



From the President's Desk

Results of hematopoietic stem cell transplantation improved over the last half-century by the combination of progress made in the three main contributing fields: clinical activities, cell collection and cell processing or cell engineering. While pharmaceutical and biotechnology industries have permitted most significant improvements through marketing of drugs, biological modifiers, devices and ancillary products, cell collection and cell processing facilities have mostly remained in and operated by academic institutions or blood banks, and have significantly contributed to innovations in the field.

Times are changing. New regulations are enforced that will accelerate the shift in perception of hematopoietic stem cell transplantation, moving away from the altruistic donation of human cells towards a more "pharmaceutical" view of human medicinal products. Among recent examples, on November 10, 2011, the U.S. Food and Drug Administration approved HEMACORD, the first licensed hematopoietic progenitor cells-cord (HPC-C) cell therapy, and a cell product that is essentially similar to a cord blood unit.

At the same time, regulations on Advanced Therapy Medicinal Products (ATMPs) find their way in Europe. They will affect production and marketing of somatic cell therapy products, gene therapy products, and engineered tissues, through the implementation of more stringent rules, such as defined in good manufacturing practices. While at the moment hematopoietic stem cell transplantation does not fall into the scope of ATMPs regulations, because these are minimally manipulated cells, prepared for a defined recipient (no batch), and that are not reimplanted or reinfused at an heterotopic site, more than minimally manipulated cell products, such as those products that include in vitro cell culture or activation are likely to fall under these regulations; the "hospital exemption" rule may alleviate some of the burden imposed upon cell engineering facilities located in academic institutions and hospitals, and that serve mostly national patients treated in partnering hospitals. However, in the long term, ATMPs regulation as well as regulations that are implemented in the US will profoundly affect and question our current organization for delivering HSCT, including the very usefulness of JACIE in its current form.

Our community will need to get prepared for these changes; awareness and information about these issues are the first step.



Christian Chabannon
JACIE President

Accreditation Statistics

Total centres registered:
249

Inspections in preparation:
First time:
33

Reaccreditation:
19

Total completed inspections:
First time:
191

Reaccreditation:
51

Accreditations:
107

Facilities correcting deficiencies:
32

Number of countries registered:
17

The 5th Edition of the FACT—JACIE Standards

Work on the next edition of the standards is entering the final phases. The public comments received during the consultation between April and July this year were all discussed by the respective standards sub-committees and changes made to the text. This text is being finalised and is expected to be sent to the FACT and JACIE Boards for approval within a few weeks. Subject to this approval, the Standards, Manual and Checklists will be published in March 2012.

The following are important dates for cellular therapy programs to remember:

- **5th Edition Publication Date: 01/03/2012** The final version of the 5th edition Cellular Therapy Standards will be officially published on 01/03/2012. This includes the Accreditation Manual and associated documents.
- **5th Edition Effective Date: 31/05/2012** The 5th edition Cellular Therapy Standards will be effective from and including 31/05/2012. All applications after this date will be assessed according to the 5th edition.

Taking into account the following aspects,

1. the publication and implementation dates
2. that JACIE requires the Inspection Checklist to be submitted along with the Application Form
3. that the 5th edition checklist will not be available until March 1st 2012
4. that JACIE Accreditation Office wishes to draw a clear line between the 4th and 5th editions in order to minimise confusion and overlap of different versions of Inspections for inspectors and centres,

the following dates should be noted by centres that expect to apply within the next 2-3 months.

- **31/12/2011** - Final date for acceptance of applications based on the 4th edition of the JACIE Standards
- Between **01/01/2012** - **28/02/2012** inclusive - No new applications accepted.
- **01/03/2012** - Earliest date for accepting applications and checklists based on the 5th editions

All centres that have already applied with the 4th edition of the JACIE Standards and are in the process of preparing for the JACIE Inspection must submit the pre-audit documentation **before 01/04/2012**. All centres that do submit the pre-audit documentation on or after **01/04/2012** will have to restart the application process against the 5th edition of the Standards and submit a new application. Given the effort required to prepare for the inspection, please consider carefully your timing for submission of documentation and completion of the Inspection Checklist.

TOP TIPS

Download and read carefully the Data Management section on the inspection guide. This document explains how to prepare for the Data Management audit.

The Clinical Program has selected a list of ten (10) consecutive allogeneic and/or five (5) consecutive autologous transplant patient records, as applicable, for audit.

Verify that a minimum of five (5) patients from each age group (pediatric and adult) and a minimum of five (5) patients from each clinical site, as applicable, have been included.

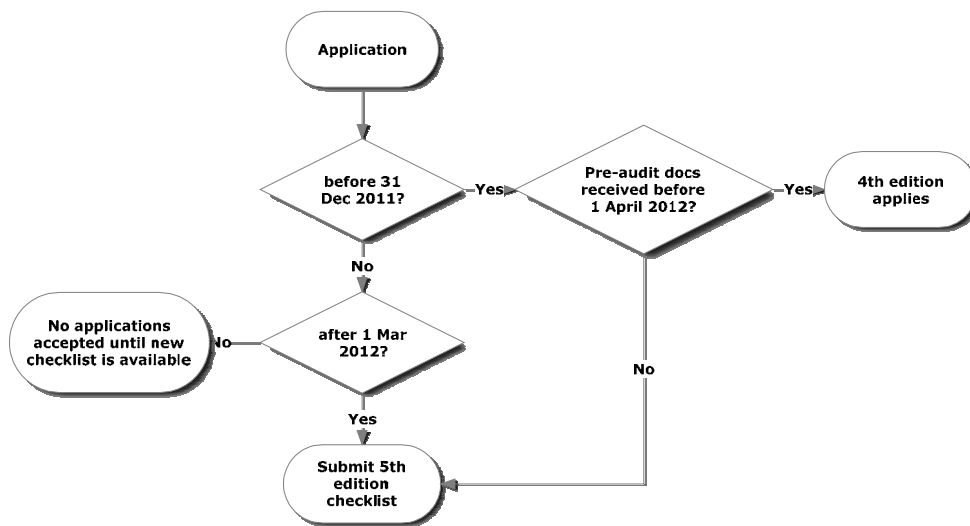
You must audit a minimum of thirty (30) data points for each type of transplant performed. This means that you should check:

a. For allogeneic AND autologous transplant = 30 x 2 transplant type = 60 datapoints in total

b. For allogeneic OR autologous transplants, 30 x 1 transplant type = 30 datapoints in total

c. For Combined Programmes, 30 x [number of units AND/OR patient types]

Below is a flowchart indicating the decisions to be taken based on key dates.



Thanks to inspectors

In this last JACE Newsletter of 2011 we would like to express our gratitude to the JACIE Inspectors. They are the eyes and ears of JACIE and making the JACIE Accreditation Process possible. Thanks to their volunteer and honorable job are contributing to improve quality in HSCT Programmes around the world.

This year JACIE has performed 44 inspections with the participation of 112 inspectors, and 32 Interim Audits with the participation of 32 Inspectors. We would like to take this opportunity to emphasize on the effort and commitment shown by these inspectors who made possible one of the busiest years for JACIE, but not only participating in the inspections, but providing their assessment and support during the whole JACIE Accreditation Process from the initial application until applying for re-accreditation.

Document Management System, document hierarchy and complying with the standards.

JACIE inspectors have encountered a wide variety of document formats and document management system. It is not uncommon for inspectors to have doubts as to whether a particular format complies with the FACT-JACIE requirements covering contents such as references, copies of worksheets, labels, etc. This commonly occurs in situations where a facility, generally collection or processing, forms part of a local, regional or national structure e.g. large university hospital, regional or national blood transfusion services. In such cases it is common to find SOPs and policy documents created at a level higher than the unit being inspected e.g. national cell processing protocols. Consequently, the unit can find it difficult to adapt their documentation to FACT-JACIE standards since they do not control the contents. In addition, different terminology may be in use so that what a facility calls a SOP could be considered a worksheet under FACT-JACIE requirements.

It is acknowledged that healthcare providers are more and more subject to different standards and regulations. JACIE allows centres to satisfy the standards in a variety of ways as long as the required principals are present.

TOP TIPS

For each type of transplant performed, five data points have been selected. They are listed on the INSPECTOR REPORT FORMS.

You must audit these five items on at least three (3) patient records = 15 items with the remaining 15 items to be either checked on additional records or 5 more data points on each of the 3 already chosen records.

Decide which data points you plan to audit and then transfer the data from the submitted MEDA forms to the data audit worksheets before the inspection.

This will save you time during the audit since you will only have to find those data points in the primary source data.

Therefore, it is important that the inspector understands the document management system by:

1. Reading the SOP about SOPs submitted as part of the pre-inspection documentation. This document should clarify terminology and formats so that it should be apparent where in the document hierarchy specific elements can be found. It would also be very useful to map the requirements of the standards to the structure used by the inspected centre e.g. references can be found in the top level policy; step-by-step instructions in the worksheet, etc.
2. Someone in the centre should be available to explain the system to the visiting inspector and to answer questions.

As an example, references to literature may be contained within the institution's policy documents but not in the SOP/worksheet. If the different document levels are clearly and easily connected to each other, then this should be acceptable for the inspector. This scenario may be common where all documentation is distributed via an electronic system e.g. hospital intranet.

Obviously if required elements from the standards can not be found in any part of the document hierarchy, then this is clearly a deficiency.

JACIE Training Courses

III Curso para enfermería en trasplante de progenitores hematopoyéticos

10th February 2012—Barcelona, Spain

Course for 60 attendees

Registration Fee: 60€

Language: Spanish

Registrations can be done through www.aulaclinic.com

Internal Audits Training Course

11th & 12th June 2012—Barcelona, Spain

Details will be announced in due course.

Centre Preparation Course

2nd & 3rd October 2012—Barcelona, Spain

Details will be announced in due course.

Inspector Training Course

4th & 5th October 2012—Barcelona, Spain

Details will be announced in due course.

Advanced QM Course

21st, 22nd, 23rd November 2012—Barcelona, Spain

Details will be announced in due course.

EBMT Annual Congress

The Programme for the Inspector Workshop that will take place during the EBMT Annual Congress in Geneva is already available at the JACIE website:

<http://www.jacie.org/portal/en/public/eventsDetail/ctnt/dD27/ / /1aw0/JACIE-Inspector-Workshop-14-00-17-00-1-April-2011-EBMT-2012-Annual-Congress-Genev.html>

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