Assisted reproductive technology/fertility services Severity Assessment Code (SAC) examples 2023

The examples below are for **guidance only; they are not intended to be prescriptive or exclude other events from review.** The final SAC rating can be changed following review based on the experience of harm for the consumer, not based on the number or type of learning opportunities developed. The viewpoints and experiences of consumers and whānau must be incorporated into the provisional and final SAC ratings. See also the <u>SAC rating and process tool</u>.

SAC 1 – Death or harm causing severe loss of function and/or requiring lifesaving intervention

- Not related to natural course of illness or treatment
- Differs from the immediate expected outcome of care
- Can be physical, psychological, cultural or spiritual

Assisted reproductive technology (ART) medical procedures

- Death that is directly caused by ART treatment including, but not limited to: ovarian hyper-stimulation syndrome (OHSS), infection, procedural complication, bleeding, ovarian torsion
- Permanent loss of physical or reproductive function, directly caused by ART treatment including, but not limited to: OHSS, infection, procedural complication, bleeding, ovarian torsion
- Medication error resulting in death or the need for permanent therapy

ART technical procedures (gametes and embryos)

- Incorrect gametes or embryos used in treatment. (Includes using gametes or embryos from wrong consumer. Consider the harm to both parties)
- Implanting an effected (wrong) embryo after genetic testing







SAC 2 – Major; harm causing major loss of function and/or requiring significant intervention

- Not related to natural course of illness or treatment
- Differs from the immediate expected outcome of care
- Can be physical, psychological, cultural or spiritual

ART medical procedures

- Indirect death a death for which the direct cause of death was not due to ART treatment, but the ART treatment had a contributing effect on a pre-existing illness or condition
- Transmission of a communicable disease from an ART procedure, causing a lifelong treatable condition that may reduce normal function and/or longevity
- Unanticipated hospitalisation **longer than 7 days** or unanticipated repeat admission, requiring significant clinical intervention that:
 - is needed because of an ART-related OHSS, infection, procedural complication, bleeding, ovarian torsion or undiagnosed severe pain
 - may include blood transfusions, laparoscopy, laparotomy, other related surgical procedures
- Emergency hospital admission within 24 hours of oocyte pick-up (OPU), with a lifethreatening event, such as significant abdominal bleeding
- Prolonged admission to hospital with possible transfer to long-term unit for further management
- Misinterpretation of endocrine result or hormone administration that directly results in loss of pregnancy
- Severe mental health event requiring hospitalisation where ART was a major contributing factor, usually occurring within 2 weeks of the completion of the treatment cycle (includes surrogates)
- Medication error resulting in significant intervention (eg, anaphylaxis from a known medication allergy)

ART technical procedures (gametes and embryos)

- Loss of viable gametes or embryo for an individual where replacement is not possible, causing major loss of reproductive function or age-related potential. Causes include, but are not limited to: equipment failure or loss, damage or mistaken disposal of cryo-stored tissue, gametes or embryos
- Loss of rights to use tissue, gametes or embryos due to lack of opportunity to apply for extension to 10-year storage limitations
- Systematic failure in validating or verifying a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos

SAC 3 – Moderate; harm causing short-term loss of function and/or requiring moderate additional intervention

- Not related to natural course of illness or treatment
- Differs from the immediate expected outcome of care
- Can be physical, psychological, cultural or spiritual

ART medical procedures

- Reduced reproductive function due to an ART-related procedure, involving one fallopian tube, ovary or testis
- Unanticipated hospitalisation **longer than 24 hours but less than 7 days**, requiring moderate clinical intervention that:
 - $\circ~$ is needed because of an ART-related OHSS, infection, procedural complication, bleeding, ovarian torsion or severe pain
 - \circ $\,$ may include interventions such as drainage of ascites, IV antibiotics, opioid type analgesics
- Interpretation of endocrine result or hormone administration that results in psychological harm
- Unanticipated hospitalisation of less than 7 days
- Medication error that requires additional intervention and monitoring

ART technical procedures (gametes and embryos)

Loss of viable gametes or embryos for an individual where replacement **is** possible with a repeated treatment cycle or alternative cryo-stored sample. Results in a similar chance of success, yet the individual has experienced significant emotional trauma. Causes include, but are not limited to: equipment failure of loss, damage or mistaken disposal of cryo-stored tissue, gametes or embryos

SAC 4 – Minor; harm causing no loss of function and requiring little or no intervention (includes near misses)

- Extra investigation or observation
- Review by another clinician
- Minor treatment
- Not related to natural course of illness or treatment
- Differs from the immediate expected outcome of care
- Can be physical, psychological, cultural or spiritual

ART medical procedures

- Medication error with no resulting harm
- Mild OHSS not requiring hospitalisation for longer than 24 hours and managed as an outpatient

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