

Serious Adverse Event (SAE): 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.



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Serious Adverse Reaction (SAR): 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, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

SAEs - Criteria

CRITERIA FOR REPORTING SAEs
Inappropriate tissues/cells have been distributed for clinical use, even if not used;
The event could have implications for other patients or donors because of shared practices, services, supplies or donors;
The event resulted in loss of any irreplaceable autologous tissues or cells or any highly matched (i.e. recipient specific) allogeneic tissues or cells;
The event resulted in the loss of a significant quantity of unmatched allogeneic tissues or cells.

Severity (SARs)

Non serious	Mild clinical consequences which do not necessitate hospitalisation and/or result in long term disability or consequences for the recipient or living donor
Serious	Adverse reaction resulted in: <ul style="list-style-type: none"> - hospitalisation or prolongation of hospitalisation and/or - persistent or significant disability or incapacity or - medical or surgical intervention to preclude permanent damage or impairment of a body function or - there is evidence of a serious transmissible infection
Life-threatening	The living donor or recipient required major intervention following procurement or tissue or cell application (vasopressors, intubation, transfer to intensive care) to prevent death or there is evidence of a life-threatening transmissible infection.
Death	Death

Imputability (SARs)

NA	When there is insufficient data for imputability assessment
0 Excluded: Unlikely:	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes. When the evidence is clearly in favour of attributing the adverse reaction to causes other than the tissues/cells.
1 Possible	When the evidence is indeterminate for attributing the adverse reaction either to the tissues/cells or to alternative causes.
2 Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the tissues/cells
3 Definite, Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the tissues/cells

Impact (SARs and SAEs)

1	Rare	Difficult to believe it could happen again
2	Unlikely	Not expected to happen but possible
3	Possible	May occur occasionally
4	Likely	Probable but not persistent
5	Almost certain	Likely to occur on many occasions

Step 1 – Probability of recurrence

Level	Impact Description	Impact on individual(s) Actual (SAR) Potential (SAE)	Impact on Transplant or Fertility System	Impact on Tissue/cell supply
0	Insignificant	Insignificant	No affect	Insignificant
1	Minor	Non-serious	Minor damage	Some applications postponed
2	Significant	Serious	Damage to system – services will be affected for short period	Many applications cancelled or postponed
3	Major	Life threatening	Major damage to system – significant time needed to repair	Significant no. of procedures cancelled - importation required to make-up short-fall
4	Severe	Death	System destroyed – need to rebuild	All allogeneic applications cancelled

Step 2 – Consequences of Recurrence

Recurrence probability Consequences	Rare 1	Unlikely 2	Possible 3	Likely 4	Almost certain 5
Insignificant 0	0	0	0	0	0
Minor 1	1	2	3	4	5
Significant 2	2	4	6	8	10
Major 3	3	6	9	12	15
Severe 4	4	8	12	16	20

Step 3 - Impact