JACIE STANDARDS[1]

Category: Standards

ABSTRACT

JACIE Standards(G) define an infrastructure required for all phases of the safe collection, processing, and administration of haematopoietic cells. They require an ongoing assessment of these activities, yet they do not prescribe the use of these therapies.

These standards are based on the standards of the Foundation for the Accreditation (G) of Cellular Therapy, and a specific centre can be Accredited by JACIE (Joint Accreditation Committee-ISCT & EBMT)

KEYWORDS

JACIE, haematopoietic cells, transplantation, bone marrow, quality management system.

OBJECTIVE

JACIE's primary aim is to promote high quality patient care and laboratory performance in haematopoietic stem cell collection, processing and transplantation centres through an internationally recognised system of accreditation.

FIELD OF APPLICATION

These Standards for Blood and Marrow Progenitor Cell Collection, Processing and Transplantation apply to all sources of haemopoietic progenitor cells and all phases of collection, processing, and administration of these cells in centres performing blood and marrow transplantation.

This includes, but is not limited to cells isolated from bone marrow, peripheral blood, or placental/umbilical cord blood; and any of a variety of manipulations including removal or enrichment of various cell populations, expansion of haemopoietic cell populations, cryopreservation, infusion, expansion or activation of lymphocyte populations for immunological therapy, and genetic modification of lymphoid or haemopoietic cells, when the cells are intended to permanently or transiently engraft in the recipient, and/or be used in the treatment of disease.

These Standards also apply to the transplantation of umbilical cord blood cells under the clinical standards for transplantation of allogeneic or autologous haematopoietic progenitor cells, as appropriate.

[1] *All material presented is taken from JACIE website (http://www.jacie.org)*

RELATED TOOLS

ISO 9001:2000 Standards

DESCRIPTION

BACKROUND INFORMATION

The Joint Accreditation Committee-ISCT & EBMT is a non-profit body established in 1998 for the purposes of assessment and accreditation in the field of haematopoietic stem cell (HSC) transplantation.

The Committee was founded by the European Group for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT), the two leading scientific organisations involved with HSC transplantation in Europe.

JACIE Standards define an infrastructure required for all phases of the safe collection, processing, and administration of haematopoietic cells. They require an ongoing assessment of these activities, yet they do not prescribe the use of these therapies.

Facilities performing haemopoietic progenitor cell collection, processing, storage and/or transplantation may apply for voluntary accreditation.

While every effort has been made to design the Standards as sound recommendations to foster good medical and laboratory practice in haemopoietic progenitor cell therapy, no standards can guarantee the successful outcome of such therapies. These Standards are minimal performance guidelines which may be exceeded as deemed appropriate by the responsible personnel in individual facilities.

STANDARDS DESCRIPTION

JACIE standards covering in general the following 3 main areas:

- *Clinical Programme Standards*
- *Haematopoietic Progenitor Cell And Therapeutic Cell Collection Standards*
- *Haematopoietic Progenitor Cell And Therapeutic Cell Processing Standards*

Critical processes covered by JACIE standards are Donor Evaluation, Selection and Management, Therapy Administration, Haematopoietic Progenitor Cell and Therapeutic Cell Collection, cell products labeling, cryopreservation, storage, trasportation and disposal.

SYSTEM DEVELOPMENT PROCESS

A quality management system is a mechanism to ensure that procedures are being carried out in line with agreed standards with full participation by all staff members.

In order to develop a Quality System according to JACIE standards someone can use various methods and tools depending to each individual situation. Still, a general methodology which can be applied in most of the cases is combined by the 5 steps presented below.

ANALYSIS OF CURRENT SITUATION

Information is gathered about the tools and methods used in current situation, according to requirements of the standard. The JACIE accreditation checklist can be used to assess current situation.

GAP ANALYSIS

For each requirement of the standard, the gap between the current situation and the required by the standard is assessed.

SYSTEM DESIGN

The Quality Management System is designed in terms of basic structure and a list of required documentation with sort descriptions is made.

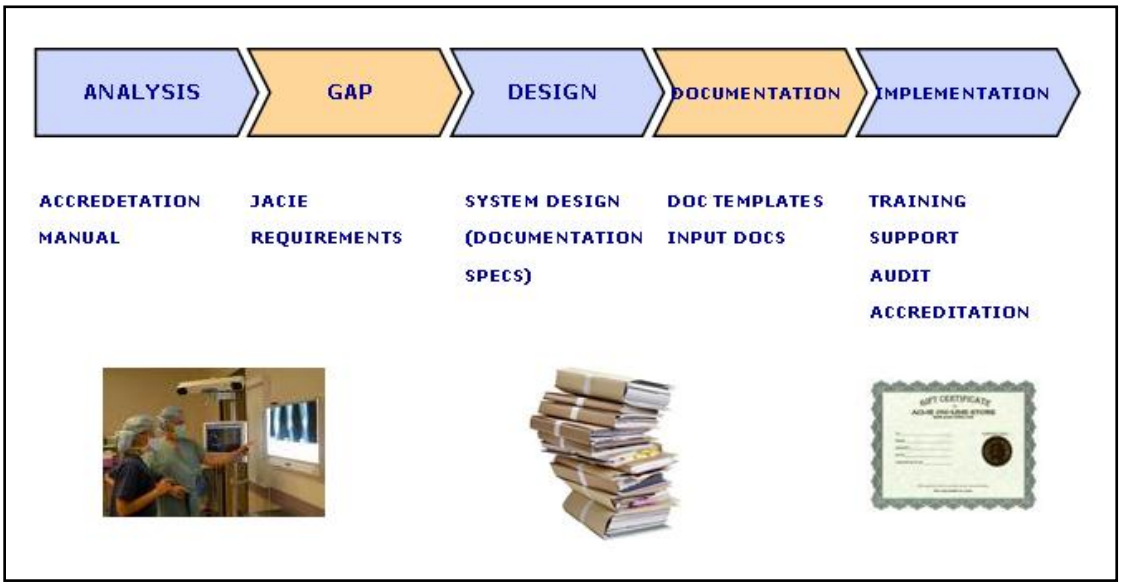
SYSTEM DOCUMENTATION

Based on the list, every document is developed.

SYSTEM IMPLEMENTATION

System is put in place, the users should be trained, and the system should begin to be implemented.

The methodology described is presented in the following figure.



ACCREDITATION PROCESS

Facilities performing haemopoietic progenitor cell collection, processing, storage and/or transplantation may apply for voluntary accreditation as follows:

- *A clinical haemopoietic progenitor cell transplantation programme may apply for accreditation alone or in conjunction with the collection facility and/or the cell processing laboratory with which it is associated. All facilities applying together should submit pre-inspection data together. If applying separately, a clinical transplant programme must use a collection facility and a processing laboratory that meet these Standards.*

- *A haemopoietic progenitor cell collection facility or service (apheresis, cord blood) may apply for accreditation as an integral part of a clinical transplant programme, as a local or regional collection service providing haemopoietic progenitor cell collection services for one or more clinical transplant programmes, or in conjunction with a cell processing laboratory if the services of haemopoietic progenitor cell collection and processing/storage are functionally linked. An accredited haemopoietic progenitor cell collection facility may provide services for clinical transplant programmes that are and/or are not accredited, but should use a processing laboratory that meets these Standards.*

- *A haemopoietic progenitor cell processing laboratory may apply for accreditation as an integral part of a clinical transplant programme, as part of a collection service or facility, or as an independent laboratory that processes and stores haemopoietic progenitor cell components for clinical programme(s) and/or collection facilities. An accredited laboratory may provide services for clinical transplant programmes that are/are not accredited.*

The application process consists of the following steps:

1. Initial Application: *The Initial Application Form is completed and submitted. This application is reviewed by the JACIE Office and approved to proceed. Questions arising at this point are raised and resolved between the JACIE Office and the applicant centre. The applicant is required to propose an approximate date by when they will be prepared for inspection. This date should be within 12 months of the initial application submission.*

2. Document Submission: *Approximately 8 weeks prior to the anticipated inspection date, the applicant centre should submit the required pre-inspection documentation as described in the Pre-Inspection Document Checklist. This is to allow the appointed inspectors sufficient time to review the files.*

3. Inspection: *The Inspection will be arranged between the JACIE Office, the Inspectors and the Applicant Centre. The time required for the on-site inspection is agreed in advance by all concerned. All inspections are conducted by persons qualified by training and experience in haematopoietic cell therapy, who have attended inspector training and who have a working knowledge of JACIE Standards and of their application to various aspects of haematopoietic progenitor cell therapy. For each inspection, inspectors are chosen to ensure that the team has the depth and breadth of expertise and experience to adequately survey the applicant programme. Applicants are entitled to request a change in inspectors prior to the inspection if there is any*

perceived conflict of interest. The on-site inspection is based on a checklist methodology, in which the applicant first answers each question, and these answers are verified by the on-site inspectors. This methodology is effective in focusing the content of the inspection on the JACIE Standards, and in promoting thoroughness and consistency among inspectors and inspections.

4. Post-inspection: *Following the inspection, the Inspection Team Leader drafts the Inspection Report based on his/her own observations and those of the other inspectors. This report is submitted to the JACIE Office and is then reviewed by the JACIE Medical Director or designated Medical Consultant. Any areas that are unclear or require further information are clarified between the inspectors and the Medical Director at this point. After this exchange, the final Inspection Report is agreed. Based on this report, the Medical Director will make his/her recommendations as to the provisional accreditation level of the applicant centre and where applicable, the changes that are needed to satisfy the requirements for full accreditation. The two reports are then sent to the applicant centre and the appropriate National Representative. Facilities and programmes are given a reasonable period of time to correct the noted deficiencies. Depending on the number and severity of the deficiencies noted, review of additional documentation by the original inspectors, JACIE Office staff or by the Executive Committee may be required and/or a focused on-site reinspection may be considered necessary. There are no penalties for not completing corrections within the suggested time period. However, accreditation will not be awarded until JACIE is satisfied that all requirements have been met.*

5. Accreditation decision: *Once evidence has been submitted to confirm that the centre has corrected all deficiencies and that it has met the requirements of the Standards, the Medical Director makes a recommendation on accreditation to the JACIE Executive Committee The completed checklists, labels and other submitted documents, the inspectors' final report and the Medical Director's final report form the basis for review by the Executive Committee. The decision of the Executive Committee is communicated to the JACIE Board for final approval. Board Members have a period of two weeks from the date of the Executive Committee decision in which to object to accreditation based on information they hold to be valid and indicating that the applicant centre has not complied in part or in full with the Standards. Once this period is ended and if no valid objections have been raised, the accreditation award decision is communicated to the applicant centre and certification is issued.*

6. Accreditation: *JACIE Accreditation(G) is valid for three years. Accredited programmes and facilities are published on the JACIE website and in the newsletters of ISCT and EBMT. Accredited programmes are required to document their continued compliance with Standards by submission of annual programme information.*

7. Appeal: *Any programme or facility that has been denied accreditation during this process is entitled to appeal that decision by written submission.*

BENEFITS

By implementing a Quality System according to JACIE standards, some of the benefits are:

- *Demonstration of performance to a required level of practice in accordance with agreed standards of excellence.*
- *Conformance with EU legislation (EU directive 2004/23/EU)*
- *Standardisation and improvement of procedures, clinical protocols etc*
- *Improvement of communication and cooperation*
- *Implementation of effective common work practices*
- *Increase guarantees for patients*
- *Reduce errors, accidents and adverse reactions*
- *Assurance of cell product transportation and exchange between centers.*

PREREQUISITES

- *Adecuate infrastracture in terms of personel and equipement as there are relevant requirements.*
- *Well trained personnel*
- *Assigned Quality Manager.*

EXAMPLES – CASE STUDY

A sample Quality Manual according to JACIE standards is presented in the Jacie web site (http://www.jacie.org/)

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