SOP3888/3 – Reporting an Organ Donation or Transplantation Incident to NHSBT

Objective

This procedure provides information to stakeholders involved in organ donation and transplantation (living and deceased) on how to report incidents which occur during any part of the pathway. Reporting incidents promotes patient safety by enabling implementation of immediate corrective actions. It subsequently allows review of the process and implementation of preventative actions to avoid reoccurrence.

Changes in this version

Change to incident submission form portal link. Inclusion of reporting requirement for organs destined for use as tissue or cells.

Important Note

Upon discovery, urgent incidents must be reported immediately to the NHS Blood and Transplant (NHSBT) Organ and Tissue Donation and Transplantation (OTDT) Directorate **Hub Operations Department** on **01179 757580**. The phone call must then be followed by the submission of the online reporting form.

Such urgent incidents include cases where there are potential implications for other organ or tissue recipients. ODT will ensure any immediate 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 report using the online reporting form.

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

Solid organs retrieved for the purpose of tissue/cell transplantation (e.g. pancreas retrieved for islets, liver retrieved for hepatocytes or heart retrieved for heart tissue) and some specific tissue retrieved from organ donors fall under The Human Tissue (Quality and Safety for Human Application) Regulations 2007 and associated guidance. However, as agreed with the Human Tissue Authority (HTA), any incidents relating to these organs/tissue must continue to be reported via the same online portal within 24 hours of discovery.

Roles

- **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 SAEs and SARs on behalf of the HTA, as an Assisted Function under the Regulation.

How to Report

1. An event is identified in the organ donation and/or transplantation process which can or does affect the donor (in the case of living donation) or recipient safety, or the quality of the organ/tissue 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 a 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 ODT Clinical website https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx or https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/
    - the NHSBT intranet home page (NHSBT employees only).

3. The incident submission form will be automatically submitted to the NHSBT Incident Management 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, NHSBT ODT Hub Operations must be contacted immediately on **01179 757580**. If the incident is not urgent, the form should be submitted once the system is available.

4. An automated response will be received by the reporter acknowledging submission of the incident. The automated e-mail will confirm the ODT incident submission unique identifying number which should 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. This may be at any time during the incident investigation.

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 the 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 with 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.

Additional Information

This procedure is in place for organs donated, retrieved and transplanted (as organs or tissue and cells) in the UK and for organs retrieved overseas which are subsequently transplanted in the UK.

The Human Tissue Authority provides information on SAEs and SARs: Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation.