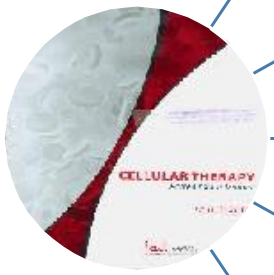
# FACT-JACIE Standards

Clinical

# FACT-JACIE Standards

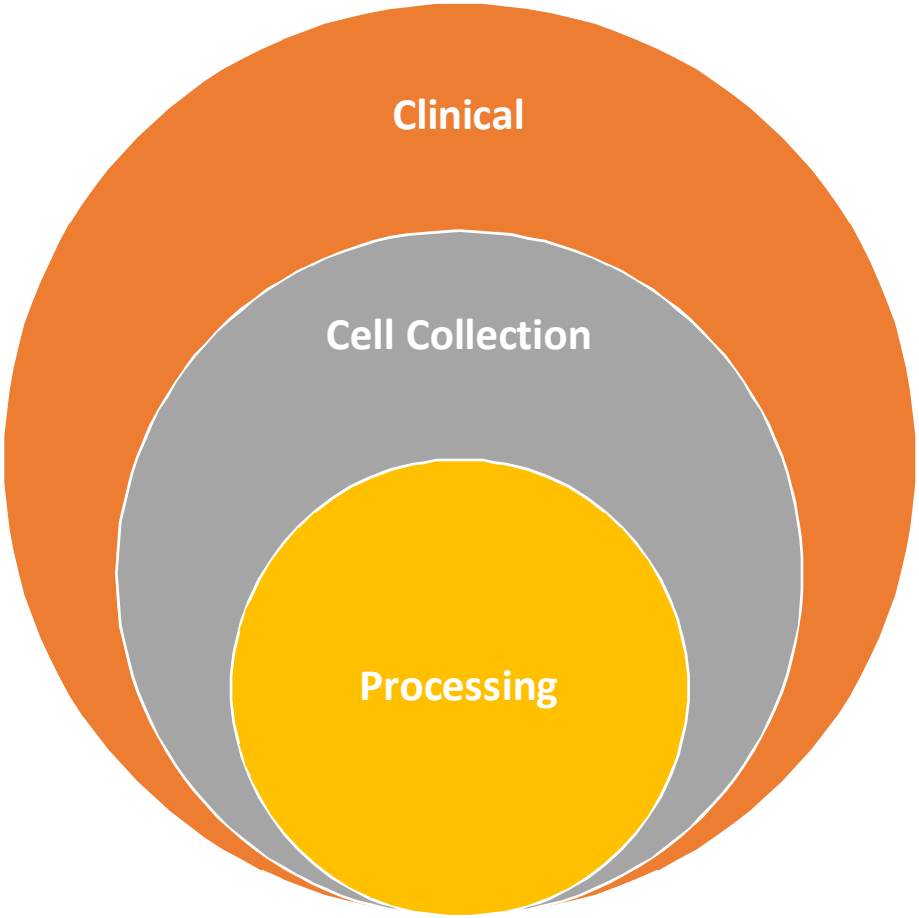



- Part A • Definitions
- Part B • Clinical
- Part CM • Bone Marrow Collection
- Part C • Apheresis
- Part D • Processing

# Clinical transplant programme

B1

# B1 Transplant Programme

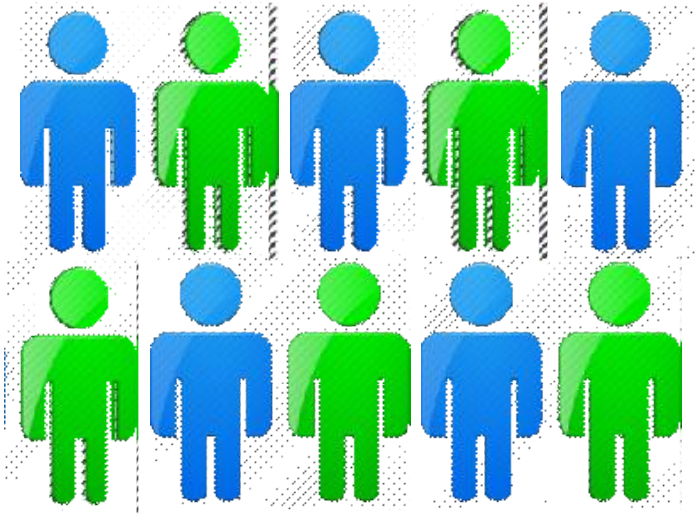


# Established

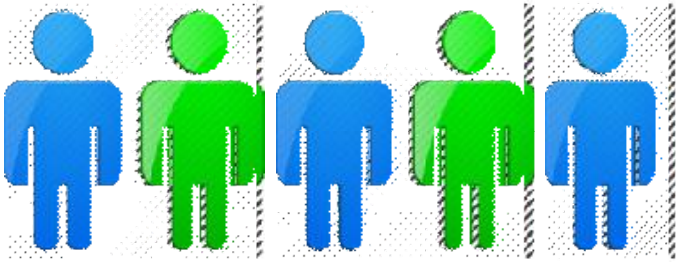
- Dedicated transplant team
  - Clinical Program Director(s)
  - one other physician trained and/or experienced in cell therapy and/or HPC transplantation
  - in place for at least twelve (12) months preceding accreditation

# B1.5 Transplant activity

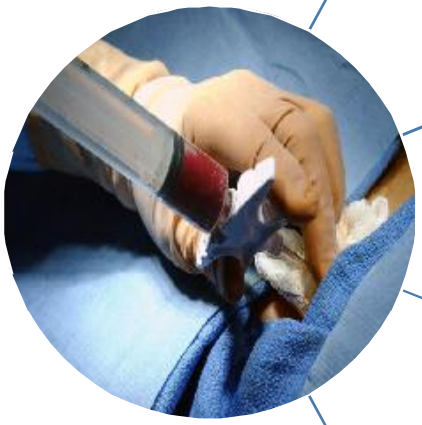
- Allogeneic (10)



- Autologous (5)



# B1.5 Minimum transplant activity



- Allo
  - 10
- Allo + Auto
  - 10 + “1” - no min for autos
- Auto
  - 5
- Adult + Ped
  - Min 5 each population

## MINIMUM NUMBER OF NEW PATIENTS FOR ACCREDITATION

Clinical Programs shall transplant at least the following number of new patients[1] before initial accreditation and annually thereafter:

| Transplant Population | Clinical Site(s) | Type of Transplant | Overall Minimum | Twelve (12) Months Prior to Initial Accreditation | Average Per Year Within Accreditation Cycle |
|---|---|---|---|---|---|
| Adult OR Pediatric (only one of these two) | Single Clinical Site | Allogeneic only[2] | 30 allogeneic | 10 allogeneic | 10 allogeneic |
| | | Autologous only | 15 autologous | 5 autologous | 5 autologous |
| | | Allogeneic and Autologous | 30 allogeneic | 10 allogeneic | 10 allogeneic |
| | Multiple Clinical Sites | Allogeneic only[2] | 15 allogeneic at each site | 5 allogeneic at each site | 5 allogeneic at each site |
| | | Autologous only | 15 allogeneic at each site | 5 autologous at each site | 5 autologous at each site |
| | | Allogeneic and Autologous | 15 allogeneic at each site<br>15 autologous at applicable sites[3] | 5 allogeneic at each site<br>5 autologous at applicable sites[3] | 5 allogeneic at each site<br>5 autologous at applicable sites[3] |
| Combined Adult AND Pediatric | Single Clinical Site | Allogeneic only[2] | 15 adult allogeneic<br>15 pediatric allogeneic | 5 adult allogeneic<br>5 pediatric allogeneic | 5 adult allogeneic<br>5 pediatric allogeneic |
| | | Autologous only | 15 adult autologous<br>15 pediatric autologous | 5 adult autologous<br>5 pediatric autologous | 5 adult autologous<br>5 pediatric autologous |
| | | Allogeneic and Autologous | 15 adult allogeneic<br>15 pediatric allogeneic | 5 adult allogeneic<br>5 pediatric allogeneic | 5 adult allogeneic<br>5 pediatric allogeneic |
| | Multiple Clinical Sites | Allogeneic only[2] | 15 adult allogeneic at each site<br>15 pediatric allogeneic at each site | 5 adult allogeneic at each site<br>5 pediatric allogeneic at each site | 5 adult allogeneic at each site<br>5 pediatric allogeneic at each site |
| | | Autologous only | 15 adult autologous at each site<br>15 pediatric autologous at each site | 5 adult autologous at each site<br>5 pediatric autologous at each site | 5 adult autologous at each site<br>5 pediatric autologous at each site |
| | | Allogeneic and Autologous | 15 adult allogeneic at each site<br>15 pediatric allogeneic at each site<br>15 adult autologous at applicable sites[3]<br>15 pediatric autologous at applicable sites[3] | 5 adult allogeneic at each site<br>5 pediatric allogeneic at each site<br>5 adult autologous at applicable sites[3]<br>5 pediatric autologous at applicable sites[3] | 5 adult allogeneic at each site<br>5 pediatric allogeneic at each site<br>5 adult autologous at applicable sites[3]<br>5 pediatric autologous at applicable sites[3] |

JACIE joint accreditation committee isct. ebmt.

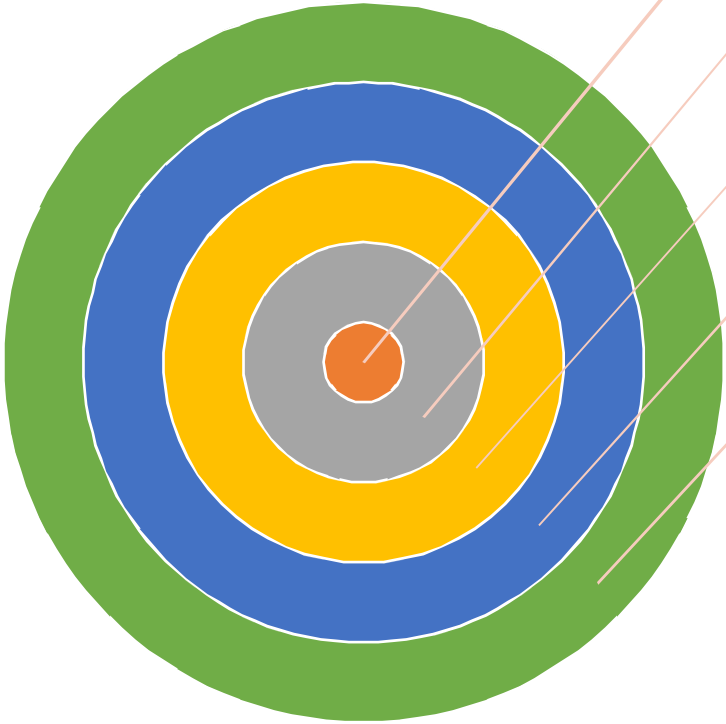
EBMT European Society for Blood and Marrow Transplantation

ISCT International Society for Cellular Therapy

# Clinical unit

B2

# Services required



Inpatient unit

24/7 physician available

Intensive care unit

Pharmacy 24/7

Outpatient unit

**Also:**

Renal support

24/7 access to CMV-appropriate / irradiated blood supplies

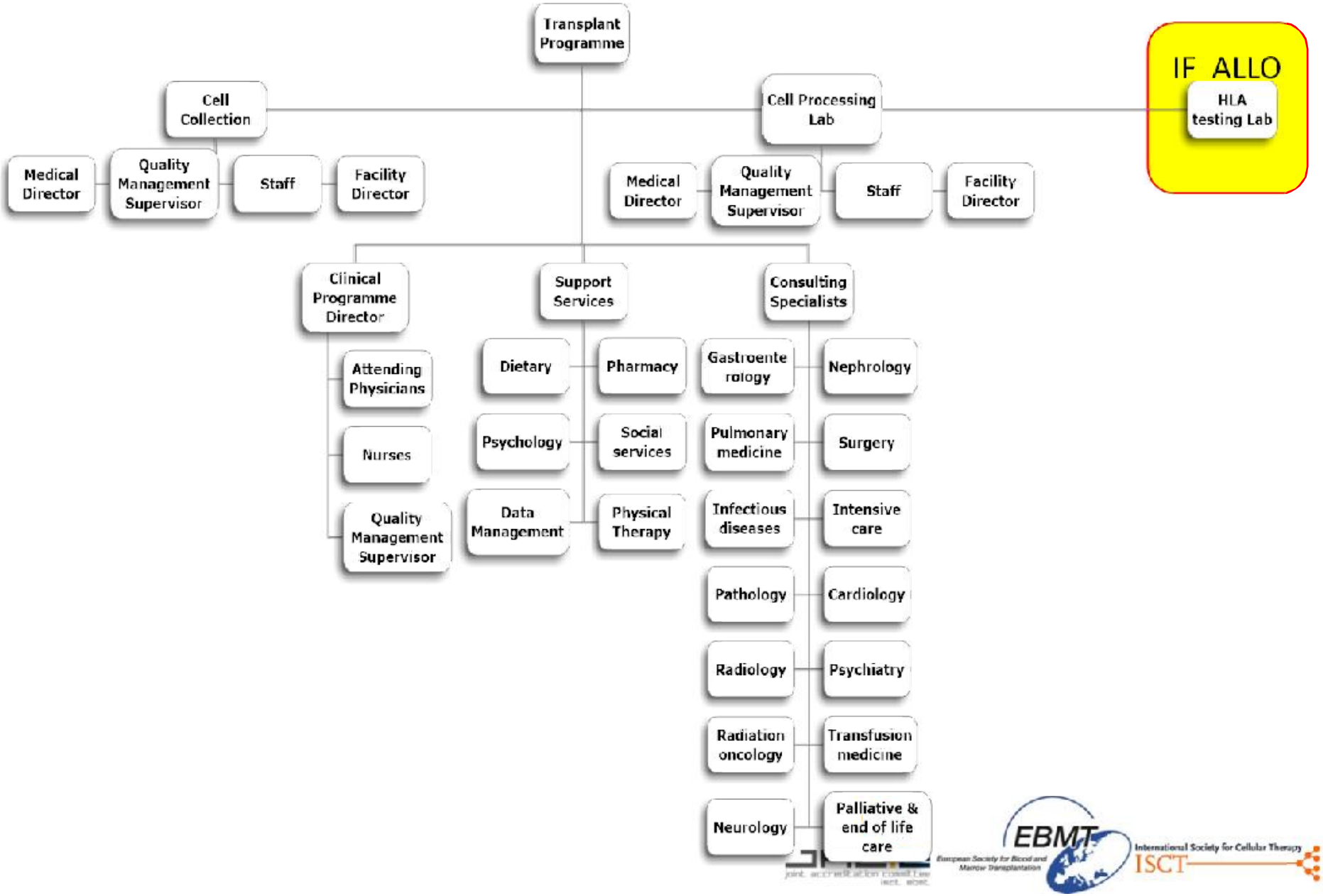
Supervised care when provided in other hospitals - must meet standards

Allogeneic:
Use EFI-accredited typing lab

# Personnel

B3

# B3 Personnel



# Pediatrics

- If you have pediatric patients, you must have physicians and nurses qualified and experienced in their care
  - B3.3.1
  - B3.6.2
  - B3.7.2
  - B5.7

# B3.1 Clinical Programme Director - responsibilities

Procedures

Administrative operations

Quality Management Program of the Facility

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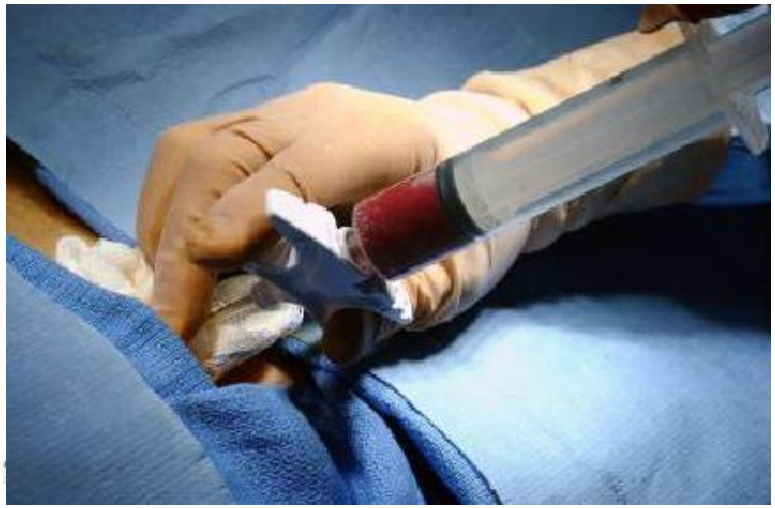
Compliance with Standards and laws and regulations

Oversight of medical care provided by Clinical Program

Verifying the knowledge and skills the transplant team

# Bone marrow harvest

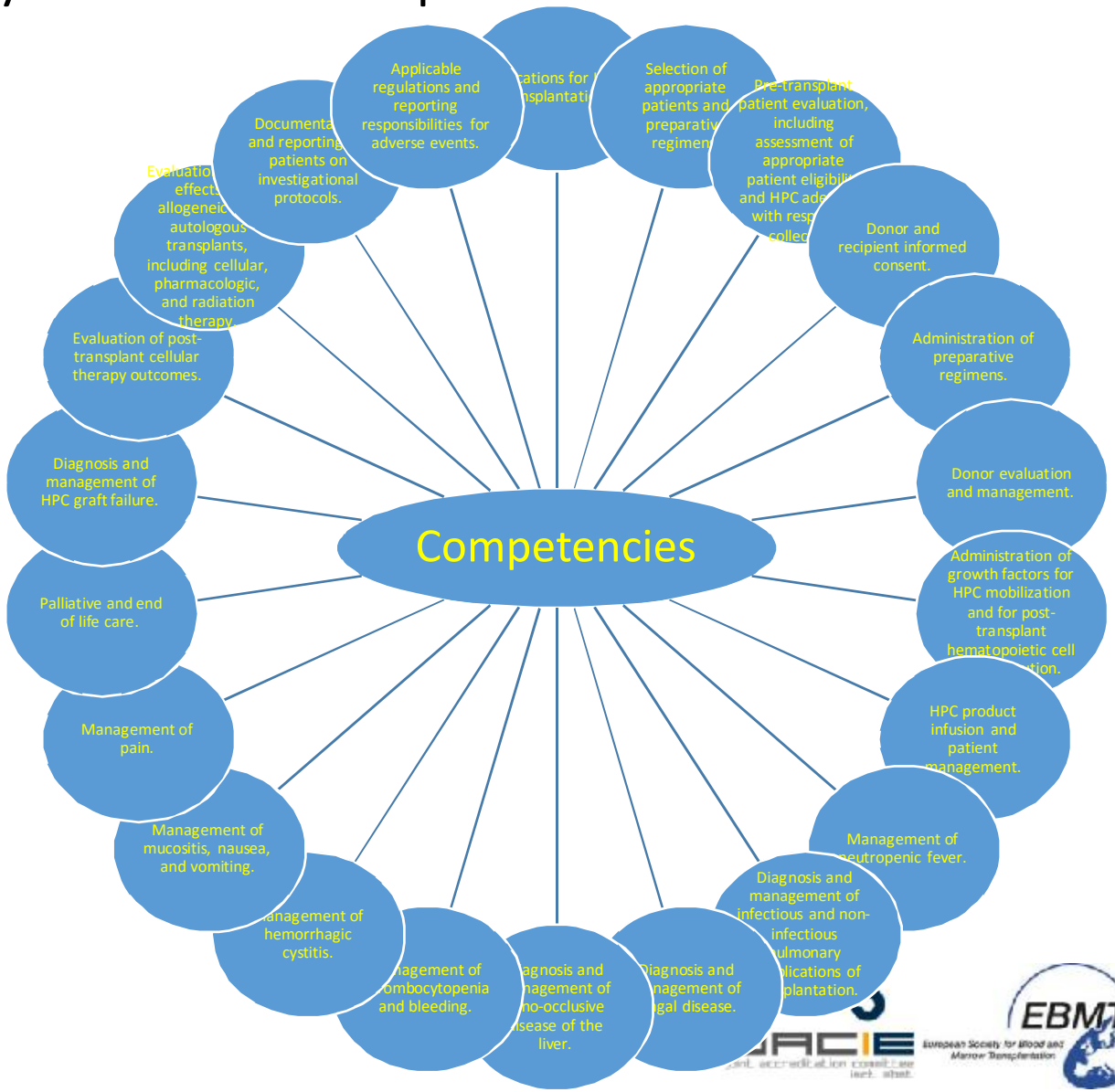
- Program shall have access to licensed physicians who are trained and competent in marrow collection and a marrow collection facility that meets these Standards.
  - CM1.4.1 **A minimum of one (1) marrow collection procedure** shall have been performed in the twelve (12) months preceding accreditation.



# B3.2 Attending physicians

| Licensed | Specialist | Education | Pediatrics |
|---|---|---|---|
| • Appropriately licensed to practice medicine in the jurisdiction of the Clinical Program | • Hematology<br>• Medical Oncology<br>• Adult or Pediatric Immunology or Pediatric Hematology/Oncology | • Participate regularly in educational activities related to the field of HPC transplantation | • Programs performing PEDIATRIC transplantation shall have a transplant team trained in the management of PEDIATRIC patients. |

# B3 Physicians' competencies



# B3.6 How many nurses?

- Adequate number of nurses experienced in the care of transplant patients
- Nurse/Patient ratio satisfactory to manage the severity of the patients' clinical status

Establish plan for:

- Increase nurse support when caseload increases
- Cover planned and unplanned absences
- **Training programme** in transplant care for hematology nurses

# B3.6 Nurses' Training/Competencies

1. • **Hematology/oncology patient care**, including an overview of CT process
2. • Recognition of cellular therapy **complications and emergencies** requiring rapid notification of the clinical transplant team
3. • Administration of **blood products, growth factors, CT products**, and other supportive therapies
4. • Administration of **preparative regimens**
5. • **Care interventions** to manage transplant complications
6. • **Palliative** and end of life care

# SOPs

# B5 Procedures (SOPs)

- Donor and recipient evaluation, selection, and treatment
- Donor and recipient confidentiality
- Donor and recipient consent
- Infection prevention and control
- Facility management and monitoring
- Disposal of medical and biohazard waste
- Emergency and disaster plan, including the Clinical Program response
- Administration of blood products
- Administration of HPC and other cellular therapy products, including exceptional release
- Administration of the preparative regimen

# Therapy administration

B7

# B7 Therapy Administration

1

- Verify availability and suitability of donor or cellular therapy product prior to initiating the recipient's preparative regimen

2

- Clinical service - notify the Processing Facility prior to requesting a cryopreserved cellular therapy product from a cord blood bank or registry

B7.2

# Policy addressing safe administration of the preparative regimen

# B7.2.1 Chemotherapy

- Policy for administration of chemotherapy
- Written order from physician
- Orders verified & documented by physician
- Pharmacist verifies doses against protocol or standardized regimen
- 2 persons verify drug & dose against orders & protocol
- 2 persons verify identity of patient

# B7.2.1.1 Treatment orders

- Include
  - Height
  - Weight
  - Specific dates
  - Daily doses (if appropriate)
  - Route of administration of each agent

# B7.2.2 Radiation Therapy

Policy for administration of radiation therapy

Consultation with radiation oncologist

Written information

Documented consultation

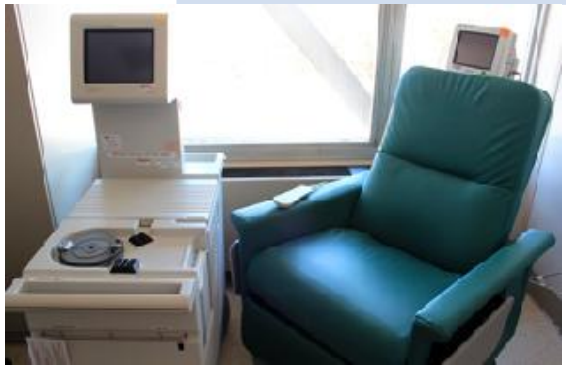
Radiation Planning

Verification of dose

Final Report supplied for patient record

# B7.3 Extracorporeal photopheresis

- Policy for administration of ECP
- Consultation with ECP facility
- Written order from physician
- ECP performed according to SOP(s)
- Final Report supplied for patient record
- Review of outcomes and adverse events on annual basis

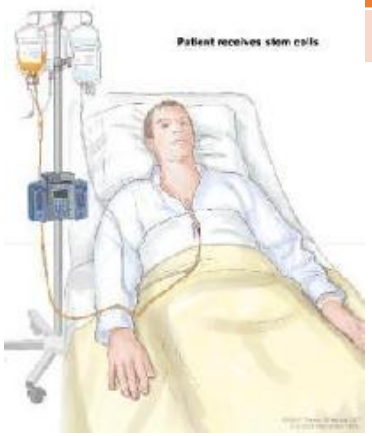


# B7.4 Administration

Policy for administration of cellular therapy products

2 persons verify identity of recipient & product & order for administration

Documentation in patient medical record of the unit identifier and a copy of the distribution record



# Clinical research

B8

# B8 Clinical Research

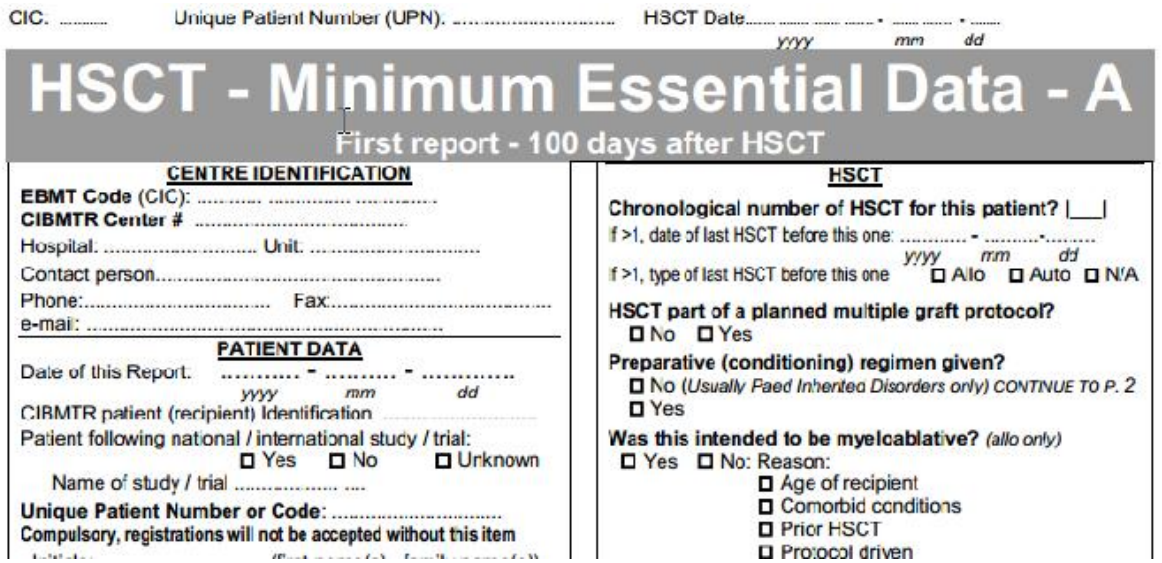
- Standards establish framework for research
  - Legal compliance
  - Pharmacy support
  - Approval by relevant bodies e.g. Ethics Committee, Regulatory Agency
  - Consent requirements

# Data management

B9

# B9 Data Management

- The Clinical Program shall collect all the data <u>necessary to complete</u> the … CIBMTR TED or EBMT MED-A forms
  - No requirement to <u>report</u> but <u>strongly</u> recommended



CIC. ..... Unique Patient Number (UPN). ..... HSCT Date..... - ..... - .....
yyyy mm dd

**HSCT - Minimum Essential Data - A**

**First report - 100 days after HSCT**

**CENTRE IDENTIFICATION**

**EBMT Code (CIC):** .....
**CIBMTR Center #** .....
Hospital. ..... Unit. .....
Contact person.....
Phone:..... Fax:.....
e-mail: .....

**PATIENT DATA**

Date of this Report. ..... - ..... - .....
yyyy mm dd
CIBMTR patient (recipient) Identification .....
Patient following national / international study / trial:
☐ Yes ☐ No ☐ Unknown
Name of study / trial .....
**Unique Patient Number or Code:** .....
**Compulsory, registrations will not be accepted without this item**

**HSCT**

**Chronological number of HSCT for this patient?** |___|
If >1, date of last HSCT before this one: ..... - .....-.....
yyyy mm dd
If >1, type of last HSCT before this one ☐ Allo ☐ Auto ☐ N/A

**HSCT part of a planned multiple graft protocol?**
☐ No ☐ Yes

**Preparative (conditioning) regimen given?**
☐ No (*Usually Paed Inherited Disorders only*) *CONTINUE TO P. 2*
☐ Yes

**Was this intended to be myelcablative?** *(allo only)*
☐ Yes ☐ No: Reason:
☐ Age of recipient
☐ Comorbid conditions
☐ Prior HSCT
☐ Protocol driven

# Records

B10

# B10 Records


Quality control
Research records
Personnel training and competency
Patient and donor records
What Records?
Facility maintenance & management
Employee records
Complaints
Other general facility issues

# B10 Records

- Establish archive policy in line with regulations and laws
  - Minimum 10 years for
    - Research records
    - Patient / Donor records