STANDARD OPERATING PROCEDURE SOP3888/2.1

Reporting an Organ Donation or Transplantation Incident to NHSBT

This SOP replaces
SOP3888/2

Copy Number

Effective **15/09/15**

Summary of Significant Changes

Update to the incident submission form link
Included note to state NHSBT may need to collaborate with the organ procurement organisation/tranplant unit/ competent authority in another country in the European Union in accordance with new regulations

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 as required under the Quality and Safety of Organs for Transplantation Regulations 2012 (the Regulations) and the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

Responsibilities

All UK establishments licensed under the Regulations - The requirement to report serious adverse events (SAEs) and serious adverse reactions (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 all SAE and SAR reports on behalf of the HTA.

Retrieval teams, transplant centres (private or NHS), donor hospitals, testing laboratories, NHSBT Specialist Nurses Organ Donation (SNODs) and other NHSBT staff, and the HTA should foster a culture of reporting SAEs and SARs.

Restrictions

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

Definitions

The Regulations - the Quality and Safety of Organs for Transplantation Regulations 2012 (SI 2012 No. 1501).

Incident – any event in the organ donation and/or transplantation process which can or does affect the donor, recipient safety or the quality of the organs for transplantation.

HTA – Human Tissue Authority

SAE - A serious adverse event 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'.

SAR - A serious adverse reaction 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'.

Items Required

Incident Submission Form:-
https://safe.nhsbt.nhs.uk/IncidentSubmission/

Human Tissue Authority - Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation

STEP	DETAILS	INFORMATION
Note All SAE and SARs should be reported within 24 hours of discovery. Urgent incidents must be reported to the NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation (ODT) Directorate 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 donors and recipients. The telephone call should be followed up with the submission of a report form.		
Note Following the implementation of the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014, an incident may be reported that relates to organs sent to or received from another country in the European Union. NHSBT may need to collaborate with the organ procurement organisation/transplant unit/competent authority in this country to investigate the incident.		
1. Incident occurs	1.1 Establishments should identify in their own procedures who are responsible for notifying NHSBT in event of an organ donation or transplantation related incident. 1.2 External submitters can access the Incident Submission form via the Organ Donation website https://safe.nhsbt.nhs.uk/IncidentSubmission/ 1.3 Internal submitters can access the Incident Submission form via the Intranet home page.	An incident may occur within the chain of organ donation and transplantation for which there is a legal requirement to report under the Regulations. Additionally, an incident may occur for which organisations may benefit from organisational or national learning. These incidents should be reported to the ODT Directorate of NHSBT.
2. Complete the Incident reporting form.	2.1 Complete incident submission form, including all mandatory fields, detailing the incident in a clear and concise manner. 2.2 The Incident Submission form will automatically be submitted to the NHSBT Incident Management IT system. 2.3 If a copy of the submission form is required to be stored locally, form must be printed before submission or a screen shot taken. 2.4 The incident should also be escalated to the appropriate manager by the reporter.	Link to incident submission form:- https://safe.nhsbt.nhs.uk/IncidentSubmission/ The incident details are then submitted electronically and managed by NHSBT (SOP 3842).

STEP	DETAILS	INFORMATION
Note If the Incident Reporting form cannot be accessed due to planned downtime of the system or IT failure an error message will notify the incident submitter Error messages will be displayed to the Incident submitter: 'NHSBT's incident reporting system is currently experiencing difficulties. If the incident is urgent please report by phone on 0117 9757580. If the incident is not urgent or has already been reported by phone please try later to report it using the incident form.' Or:- 'Thank you for attempting to submit this incident to ODT. Unfortunately your incident form was not successfully received. Please contact the ODT Clinical Governance team at clinicalgovernance.odt@nhsbt.nhs.uk quoting the date and time you attempted to report the incident.'		
3. An automated response is received by the reporter acknowledging submission of the incident	3.1 The e-mail will confirm the ODT Incident submission unique identifying number to be used for any queries. 3.2 Incidents identified as an SAE or SAR will be reported to the HTA by NHSBT	If the incident is identified as an SAE or SAR, an email is sent to the clinical contact at the unit/centre reporting the incident and any unit/centre referred to in the incident report. This email informs them that the incident has been identified as a potential SAE or SAR and has been notified to the HTA. NHSBT has responsibility to receive and investigate reports of SAEs and SARs on behalf of the HTA, as an Assisted Function under the Regulations
4. Incident is investigated by ODT	4.1 If further information is required, the Quality Assurance or Clinical Governance department will contact the relevant personnel at donor hospitals, transplant centres, follow up units or departments within ODT. 4.2 Following the investigation a response will be sent to the Incident submitter with details of the investigation and the outcome.	SOP3842 (ODT only) All efforts should be made to close incidents including actions from incidents **within 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.