Hematopoietic Stem Cell Transplantation Laboratory

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Hematopoietic Stem Cell Collection and Processing Facility

INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

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APHERESIS COLLECTION FACILITY

The following facilities and services shall be made available:

3.2.1 An adequate and confidential space for donor examination, evaluation and counseling.

3.2.2 A 24 hour emergency and intensive care medical services.

3.2.3. An out-patient clinic follow-up visit.

3.2.4 A designated area for appropriate preparation and storage of the consumables, reagents and equipments needed for performing the collection procedure.

3.2.5 A formal arrangement with an accredited laboratory to perform all the tests required. Refer Section 3.5.7.

3.2.6 An appropriately equipped and staffed operating theatre.

3.2.7 A transfusion facility or blood bank providing 24-hour blood component support including irradiated blood components and components suitable for CMV negative recipients.

3.2.8 Collection facility should be organised to avoid any potential errors with donor records or labels.

PROCESSING STANDARDS

LABORATORY FACILITIES

4.1.1 The facility responsible for processing and storage of cells shall be of adequate space and design for the intended purposes.

4.1.2 There shall be adequate equipment for the procedures performed at the facility.

4.1.3 The facility shall be maintained in a clean and orderly manner and not to be used for purposes other than those designated.

4.1.4 The facility shall be secured to prevent the admittance of unauthorized personnel.

4.1.5 Laboratory equipment is not to be used for microbial cultures or non-patient related work involving cell lines or genetically altered cells.

TYPES OF PROCESSING

4.4.1 Routine Processing

These are procedures regularly undertaken in clinical transplantation facilities. Section 2.4 applies.

4.4.2 Specialised Processing

A procedure mentioned in Section 2.4 applies. Investigational procedures shall only be performed as part of a research project.

Testing of Products for Routine Processing

4.6.1.1 The laboratory shall define tests and procedures for measuring, assaying or monitoring properties of the cell products essential to the evaluation of their safety and usefulness.

4.6.1.2 Results of all such tests and procedures shall become part of the permanent record of the material processed.

4.6.1.3 As a minimum, the following test shall be performed:

a. Nucleated Cell Counts

- A nucleated cell count shall be performed for any product after collection and after any subsequent processing.

b. CD34+ and/or CD3+ Cell Counts

- CD34+ and/or CD3+ cell count shall be performed on the final HPC and TC products.
- Target CD34+, CD3+ cell count or nucleated cell count should be determined for each product and monitored against transplant outcomes.

c. Microbial Testing

- Cell collection and processing facilities shall perform and document microbial testing of HPC or TC products after collection and post processing.
- The results of microbial cultures shall be reviewed by the Laboratory Director or designee in a timely manner.
- The recipient's transplant physician shall be notified in a timely manner of any positive microbial cultures.

d. ABO/Rh Group Tests

- Where applicable, tests for ABO and Rh groups shall be performed.
- In ABO Mismatch transplantation, ABO isohaemagglutinin titer shall be tested.

e. Viability Testing

- Viability testing shall be performed on post processing and pre infusion.

· STORAGE STANDARDS

STORAGE OF FRESH CELLS IN LIQUID STATE

5.2.1 General

Cells stored in a liquid state shall be maintained at a temperature and for a period of time specified in a protocol validated by the laboratory.

5.2.2 Storage Duration / Expiry Date

5.2.2.1 If storage cannot be avoided, the temperature and duration of storage should be according to the following guidelines:

a. Storage and transportation at 20 to 24°C.It is recommended that products should be infused or further processed in less than 48 hours after collection.

b. Storage and transport at 2 to 6°C. It is recommended that products should be infused or further processed in less than 72 hours after collection

STORAGE OF CRYOPRESERVED CELLS IN FROZEN STATE

5.3.1 General

5.3.1.1 Storage shall be within a temperature range –80°C to –196°C as determined to be appropriate for the cryoprotectant used.

5.3.1.2 Storage systems should be designed to minimise the potential of microbial cross-contamination.

5.3.2 Storage Facilities

The storage device shall be located in a secure area but emergency access should be available

5.3.3 Monitoring Systems

5.3.3.1 Refrigerators and freezers for product storage shall have a system to monitor and record the temperature continuously. This is best done with an automated system but manual check is also acceptable.

5.3.3.2 Liquid nitrogen freezers shall have a system to monitor liquid nitrogen levels. An automatic fill mechanism is recommended.

Laboratory Facility for Allogenic Transplantation

Hindawi
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Establishing Hematopoietic Stem Cell Transplant Unit in Resource Limited Setting: A Critical Analysis of Indian Council of Medical Research 2017

Kunal Das,[1] **Tanvi Khanna**,[1] **and Nitika Agrawal**[2]

S. K. Hashmi, A. Srivastava, W. Rasheed et al., "Cost and quality issues in establishing hematopoietic cell transplant program in developing countries," *Hematology/Oncology and Stem Cell Therapy*, vol. 10, no. 4, pp. 167–172, 2017.

E. Gluckman, D. Neiderwieser, and M. Aljurf, *Establishing a Hematopoietic Stem Cell Transplant Unit: A Practical Guide*, Springer, 2017.

Support Services or Not?

- Molecular Laboratory
- Cytogenetic Laboratory
- Flow cytometry Laboratory
- HLA Laboratory

Essential:

- Blood bank facility should be available and with proper license for apheresis, blood components, and stem cell collection and storage.
- Blood irradiation facility is also essential .
- Some tests are routine and require in-house facility like CBC, flow cytometry capable of doingCD34 counts

Outsourced to central laboratory:

- HLA typing, Advanced Molecular lab
- Donor specific antibody screen, chimerism,
- fluorescent in situ hybridization & Cytogenetic
- Drug levels
- Flow cytometry
- And so on

THANKS!