

*To WMDA members and affiliated transplant & collection centres,
professional societies and all that this may concern*

S(P)EAR alert: December 2019

Description of the serious events

The S(P)EAR Committee of WMDA has recently been notified of a serious event in which a bone marrow product was completely lost, as described in more detail below. A subsequent donation was necessary. Both donor and patient are progressing as expected.

The bone marrow product was lost because transfer bags from a bone marrow collection system were ruptured during centrifugation for plasma separation at the transplant centre.

This is the second time that an incident of this sort was reported to WMDA. In the previous case, a sufficient portion of the product could be salvaged and used for a successful transplant. In both cases, the manipulation step was consistent with standard operating procedure, and not the result of error.

Root cause analysis

These frequently-used transfer bags are generally not certified or validated for centrifugation, storage, or cryopreservation.

Recommendations of the WMDA S(P)EAR Committee

- Transplant centres should be aware that these transfer bags are generally unsuitable for centrifugation. Before any processing steps are undertaken, it is recommended that stem cell products be transferred to a bag which is validated by the manufacturer and any appropriate regulatory agency for the purpose intended. WMDA further recommends that transplant centres and processing stem cell laboratories check the specifications of all bags to ensure consistency with any intended use, including but not limited to manipulation (*e.g.*, centrifugation), storage, and infusion.
- WMDA recommends that the transplant centre be provided with any necessary documentation and/or statements regarding type and specification of transfer bags no later than at hand-over of the stem cell product.