

# **Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation**

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## Introduction

This document provides guidance on the statutory requirement of reporting serious adverse events and serious adverse reactions (SAEARs) under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Regulations). The Regulations transpose the requirements of EU Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation, into UK law.

- ***The HTA directs under Regulation 11 that the time period for notifying serious adverse events and reactions (i.e. the initial report) to NHSBT must be within 24 hours of the discovery of the SAE or SAR by the licence holder. In cases where an urgent notification and recall is required, the establishment must telephone the Organ Donation and Transplant (ODT) duty office (01179 757575) immediately upon discovery of the SAE or SAR. Urgent notification would be required in cases where there are potential implications for other recipients.***
- ***The HTA directs under Regulation 6 that all records associated with the SAE or SAR must be retained for 30 years after donation.***

### The SAEARs reporting system serves two primary functions:

- To raise an alert if there is any unexpected complication or if there are any concerns noted during procedures related to organ donation, particularly if other recipients or living donors may be at risk.
- To ensure the quality and safety of organs during the entire chain, from donation to transplantation, by requiring SAEARs to be reported, investigated, and that corrective and preventative measures are implemented.

Additionally, such reporting will provide the basis for shared learning.

**If there is any doubt about reporting SAEARs, we would always encourage establishments to contact either NHSBT or the HTA for advice.**

## **This guidance includes:**

1. Definitions of reportable SAEARs
2. Roles and responsibilities, and procedures for notification and management of SAEARs
3. Examples of SAEARs

## Definitions of Serious Adverse Events and Serious Adverse Reactions

### Serious Adverse Events

1. A serious adverse event (SAE) is defined in the Regulations as ‘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.

### Serious Adverse Reactions

2. A serious adverse reaction (SAR) is defined in the Regulations as ‘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.

## Roles, responsibilities, and procedures for notification and management for retrieval and transplant centres

3. The requirement to report SAEARs applies to all establishments licensed under the Regulations.

4. Any SAEAR relating to donor characterisation must be reported to NHSBT.

5. Although not directly licensed by the HTA, any SAEAR in relation to donor or organ characterisation which involves a testing laboratory must be reported. It is the responsibility of the licence holder to report SAEARs directly to NHSBT; however, laboratories are also able to report to NHSBT.

6. Implementing Directive 2012/25/EU, sets out rules for the transmission of information when organs are exchanged between Member States and these requirements have been transposed into UK law via the Quality and Safety of Organs Intended for Transplantation Regulations 2012 as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. Organs sent outside of the UK must be accompanied by information for the receiving establishment on how to report any SAEARs following transplantation or which may relate to donation, characterisation, retrieval, preservation, or transport carried out in the UK.

7. It is a **statutory condition** of the licence for the procurement activity of retrieval of an organ, that licence holders must have suitable arrangements in place to try to follow-up living donors. Licence holders involved in living donation must provide information to living donor and recipient referral centres on how to identify and report any SAEARs that may result from a donation or transplant. Living donors should be encouraged to discuss their donation with their families and general practitioners, with SAEARs in mind. This is particularly relevant for donors from overseas who travel to the UK to donate.

8. It is a condition of a licence that SAEARs are reported, and licence holders are expected to collaborate fully in the investigation of a suspected SAEAR, including the submission of a follow up report. This should be provided within 90 days of reporting the SAEAR and should include the corrective and preventative actions taken or

planned to prevent or mitigate reoccurrence. Where it is not possible to submit a follow up report within 90 days, NHSBT will liaise with the HTA.

9. The system of reporting and investigating SAEARs is managed by NHSBT on behalf of the HTA, as an assisted function. Any suspected SAEARs should be reported to NHSBT using the online incident reporting system:

<https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx>

10. Further information on how to report SAEARs can be found in the following procedure on the HTA website:

[https://www.hta.gov.uk/sites/default/files/Reporting an Organ Donation or Transplantation Incident to NHSBT - SOP3888.pdf](https://www.hta.gov.uk/sites/default/files/Reporting%20an%20Organ%20Donation%20or%20Transplantation%20Incident%20to%20NHSBT%20-%20SOP3888.pdf)

11. All SAEARs should be reported **within 24 hours** of discovery by the licence holder. In cases where an urgent notification is required, the establishment must telephone the **NHSBT Organ Donation and Transplantation Directorate duty office on 01179 757575 immediately** upon discovery. The telephone call must be followed up by an online submission of a report form detailing any immediate actions taken. Such urgent notification would be required in cases where there are potential implications for other recipients.

12. NHSBT will inform the HTA of any SAEARs that have been reported, of the steps being taken to manage the SAEAR, and to confirm when all actions associated with the SAEAR have been concluded, by submitting a follow up report.

A follow up report should include:

- All relevant and necessary information concerning SAEs that may influence the quality and safety of organs, and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any SAR observed during or after transplantation, which may be connected to those activities.

- The management measures taken with regard to SAEs or SARs, ensuring that staff responsibilities for the management of SAEARs are clearly defined, and that immediate actions have been taken.

13. Under the current service level agreement with NHSBT, the HTA, as the Competent Authority, participates in regular meetings with NHSBT to discuss all reported incidents and those which were reported as SAEARs.

14. As NHSBT manages the SAEARs reporting system on behalf of HTA, there is no requirement for licence holders to report directly to the HTA. However, if the licence holder or any party involved in a SAEAR has concerns relating to a potential conflict of interest involving NHSBT and a specific event or reaction, they can contact the HTA directly by emailing [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk). In cases where a conflict of interest is confirmed, the HTA may take on the responsibility for overseeing the investigation.

15. In certain cases, following a report of a SAEAR and where justified on the basis of risk to the quality and safety of organs, the HTA may initiate an audit of a licence holder.

16. The HTA retains responsibility for liaising with other competent authorities and government bodies, and for issuing any regulatory alerts to licence holders. However, they may be assisted in this regard by NHSBT as appropriate.

### **Safety of Blood, Tissues and Organs (SaBTO) Guidance**

17. In order to promote good practice in organ transplantation, the HTA advises establishments to review guidance provided by expert independent committees such as SaBTO (The Advisory Committee on the Safety of Blood, Tissues and Organs) who advise the UK Government and Devolved Administrations on the safety of organs, tissues and cells for patient treatment and organ transplantation. SaBTO guidelines and recommendations help to identify and minimise the risk of transmissible infections and malignancies, and provide risk management options which surgeons can use to help decide whether or not to accept an organ for transplantation.

SaBTO guidance (<https://www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation>)

can also result in the introduction of control measures, in cases of emerging infection risks, or the phasing out of control measures when the risk to patients are no longer regarded as significant. SaBTO takes steps to ensure that its guidance is consistent with the EU Directives on blood, tissues, cells, and organs, and also takes into account the need to maintain adequate supplies of organs, and its impact on donors and recipients.

### **NHSBT Clinical Microsite**

18. Further information on the clinical aspects of organ transplantation can be found on the NHSBT clinical Microsite: <http://www.odt.nhs.uk/>.

19. Detailed information on the statutory requirements relating to SAEARs can be found in the HTA framework document.

[https://www.hta.gov.uk/sites/default/files/Organs\\_Intended\\_for\\_Transplantation\\_-\\_a\\_documentary\\_framework\\_-\\_July\\_2014.pdf](https://www.hta.gov.uk/sites/default/files/Organs_Intended_for_Transplantation_-_a_documentary_framework_-_July_2014.pdf)



## Examples of SAEARs

19. The following are examples of potential SAEARs; this list is not exhaustive but illustrative of a range of reportable SAEARs. There are also examples of when a serious adverse event becomes reportable as a serious adverse reaction.

Examples of reportable SAEARs	
<p><b>Damage to an organ during retrieval.</b></p> <p>An organ was inadvertently damaged during retrieval. The damage associated with retrieval resulted in an otherwise transplantable organ rendered unsuitable for transplantation.</p>	SAE
<p><b>Transmission of a communicable disease.</b></p> <p>A cytomegalovirus (CMV) test result was reported incorrectly as negative when the actual test result was positive. At the time of implantation in a CMV negative recipient the transplant surgeon was unaware that the donor test was CMV positive.</p> <p>The recipient will be subject to monitoring. <b>If CMV related disease develops</b> (transmission of disease), this will be reported as a serious adverse reaction.</p>	SAE
<p><b>An unnecessary procedure performed on organ recipient.</b></p> <p>An organ recipient was anaesthetised in preparation for an organ transplant. On inspection of the organ, the surgeon following a risk and benefit analysis found the organ was unsuitable for transplantation and the procedure was aborted.</p>	SAR
<p><b>Donor malignancy discovered during post mortem.</b></p> <p>The organ donor's medical history did not indicate potential malignancy and lesions were not evident at retrieval.</p> <p>The recipient will be subject to monitoring. <b>If a related malignancy develops</b> (transmission of disease), this will be reported as a serious adverse reaction.</p>	SAE
<p><b>Surgical removal of transplanted organ.</b></p> <p>An organ damaged during retrieval was repaired and implanted. Following implantation, the recipient developed complications associated with the transplant and the organ had to be removed.</p>	SAR
<p><b>Extended cold ischaemic time (CIT).</b></p> <p>An unlabelled organ box was not accepted for transport resulting in extended CIT. Following delay, the organ was unsuitable for transplantation.</p>	SAE
<p><b>Donor had previous history of malignancy which was known at the time of donation.</b></p> <p>Past and present donor medical history was communicated to the implanting surgeon. The recipient was fully informed and the organ was accepted on the basis of a clinical risk and benefit analysis.</p>	Not SAE or SAR
<p><b>Damage to vessel during retrieval from living donor.</b></p> <p>The living donor required unplanned surgical intervention following retrieval of an organ.</p>	SAR
<p><b>Incorrect Perfusion Fluid.</b></p> <p>The use of incorrect perfusion fluid resulted in an organ being unsuitable for transplantation.</p>	SAE