SOP3888/3.2 – 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

Removal of hyperlink for information on SAR and SAE in Additional Information section as not working.

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.

Training Plan for Documents:

Type of Change	<Change to Existing Process>	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	All staff within NHSBT reporting organ donation incidents and relevant tissue donation incidents.	All staff within NHSBT reporting organ donation incidents and relevant tissue donation incidents.
Knowledge required prior to training	NA	Trained to previous version.
Critical aspects of process	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.	

Training Plan:

	Trainee new to the process	**Trainee trained to the previous revision.**
Recommended Training Method	As per individual's departmental induction or training process for reporting of organ donation incidents and relevant tissue donation incidents.	Read only as very minor change- removal of hyperlink.
Assessment	• FRM511	• FRM511
Cascade Plan	• Anyone trained can cascade training	• Anyone trained can cascade training

Training Score – Training Plan Risk Matrix (Collapsible – Click ▶ icon to open/close)

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance:

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services.
2. Minor	A process whose failure, in full or in part, **may**:

	(i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).
3. Moderate	A process whose failure, in full or in part, **may**: (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is **likely** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is **certain** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
Process Criticality Score	4

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.

5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	1

Training Plan Risk Matrix:

Process Criticality →

Criticality of Change ↓	1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
1. Low	1	2	3	4	5
2. Moderately Low	2	4	6	8	10
3. Moderate	3	6	9	12	15
4. High	4	8	12	16	20
5. Very High	5	10	15	20	25

	Trainee new to the process	**Trainee trained to the previous revision.**
Process Criticality Score	4	
Criticality of Change Score	1	1
Training Score	4	4

Recommended Training Method and Assessment:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent