Human Tissue Authority
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London
SW1W 9SZ

Tel 020 7269 1900
Web www.hta.gov.uk
Email enquiries@hta.gov.uk
Date 18 April 2019

[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 21 March 2019. Your email outlined the following request:

FREEDOM OF INFORMATION ACT REQUEST

For (i) 2016, (ii) 2017 and (iii) 2018 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.

Yours Sincerely,

Response

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 (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.

The 2012 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 investigate the reports they receive and report 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.

In considering what information should be released to meet this FOIA, we have excluded certain information on the grounds of the exemption available under Section 31(1)(g) FOIA. This 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".

SAEARs in the ODT sector must be reported to the HTA under the 2012 Regulations, as noted above. We consider that the HTA's function under the 2012 Regulations therefore fall within the scope of s31(1)(g) FOIA.

Section 31(1)(g) FOIA provides a qualified exemption, to which the public interest test must be applied.

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 to us. 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 us with 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:

- details of incidents still under consideration or investigation; and
- precise detail of each individual resolved incident, including the identification of any disease or infection potentially transmitted.

We have therefore not disclosed this information in our response.

In addition, section 40(3)(a)(i) FOIA provides that information is absolutely exempt if its disclosure would breach data protection principles. We have concluded that disclosure of personal information in the reports would be unfair to the individuals affected by the descriptions who could have no expectation that information relating to them would be made public.

The descriptions provided in this response have therefore been summarised so that they do not include any information which could lead to a person being identified which would otherwise be possible given the relatively small number of incidents.

ODT sector SAEARs in 2016, 2017 and 2018

We have performed a search of our system and 145 ODT SAEARs were reported to the HTA, through NHSBT, by licensed establishments in the ODT sector in each of the calendar years 2016, 2017 and 2018. This represents a very small proportion of activity in this sector. Below is a table of the numbers of donors and transplants for each of the years ending 31 March 2016, 2017 and 2018.

Year to 31 March	31 March 16	31 March17	31 March18
Deceased Donors	1364	1413	1574
Deceased Donor Transplants	3528	3719	4039

	2015-16	2016-17	2017-18
Adult living donor kidney Transplants	1025	1000	1010

The classification and description of each of the ODT SAEARs can be found in the table below by calendar year. Where cases remain open because investigations are ongoing, we have made this clear by stating that no information will be released.

2016: 51 Incidents

Number	Subject	Description of Incident
1	ODT SAE	Organ damage, organ not transplantable
2	ODT SAR	Organ damage, prolonged hospitalisation
3	ODT SAE	Organ damage, organ not transplantable
4	ODT SAR	Delayed transplantation
5	ODT SAR	Possible transmissible infection
6	ODT SAR	Haematuria in recipient post-transplant
7	ODT SAE	Malignancy in living donor post donation
8	ODT SAE	Incorrect packaging of organ, organ not transplantable
9	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation

10	ODT SAR	Organ damage, prolonged hospitalisation
11	ODT SAE	Organ not transplantable
12	ODT SAE	Organ not transplantable
13	ODT SAE	Organ damage, solid organ not transplanted
14	ODT SAR	Malignancy transmission
15	ODT SAE	Organ damage, organ not transplantable
16	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation
17	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation
18	ODT SAE	Organ not transplantable following retrieval
19	ODT SAE	Organ damage, organ not transplantable
20	ODT SAR	Possible transmitted infection
21	ODT SAE	Organ damage, organ not transplantable
22	ODT SAE	Organ damage, organ not transplantable
23	ODT SAE	Malignancy transmission
24	ODT SAR	Haemorrhage in recipient post-transplant
25	ODT SAE	Organ not transplantable following retrieval
26	ODT SAR	Haemorrhage in recipient post-transplant
27	ODT SAE	Organ not transplantable following retrieval
28	ODT SAE	New clinical information identified post-transplant
29	ODT SAR	No information will be released as case ongoing
30	ODT SAR	No information will be released as case ongoing
31	ODT SAE	Malignancy in living donor post donation
32	ODT SAR	Transmissible infection
33	ODT SAR	Transmissible infection

34	ODT SAR	Transmissible infection
35	ODT SAE	New clinical findings post-transplant
36	ODT SAE	Expired perfusion fluid used during back bench preparation
37	ODT SAE	Organ damage, organ not transplantable
38	ODT SAE	Organ not transplantable following retrieval
39	ODT SAE	Perfusion inadequate, organ not transplantable
40	ODT SAR	Prolonged hospitalisation
41	ODT SAE	Organ not transplantable following retrieval
42	ODT SAR	Graft failure post-transplant
43	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation
44	ODT SAE	Organ damage, organ not transplantable
45	ODT SAE	Transmissible infection
46	ODT SAR	New clinical information received post-transplant
47	ODT SAE	Organ damage, organ not transplantable
48	ODT SAE	Discrepant clinical information post-transplant
49	ODT SAE	Organ damage, organ not transplantable
50	ODT SAR	Organ damage, prolonged anaesthesia
51	ODT SAE	Organ damage, organ not transplantable

2017: 46 Incidents

Number	Subject	Description of Incident
1	ODT SAE	Organ not transplantable following retrieval
2	ODT SAE	Organ not transplantable following retrieval
3	ODT SAE	Organ damage, organ not transplantable

4	ODT SAE	Organ damage, organ not transplantable
5	ODT SAE	Organ damage, organ not transplantable
6	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation
7	ODT SAE	Organ damage, organ not transplantable
8	ODT SAR	Malignancy transmission
9	ODT SAE	Organ damage, organ not transplantable
10	ODT SAR	Malignancy transmission
11	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation
12	ODT SAR	New clinical information, prolonged anaesthesia
13	ODT SAE	Organ not transplantable following retrieval
14	ODT SAE	Organ not transplantable following retrieval
15	ODT SAR	Malignancy transmission
16	ODT SAR	Organ not transplantable, prolonged anaesthesia
17	ODT SAE	Organ damage, organ not transplantable
18	ODT SAE	Organ not transplantable following retrieval
19	ODT SAE	Organ damage, organ not transplantable
20	ODT SAE	Organ damage, organ not transplantable
21	ODT SAE	Malignancy transmission
22	ODT SAE	Organ not transplantable following retrieval
23	ODT SAE	New clinical findings post-transplant
24	ODT SAR	Transmissible infection
25	ODT SAE	Organ damage, organ not transplantable
26	ODT SAE	Organ damage, organ not transplantable
27	ODT SAE	Organ damage, organ not transplantable

28	ODT SAR	Transmissible infection
29	ODT SAE	Organ damage, organ not transplantable
30	ODT SAR	Organ not transplantable following retrieval
31	ODT SAE	Malignancy transmission
32	ODT SAR	Possible transmissible infection
33	ODT SAE	Organ damage, organ not transplantable
34	ODT SAE	Organ damage, organ not transplantable
35	ODT SAE	Malignancy in living donor post donation
36	ODT SAR	Transplant cancelled resulting in prolonged hospitalisation
37	ODT SAR	New clinical findings post transplantation
38	ODT SAR	Possible transmissible infection
39	ODT SAR	Organ damage resulting in prolonged hospitalisation
40	ODT SAE	Organ damage, organ not transplantable
41	ODT SAE	Unexpected finding identified post-transplant
42	ODT SAR	Transmissible infection
43	ODT SAR	Transmissible infection
44	ODT SAR	Organ damage resulting in prolonged hospitalisation
45	ODT SAE	Organ damage, organ not transplantable
46	ODT SAR	Transmissible infection

2018: 48 Incidents

Number	Subject	Description of Incident
1	ODT SAE	Organ damage, organ not transplantable
2	ODT SAE	Organ damage, organ not transplantable

3	ODT SAR	Transmissible infection
4	ODT SAE	Organ damage, organ not transplantable
5	ODT SAR	Malignancy transmission
6	ODT SAR	Malignancy transmission
7	ODT SAR	No information will be released as case ongoing
8	ODT SAR	Haematuria in recipient post-transplant
9	ODT SAR	Possible transmissible infection
10	ODT SAR	Possible transmissible infection
11	ODT SAR	Haemorrhage in recipient post-transplant
12	ODT SAE	Organ damage, organ not transplantable
13	ODT SAR	Haemorrhage in recipient post-transplant
14	ODT SAR	No information will be released as case ongoing
15	ODT SAR	No information will be released as case ongoing
16	ODT SAE	Organ damage, organ not transplantable
17	ODT SAE	Organ damage, organ not transplantable
18	ODT SAE	Organ damage, organ not transplantable
19	ODT SAR	Organ damage resulting in prolonged hospitalisation
20	ODT SAE	Organ damage, organ not transplantable
21	ODT SAE	New clinical findings post-transplant
22	ODT SAR	No information will be released as case ongoing
23	ODT SAR	Possible transmissible infection
24	ODT SAE	Organ damage, organ not transplantable
25	ODT SAE	Organ damage, organ not transplantable
26	ODT SAE	No information will be released as case ongoing

27	ODT SAR	No information will be released as case ongoing
28	ODT SAE	No information will be released as case ongoing
29	ODT SAR	No information will be released as case ongoing
30	ODT SAE	Organ damage, organ not transplantable
31	ODT SAE	Organ damage, organ not transplantable
32	ODT SAR	Possible transmissible infection
33	ODT SAR	No information will be released as case ongoing
34	ODT SAR	Haemorrhage in recipient post-transplant
35	ODT SAR	Possible transmissible infection
36	ODT SAR	Possible transmissible infection
37	ODT SAE	Organ damage, organ not transplantable
38	ODT SAR	No information will be released as case ongoing
39	ODT SAE	No information will be released as case ongoing
40	ODT SAE	Organ damage, organ not transplantable
41	ODT SAE	Possible transmissible infection
42	ODT SAR	Haemorrhage in recipient post-transplant
43	ODT SAE	Possible transmissible infection
44	ODT SAE	Possible transmissible infection
45	ODT SAE	Possible transmissible infection
46	ODT SAE	Possible transmissible infection
47	ODT SAE	No information will be released as case ongoing
48	ODT SAR	No information will be released as case ongoing

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