	WMDA Rapid Alert May 2020			
	Document type	Rapid Alert	Pillar	Donor Care
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To WMDA members and affiliated transplant & collection centres, professional societies and all whom this may concern.

S(P)EAR alert: May 2020 - update 11 June 2020 in red

Adverse events and reactions related to cryopreservation of stem cell products during the COVID-19 pandemic.


In order to ensure the safe arrival of hematopoietic stem cell products at the transplant centre prior to the start of patient conditioning, cryopreservation of the product on arrival is strongly recommended¹², if not locally required³, and has been since early March, 2020. Where the anticipated prolonged travel times may be prolonged, some requesting registries/transplant centres may prefer cryopreservation at collection.

While WMDA's S(P)EAR Committee⁴ has so far received no reports or notifications of serious events or reactions *directly* related to COVID-19 infection, we have been informed of several cryopreservation-related reports. Adverse events include unintended (due to miscommunication) cryopreservation at the collection site, a cryopreserved product that was misplaced and hence partly thawed during transport, and several PBSC or BM products with (anticipated) low cell count after thawing, where the product could not be used, or the same donor was requested for an urgent second donation.

While cryopreservation is certainly justified in the light of travel restrictions, transport limitations, and potential impact on donor and recipient availability, additional expert assessments, procedures, and policies for registries and donor / collection and transplant centres are absolutely required, as would be the case for any situation requiring cryopreservation (including of autologous products) in compliance with FACT-JACIE International Standards for Hematopoietic Cellular Therapy (7th edition)⁵, and AABB Standards for Cellular Therapy Services (9th edition)⁶.

The following are strongly recommended:

- Agree and make clear written specifications about where the cryopreservation will take place. Transplant centres and sending registries should feel free to ask for accreditation certificates from processing facilities that are responsible for cryopreserving the hematopoietic stem cells.
- Assess the feasibility of the request of the transplant centre before collecting the product. Attempts should be made to determine whether it will be possible to obtain the required cell counts taking into account the potential losses during cryopreservation.
- If the above cannot be comfortably expected and if shipping and donor availability are not deemed critical, consult with the transplant centre about continuing without cryopreservation.
- Adjust transport arrangements if the product is going to be transported after cryopreservation and make sure the transport is performed by a courier company specialized in transport of cryopreserved stem cells in dry shippers, according to accepted standards.
- Make sure that the site performing the transplant has implemented validated assays and test procedures for the evaluation of thawed cellular therapy products⁵.
- If the post-thaw viable cell count tested on a representative sample is too low for successful engraftment, consider the option to check if it is feasible that the donor donates for a second time

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and combine the two products in one transfusion, rather than discarding the first product and choose a different source.

- Communicate the test results and if the cellular therapy product is used (including infusion date) back to the sending registry for evaluation of the process. If the cellular therapy product is not used, the registry must be informed.
- WMDA strongly recommends that **except where local circumstances assure the quality of the product**, conditioning not be commenced until the viability of the cellular therapy product is established using an attached segment or vial.

See here informational links.

¹ <https://www.ebmt.org/covid-19-and-bmt>

² <https://share.wmda.info/pages/viewpage.action?pageId=344866320#/>

³ <https://network.bethematchclinical.org/news/nmdp/be-the-match-response-to-covid-19/updates-for-transplant-centers-and-cooperative-registries/#Cryopreservation>

⁴ <https://wmda.info/professionals/promoting-donor-care/adverse-events-searspear/>

⁵ <https://www.ebmt.org/sites/default/files/2018-06/FACT-JACIE%207th%20Edition%20Standards.pdf>

⁶ <https://marketplace.aabb.org/ebusiness/Default.aspx?TabID=251&productId=14253167>

⁷ [https://www.celltherapyjournal.org/article/S1465-3249\(19\)30870-9/fulltext](https://www.celltherapyjournal.org/article/S1465-3249(19)30870-9/fulltext)