

	S(P)EAR examples of what to report and what not to report			
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S(P)EAR: Examples of what to report and what not to report

The S(P)EAR SOP states that:

If an event/reaction is deemed to be one of the following it should be reported:

- Serious/unexpected/medically relevant/previously unknown.
- Hospitalisation per se should NOT be reported, unless for an event that is life threatening or fatal or unexpected.
- Expected events (e.g. nausea/pain) should NOT be reported unless life-threatening or fatal.
- Reporting of less than expected cell count. Cell counts less than requested or expected should not be reported as a S(P)EAR unless a clinical consequence occurred or an error was responsible for the low count.

In addition to these general principles, the following specific events are given as indicators what should be reported:

SEAR SPECIFIC EXAMPLES

- Any serious event or reaction during anesthesia should be reported.
E.g.: Profound bradycardia during anesthesia requiring emergency treatment, laryngospasm during anesthesia, severe adverse reactions to drugs or IV fluids
- Any serious cardiac complication should be reported.
- Any serious infection should be reported.
E.g.: Infections at site of marrow collection/line infections, sepsis, osteomyelitis
- Any serious mechanical injury should be reported.
E.g.: Nerve damage from marrow collection or IV lines, damage to SI joint, fractures of iliac crest, retroperitoneal hematoma or injuries
- Any serious incident in hemostasis should be reported
E.g.: Thrombosis, embolism, after marrow or PBSC harvest, abnormal bleeding secondary to thrombopenia complicating PBSC harvest
- Any serious (late) effect of marrow or PBSC donation should be reported.
E.g.: Auto-immune, malignancy
- Any donor death (from initiation of donation until day 30 post donation; or at any time if the donation is implicated)

SPEAR SPECIFIC EXAMPLES

Processing, labelling, handling and transport errors/problems

- Wrong stem cell product transfused
- Wrong stem cell product received
- Serious problems in transportation
- Damage to bag
- Inadequate cell dose in the stem cell product
- Clotting or other loss of product viability
- Contamination leading to serious infection in recipient

Any serious unpredicted transmissible infection

- HIV, Hepatitis B, Hepatitis C
- Not to be reported: CMV-positivity, EBV-positivity
- Not to be reported: Contamination in product without infection in recipient

Any serious unpredicted non-infectious transmissible disease (e.g. malignant)

- E.g.: Malignancy, auto-immune disease, congenital anomaly