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Date 12 April 2016

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 17 March 2016. Your email outlined the following request:

"In a previous FoI response from the HTA dated 26.2.15 you gave details on the number and nature of SAEARs.

In relation to the SAEARs you disclosed for 2013 and 2014 in relation to the transplantation sector I would like the same data, but with most information around each case. So for example when you say organ in each case I'd like to know what organ. When you say incorrect or poorly packaged what was incorrect or poor about it. When you say blood group error what was the error. When you say incorrect donor HLA what exactly was the error and how did it occur. Where an infection is noted what was the infection. If there was a delay in transport what caused the delay?

Could you provide me with similar data for 2015? Ie information on SAEARs in relation to the transplantation sector but with more detail than in your previous response covering 2013 and 2014?"

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 HTA is the Competent Authority for the implementation of the EU Organ Donation Directive, transposed into UK law by the 2012 Regulations. 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, 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.

a) ODT sector Serious Adverse Events (SAEs) reported to the HTA in 2015

We have performed a search of our system and 37 ODT SAEARs were reported to the HTA, via NHSBT, by licensed establishments in the ODT sector during 2015. To add some context to this figure, a total of 2389 living and deceased donors donated organs which resulted in 4501 transplants during 2015.

The category and description of each of the 2015 ODT SAEARs is in the table below:

Ref. no.	Category	Description
1.	Retrieval	Unable to transplant organ - extended cold ischemic time (CIT)
2.	Transport	Original recipient became unavailable for transplant and organ lost through extended CIT
3.	Perfusion	Poorly perfused organ, organ not transplanted
4.	Perfusion	Incorrect perfusate used. Reported as a SAE and then led to a SAR.
5.	Perfusion	Automated perfusion failure
6.	Packaging	Poor packaging of organ resulted in extended CIT
7.	Retrieval	Organ not transplantable following retrieval
8.	Retrieval	Organ not transplantable following retrieval
9.	Retrieval	Organ not transplantable following retrieval
10.	Retrieval	Organ not transplantable following retrieval; recipient already anaesthetised. Reported as a SAE and then led to a SAR.
11.	Perfusion	Poorly perfused organ, organ not transplanted
12.	Perfusion	Poorly perfused organ, organ not transplanted
13.	Retrieval	Organ not transplantable following retrieval
14.	Retrieval	Organ not transplantable following retrieval
15.	Transmissible disease	Organ removed from recipient due to medical complications. Following removal there was an incidental finding of carcinoma which was not present at time of implantation.
16.	Retrieval	Organ not transplantable following retrieval
17.	Retrieval	Organ not transplantable following retrieval
18.	Retrieval	Organ not transplantable following retrieval

Ref. no.	Category	Description
19.	Retrieval	Organ not transplantable following retrieval
20.	Retrieval	Organ not transplantable following retrieval
21.	Communication	Delay in declining organ led to extended CIT
22.	Testing	Delay in testing resulted in extended ischemic time
23.	Testing	Incorrect test results, no known impact on recipients
24.	Perfusion	Poorly perfused organ, organ not transplanted
25.	Retrieval	Organ not transplantable following retrieval
26.	Transport	Lack of appropriate air transportation led to extended CIT for organ, organ not transplanted
27.	Packaging	Incorrect packaging and transport led to extended CIT for organ, organ not transplanted

ODT sector Serious Adverse Reactions (SARs) reported to the HTA in 2015

Ref. no.	Patient the reaction occurred in	Category	Description
1.	Recipient	Retrieval	Extended hospitalisation required following repair to pulmonary artery
2.	Recipient	Transmissible infection	Transmission of donor acquired infection
3.	Recipient	Transmissible infection	Transmission of donor acquired infection
4.	Recipient	Transmissible disease	Transmission of donor derived disease
5.	Recipient	Transmissible disease	Transmission of donor derived disease
6.	Recipient	Transmissible disease	Transmission of donor derived disease
7.	Recipient	Retrieval	Extended hospitalisation required following repair to organ
8.	Donor	Retrieval	Reaction in donor following nephrectomy

Ref. no.	Patient the reaction occurred in	Category	Description
9.	Recipient	Testing	Transmission of donor derived infection
10.	Recipient	Retrieval	Nephrectomy performed following transplant due to failure to graft

b) Further details regarding the ODT SAEARs reported to the HTA in 2013 and 2014 and the same level of further detail for ODT SAEARs reported to the HTA in 2015

Section 31 FOIA

Section 31(1)(g) 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".

Although SAEARs in the ODT sector must be reported under the 2012 Regulations, our view is that the disclosure of the amount of detail you have requested would have an adverse impact on the quality of reports supplied to us, particularly the level of detail supplied in the body of the report. The prospect of disclosure under FOIA is likely to result in a cautious and restrictive approach to SAEARs reporting because of fear of adverse publicity on the part of establishments, which could in turn be a risk to public safety.

Our assessment is that 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, insofar as they relate to the supervision of licensed centres and the investigation of SAEARs in the ODT sector, and that section 31(1)(g) therefore applies.

Public interest test

Section 31 FOIA is a conditional or qualified exemption. This means that, even where it is considered to apply, it may be relied on only if the public interest in applying the exemption outweighs the public interest in disclosure.

We acknowledge that there is a significant public interest in accessing information regarding SAEARs that take place in the ODT sector and there is also real public interest in access to information that relates to our effectiveness as a regulator. We also appreciate there is a public interest in openness and transparency generally.

We are mindful that we have already released summary information regarding the SAEARs reported to the HTA in 2013 and 2014 in the previous response you have referred to, and we

have released the same level of detail for incidents reports to us in 2015 above. This information gives a sufficiently full and fair indication of the nature of reported incidents. We are not satisfied that disclosure of any further detail in the reports would be likely to add significantly to public understanding of the issues raised.

There are a number of reasons why it would be contrary to the public interest for the substance of the reports to be disclosed. There is a very strong public interest in ensuring that licensed establishments in the ODT sector are regulated effectively and report SAEARs so that the incidents can be investigated and corrective and preventative actions put into place. As indicated above, the prospect of publication is likely to have an adverse effect on the quality of future SAEARs reporting and there is a real risk that this in turn would have an adverse impact on our ability to scrutinise reported incidents and to identify cases where regulatory action is required. This in turn would jeopardise our regulatory function to protect and uphold patient safety and public confidence in the sectors we regulate.

Furthermore, we rely on the submission of full and frank SAEARs reports from licensed establishments to enable us to identify trends or sector specific risks in order to issue alerts or guidance. The provision of frank and suitably detailed reports makes a very important contribution to our ability to raise standards and take appropriate action to prevent similar incidents happening elsewhere. In order to carry out this work, we need access to detailed information about incidents and the circumstances which lead to them. It is clearly in the public interest that establishments should not be inhibited from supplying us with information at the necessary level of detail.

In view of the very considerable public interest in ensuring that licensed establishments should not be deterred from supplying us with the information we require in order to discharge our statutory and regulatory functions and promote safe practice, we have concluded that the public interest test in this case favours the application of the section 31(g) exemption to justify the summary disclosure rather than further details of each report. We do not believe that the public interest is served by providing a further level of detail which may jeopardise the effectiveness of the SAEARs notification system, which in turn would reduce the effectiveness of our regulatory activity in this area and our ability to protect patient safety.

Section 40 and section 41 Freedom of Information Act (FOIA)

In reviewing the information you requested we noted some of the descriptions contain information which is exempt by virtue of the fact that it is personal data, disclosure of which would be unfair to the individuals concerned, or which is confidential information relating to deceased individuals which could amount to personal data relating to some of their family members.

Section 40(3)(a)(i) FOIA provides that information is absolutely exempt if its disclosure would breach any of the Data Protection Act's data protection principles. Insofar as the reports contain information relating to identifiable staff members and relatives of deceased individuals, we have concluded that disclosure under FOIA would breach the first data protection principle. One of our rationale for this conclusion is the relatively low number of organ donations and transplantations that take place in the UK each year. Disclosure of personal information in the reports would be unfair to the individuals mentioned in the incident descriptions, who could have no expectation that information relating to them in the incident report descriptions would be made public.

Section 41 FOIA is an absolute exemption, which applies if disclosure of information supplied to us would amount to a breach of confidence actionable by any person. It has been established in a series of decided cases that confidential information relating to deceased identifiable hospital patients is exempt from disclosure under section 41, given that the disclosure of such information to the public at large would give rise to an actionable breach of confidence.

In accordance with section 40 and section 41 FOIA, the descriptions provided in this response have been summarised so that they do not include any information which could lead to a person being identified, such as names of staff, patients, health conditions, causes of death and dates of birth and death.

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

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