

Guidelines for the Blood Transfusion Services

21.8: Notification of serious adverse events and reactions

<http://aws-lon-jpac.targetservers.uk/red-book/chapter-21/21-8-notification-of-serious-adverse-events-and-reactions>

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Tissue Establishments in the UK are required to report serious adverse events and reactions to the Human Tissue Authority (HTA), within 24 hours of the incident being identified, through the Serious Adverse Events and Reactions system. For the purposes of reporting, a serious adverse reaction (SAR) is defined as an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalisation or morbidity. A serious adverse event (SAE) is defined as any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.

Tissue Establishments shall ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events and reactions. A root cause analysis should be performed. Moreover, each Tissue Establishment shall ensure that an accurate, rapid and verifiable procedure is in place which will enable it to recall from distribution any product which may be related to an adverse event or reaction.