

Reporting an Organ Donation or Transplantation Incident to NHSBT

Purpose

The purpose of this procedure is to provide information for all involved in organ donation and transplantation (living and deceased) on how to report an incident which may occur during the chain from donation to transplantation.

This procedure helps ensure patient safety by providing instruction on how to report incidents that occur during the chain from donation to transplantation. This allows corrective and preventative actions to be put in place to avoid reoccurrence.

Important Note

Urgent incidents must be reported to the NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation (ODT) Directorate **Hub Operations** (formally the **Duty Office**) on **01179 757580** immediately upon discovery.

Such urgent incidents would include cases where there are potential implications for other recipients. ODT will ensure any immediate corrective actions are implemented to minimise the risks to living donors and recipients. The telephone call should be followed up with the submission of an incident form.

All incidents believed to be a Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) should be reported within 24 hours of discovery as required under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Regulations) and the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

How to Report

- 1 An Establishment identifies any event in the organ donation and/or transplantation process which can or does affect the donor or recipient safety, or the quality of the organs for transplantation.
 - An incident may occur that may have wider national learning.
 - An incident may occur for which there is a legal requirement to report under the Regulations.
 - An incident may be reported that relates to organs sent to or received from another country in the European Union.
- 2 Complete the incident submission form, including all mandatory fields, detailing the incident in a clear and concise manner.
 - The Incident Submission form can be accessed via the Organ Donation website <https://safe.nhsbt.nhs.uk/IncidentSubmission/> or the NHSBT intranet home page (NHSBT employees only).
- 3 The Incident Submission form will automatically be submitted to the NHSBT Incident Management IT system.

If the Incident Reporting form cannot be accessed due to planned maintenance or IT failure, an error message will notify the incident submitter and inform them of the steps to take.

If the incident is urgent, the Hub Operations at NHSBT must be contacted immediately. If the incident is not urgent, the form should be submitted at a later time.

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- 4 An automated response is received by the reporter acknowledging submission of the incident. The automated e-mail will confirm the ODT Incident submission unique identifying number which should to be used for any queries.
- 5 Following review by NHSBT, incidents identified as an SAE or SAR will be reported to the Human Tissue Authority (HTA) by NHSBT. The reporter and those involved in the incident will be informed of the report to the HTA.
6. Following completion of the investigation a response will be sent to the incident reporter with details of the investigation and the outcome.

The target time frame to investigate and close an incident is **90 days from receipt of incident**. This timeframe will be dependent on relevant personnel at donor hospitals, transplant centres or follow up units ensuring that investigations are completed as a priority and that the report and any further information required is sent to NHSBT.

If the incident does not relate to the organ donation or transplantation pathway, it may be investigated outside of the ODT sector. If this is the case, the reporter will be informed of such and provided the contact details of the area investigating. A response may not be sent to the reporter following investigation by other areas outside the ODT directorate.

Summary of Significant Changes

Layout change to document, and change in name of Duty Office to Hub Operations.
No process change

Responsibilities

All UK establishments licensed under the Regulations - The requirement to report SAEs and SARs applies to all UK establishments licensed under the Regulations, regardless of geographical location or whether they are a private or an NHS organisation.

NHS Blood and Transplant - Receive and investigate reports of all SAE and SAR reports on behalf of the HTA, as an Assisted Function under the Regulations.

Additional Information

This procedure is in place for organs donated, retrieved and transplanted in the UK and for organs retrieved overseas which are subsequently transplanted in the UK.

Human Tissue Authority - [Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation – provides further information on SAEs and SARs](#)