Guidelines for the Blood Transfusion Services

22.10: Storage of cellular therapy products


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Policies must be in place for the storage of all material whether or not destined for cryopreservation, e.g. HPC-M undergoing red cell depletion and for other HPCs prior to cryopreservation. Details should be specified for all types of storage conditions. These should cover:

- labelling
- primary and secondary containers
- storage temperature and duration
- cell concentration

It is recommended that donations with a nucleated cell concentration above $200 \times 10^9$/L are diluted to less than $200 \times 10^9$/L, preferably with autologous plasma. HPC-A donations must be placed at $4 \pm 2^\circ$C if they are for liquid storage and/or are not being processed immediately. It is recommended that the final concentration after addition of the cryoprotectant is less than $100 \times 10^9$/L.

- transport if appropriate.

Where donations of known virology or bacteriology positive material are stored, appropriate risk assessments ensuring adequate controls are in place must be completed.

22.10.1: Duration

Facilities storing HPC components shall establish policies for the duration and conditions of storage and indications for discard. Patients, donors and associated transplant centres should be informed about these policies and consent obtained where appropriate.

22.10.2: Alarm systems

- Storage devices shall have alarm systems that are continuously active.
- Alarm systems shall have audible signals.
- If laboratory personnel are not always present in the immediate area of the storage device, a remote alarm device shall be required at a location staffed 24 hours a day. Alternatively an auto-dial facility connecting to an on-call member of staff may be satisfactory.
• Alarms shall be set to activate at temperatures, or an unsafe level of liquid nitrogen, to allow time to salvage components.

• There shall be a written procedure to be followed if the storage device fails.

• A procedure for notifying laboratory personnel should be in place.

• Alarm systems shall be checked periodically for function.

• Additional storage devices of appropriate temperature shall be available for component storage if the primary storage device fails.

22.10.3: Inventory control

There shall be an inventory control system to enable component and quality control vials to be located. It should include the donor name or unique identifier, date of collection, type of storage device and location within it, and state the number of containers and vials and number issued, dates of issue and numbers of containers and vials remaining.

22.10.4: Cryopreservation

• Archive samples Aliquots of the HPC component, processed and stored under the same conditions as the HPC component, must be available for additional testing as necessary.

• Methods should be validated, taking into account critical pre-freeze variables such as temperature, duration of storage, cell density and type of cryoprotectant.

• A secondary container, ‘double bagging’, must always be used to prevent cross-contamination between donations and to effectively quarantine the unit.

• The containers must be clearly and unambiguously labelled using labels that have been validated for use under the required storage conditions. The data on the labels must be in accordance with FACT-JACIE and NetCord-FACT Standards.

• Cryopreservation of the HPC product must be with an established cryoprotectant (e.g. 10% DMSO), used in a validated procedure with defined times and temperatures of exposure to specified concentrations.

• Established conditions of time and temperature of exposure of the HPC component to the cryoprotectant must be observed. These must be specific to the cryoprotectant system used. Validated storage conditions for the cryoprotectant must be observed.

Frozen HPCs should be stored at a sufficiently low temperature to ensure recovery of living cells after the intended preservation period. HPC donations are generally stored for named patients in low volumes using containers with a high surface area. To minimise the risk of transient warming events that may reduce viability and to maximise the time available to salvage donations should a storage device fail a temperature below –150°C should be used.

It is recommended that the vapour phase of liquid nitrogen is used to reduce the risk of cross-contamination. It is recognised, however, that this is associated with a greater temperature fluctuation and measures should be taken to ensure that the paragraph above applies. Some facilities may employ total or
partial immersion in liquid phase to store HPC donations. Whatever method of storage is used it must always be assumed that liquid nitrogen is microbially contaminated and secondary enclosure must be employed.

For vapour phase the storage vessels should be fitted with a minimum of two temperature probes that are linked to a remote central monitoring system manned continuously. For liquid phase storage the vessel should be fitted with a minimum of a single probe. Records must be kept of these temperatures.

If liquid nitrogen refrigeration is used an automatic filling mechanism or a standardised manual procedure must be provided to ensure and document that adequate levels of liquid nitrogen are maintained.