**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.*

# EUSTITE V&S TOOLS V2.1

**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 a mix-up of gametes or embryos; |
| 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/psychological consequences. No hospitalisation. No anticipated long term consequence/disability |
| Serious | - hospitalisation or prolongation of hospitalisation and/or<br>- persistent or significant disability or incapacity or<br>- intervention to preclude permanent damage or<br>- evidence of a serious transmitted infection or<br>- birth of a child with a serious genetic disease following ART with donor gametes or embryos. |
| Life-threatening | - major intervention to prevent death or<br>- evidence of a life-threatening transmissible infection or<br>- birth of a child with a life-threatening genetic disease following ART with donor gametes or embryos. |
| Death | Death |

Report to CA

## Imputability (SARs)

| | |
|---|---|
| NA<br>Not assessable | Insufficient data for imputability assessment |
| 0.<br>Excluded | Conclusive evidence beyond reasonable doubt for attributing to alternative causes. |
| 1.<br>Unlikely | Evidence clearly in favour of attributing to other causes. |
| 2.<br>Possible | Evidence is indeterminate. |
| 3.<br>Likely,<br>Probable | Evidence in favour of attributing to the tissues/cells. |
| 4.<br>Definite,<br>Certain | Conclusive evidence beyond reaonable doubt for attributing 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**