplant
41	ODT SAR	Living donation - finding in donor - donation did not proceed
42	ODT SAE	Living donation - finding in donor - long chain did not proceed
43	ODT SAE	Cross-matching not completed prior to transplantation
44	ODT SAR	Extended recipient anaesthetic
45	ODT SAR	Probable donor transmitted infection
46	ODT SAE	Probable donor transmitted infection
47	ODT SAR	Possible donor transmitted infection

48	ODT SAE	Possible donor transmitted infection
49	ODT SAE	Possible donor transmitted infection
50	ODT SAE	Damage to liver - not transplanted
51	ODT SAE	Damage to kidney - not transplanted
52	ODT SAR	Probable donor transmitted infection
53	ODT SAE	Probable donor transmitted infection
54	ODT SAE	Unexpected finding post-transplant
55	ODT SAE	Damage to liver - not transplanted
56	ODT SAE	Damage to pancreas - not transplanted
57	ODT SAR	Potential for donor derived disease
58	ODT SAE	Unexpected finding post-transplant
59	ODT SAE	Extended cold ischaemic time to heart - not transplanted
60	ODT SAR	Recipient anaesthetised – transplant did not proceed
61	ODT SAE	Biopsy site bleed
62	ODT SAR	Biopsy site bleed
63	ODT SAR	Biopsy site bleed
64	ODT SAE	Biopsy site bleed
65	ODT SAE	Damage to pancreas - not transplanted

66	ODT SAE	Inadequate kidney perfusion – not transplanted
67	ODT SAE	Kidney offer outcome not communicated - not transplanted
68	ODT SAR	Biopsy site bleed
69	ODT SAE	Damage to kidney - not transplanted
70	ODT SAE	Damage to liver - not transplanted
71	ODT SAE	Damage to kidney - not transplanted
72	ODT SAE	Damage to kidney
73	ODT SAR	Damage to kidney
74	ODT SAE	Loss of liver due to transport incident
75	ODT SAE	Possible donor derived infection
76	ODT SAE	Possible donor derived infection
77	ODT SAR	Potential donor derived infection
78	ODT SAR	Damage to split liver
79	ODT SAE	Damage to split liver
80	ODT SAE	Finding post-transplant
81	ODT SAR	Prolonged retrieval
82	ODT SAR	Damage to liver
83	ODT SAE	Damage to pancreas - not transplanted

84	ODT SAE	Potential for donor derived disease
85	ODT SAE	Potential for donor derived disease
86	ODT SAR	Probable donor derived infection
87	ODT SAE	Probable donor derived infection
88	ODT SAE	Potential for donor derived disease
89	ODT SAR	Potential for donor derived disease
90	ODT SAE	Potential for donor derived disease
91	ODT SAR	Potential for donor derived disease
92	ODT SAE	Biopsy site bleed
93	ODT SAR	Biopsy site bleed
94	ODT SAE	Damage to pancreas - not transplanted
95	ODT SAR	Living donation - kidney removed following re-perfusion at transplantation
96	ODT SAE	Complications during retrieval process
97	ODT SAR	Recipient impacted post-transplant
98	ODT SAE	Damage to organ - not transplanted
99	ODT SAE	Living donation - damage to kidney - not transplanted
100	ODT SAE	Probable donor transmitted infection
101	ODT SAR	Probable donor transmitted infection

102	ODT SAE	Damage to kidney - not transplanted
103	ODT SAR	Damage to liver
104	ODT SAE	Damage to liver
105	ODT SAE	Organ packing - not transplanted
106	ODT SAE	Damage to organ
107	ODT SAE	Damage to organ
108	ODT SAE	Unexpected finding post-transplant
109	ODT SAE	Damage to pancreas - not transplanted
110	ODT SAE	Damage to pancreas - not transplanted

January – March 2020 18 incidents:

Number	**Subject**	**Description of incident**
1	ODT SAE	Damage to heart - not transplanted
2	ODT SAE	Damage to organ - transplanted
3	ODT SAR	Damage to organ - transplanted
4	ODT SAE	Damage to organ - not transplanted
5	ODT SAE	Damage to pancreas - not transplanted
6	ODT SAE	Damage to organ - not transplanted
7	ODT SAE	Damage to organ
8	ODT SAE	Damage to organ
9	ODT SAE	Damage to organ - not transplanted
10	ODT SAE	Damage to organ

11	ODT SAE	Damage to pancreas - not transplanted
12	ODT SAR	Possible donor derived disease
13	ODT SAE	Possible donor derived disease
14	ODT SAE	Damage to organ - not transplanted
15	ODT SAR	Recipient anaesthetised - transplant did not proceed
16	ODT SAE	Organ characterisation
17	ODT SAE	Organ flushed with incorrect solution
18	ODT SAR	Organ flushed with incorrect solution