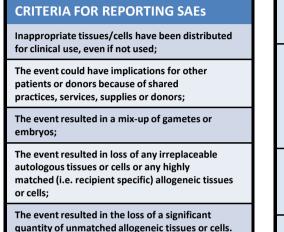


SAEs - Criteria

prolong, hospitalisation or morbidity.





Public Health

Severity (SARs)

Non serious	Mild clinical/psychological consequences. No hospitalisation. No anticipated long term consequence/disability			
Serious Report to C	 hospitalisation or prolongation of hospitalisation and/or persistent or significant disability or incapacity or intervention to preclude permanent damage or evidence of a serious transmitted infection or birth of a child with a serious genetic disease following ART with donor gametes or embryos. 			
Life-threatening	 major intervention to prevent death or evidence of a life-threatening transmissible infection or birth of a child with a life-threatening genetic disease following ART with donor gametes or embryos. 			
Death	Death			

World Health Organization

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, lifethreatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Imputability (SARs)

NA Not assessable	Insufficient data for imputability assessment					
0. Excluded	Conclusive evidence beyond reasonable doubt for attributing to alternative causes.					
1. Unlikely	Evidence clearly in favour of attributing to other causes.					
2. Possible	Evidence is indeterminate.					
3. Likely, Probable	Evidence in favour of attributing to the tissues/cells.					
4. Definite, 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	Level	Impact Description	Impact on individual(s) Actual (SAR) Potential (SAE)	Impact on Transplant or Fertility System	Impact on Tissue/cell supply	Recurrence probability Consequences	Rare 1	Unlikely 2	Possible 3	Likely 4	Almost certain 5		
2	2 Unlikely	Not expected to happen but possible	0	Insignificant	Insignificant	No affect	Insignificant	Insignificant 0	0	0	0	0	0		
			1	Minor	Non-serious	Minor damage	Some applications								
3 Possibl	Possible	sible May occur occasionally	ible May occur occasionally	May occur occasionally					postponed	Minor	1	2	3	4	5
			2	Significant Serious	Serious	Damage to system – services will be	Many applications cancelled or	1	-						
						affected for short period	postponed	Significant	2	4	6	8	10		
4 Likely	Likely	Probable but not persistent		3	Major	Life threatening	Major damage to	Significant no. of	2						
							system – significant time needed to repair	procedures cancelled - importation required to make-up short-fall	Major 3	3	6	9	12	15	
5 Almost certain		Likely to occur on many occasions						to make-up short-rail	Severe	4	8	12	16	20	
	certain			4	Severe	Death	System destroyed – need to rebuild	All allogeneic applications cancelled	4	4	0	12	10	20	