

Adverse reactions in donors and recipients

Standard operating procedure (SOP) | BLD-SOP-005

Document type	Standard operating procedure (SOP)
Title	Adverse reactions in donors and recipients
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Prepared by	{{roles.quality_lead.name}}, Quality lead
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Effective date	{{document.effective_date}}
Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	None (new document)
Standards and criteria supported	Standard 5 (Blood Bank), criterion 5.7
Evidence basis	E-006, E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

At a glance: what to do

1. Every adverse reaction in a donor or a recipient is recorded.
2. Each reaction is investigated by the blood bank and the clinical team together.
3. Serious reactions are reported to the national haemovigilance system as required.
4. Each investigation has an outcome and an action.

Stop and get help straight away if: a transfusion reaction is not recorded or investigated.

1. Purpose

To find and stop the causes of reactions, and to report them (5.7).

2. Scope

Applies to	Clinical and support staff in the hospital
Locations	All wards, clinics and departments of {{facility.legal_name}}
When	Whenever the activity described is carried out
Does not apply to	Activities covered by another document listed in section 15

3. Definitions and abbreviations

Term	Meaning in this SOP
Clinical lead	The doctor or nurse in charge of the area at the time

4. Background and rationale

To find and stop the causes of reactions, and to report them (5.7).

5. Responsibilities

Role	Duties in this SOP	Competence needed
Blood bank director	Leads the investigation	Clinician
Responsible clinician	Records the reaction at the bedside	Doctor or nurse

6. Equipment, materials and resources

Item	Specification or standard	Check before use
Records and forms named in this document	Current version	Checked before use

7. Safety and infection prevention

- Stop and call for help if a patient is at immediate risk. Do not delay urgent care to complete paperwork.

8. Before you start

- Confirm the forms and equipment named in this document are available and current.

9. Procedure

Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.

Step	Action	How to do it	Key point
1	Record.	• Record the reaction at once (HOS-FRM-007), with the unit number and the time.	At once.
2	Investigate.	• Investigate with the clinical team, and check the unit and the process.	Both sides investigated.
3	Report.	• Report serious reactions to the national reporting system, and record the report number.	Reported and recorded.

Decision points

- No decision points in this procedure.

10. Special situations

Situation	What to do
Out of hours	Follow the same steps. Use the on-call contact on the wall of the area.

11. Problems and escalation

- Any serious problem goes to the duty clinical lead at once and to the clinical director the same day.

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
Reactions recorded and investigated	100%	Monthly	Blood bank director	Escalate to governing body
Serious reactions reported	100%	Monthly	Blood bank director	Escalate to governing body

13. Records

Record	Where it is kept	Kept for
Record named in this document	Patient record or the area file	{{facility.records_retention_years}} years

14. Training and competence

- Staff are trained in this document at induction and refreshed each year, with a recorded competency check.

15. Related documents

ID	Title	Relationship
BLD-FRM-003	Adverse reaction report	Report
HOS-FRM-007	Bedside transfusion check and reaction record	Bedside

16. Evidence

ID	Source and status
E-009	Based on the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components.
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.

17. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	First version	Pending Expert Committee approval