

JACIE Newsletter



April 2011

Issue 6

From the President's Desk

A GROWING CONCERN FOR QUALITY AND OUTCOME MEASUREMENTS: MOVING HEMATOPOIETIC STEM CELL TRANSPLANTATION FROM PROOF OF CONCEPT TO A WIDELY ACCEPTABLE MEDICAL PROCEDURE?

In 2011, more than 50 years after the first in human allogeneic transplantations (for a review, see (1), allogeneic and autologous hematopoietic stem cell transplantations are widely used medical procedures, at least in developed and emerging countries that can afford the costs (2). The use of autologous transplantation with high-dose chemotherapy may somewhat recede with the introduction of so-called "targeted therapies" that usually produce less myelotoxicity as side effect. At the same time, allogeneic transplantation has entered new developments, with the increasing comprehension that it is the support for immune-mediated anti-tumour effects, and with the opportunity to use unrelated donors in a higher proportion of cases, as well as different stem cell sources including umbilical cord blood. As the field matures, it appears increasingly important that the actual effectiveness of allogeneic HSCT be accurately measured and updated in the context of evolving medical practices, increasing financial pressure, and changing demands from patients who expect not only control of their disease, but also the recovery of an as much "normal" as possible lifestyle. Several recent publications have approached these issues (3-7), and suggest improvement of clinical outcome in various categories of disease, as the result of multiple progress and changes in science, medical practices, healthcare organization and quality management. With much humility and determination, JACIE intends to play its role in these ongoing and positive changes.

Christian Chabannon
President, JACIE

SELECTED REFERENCES

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3. Koreth J, Schlenk R, Kopecky KJ, Honda S, Sierra J, Djulbegovic BJ, et al. Allogeneic stem cell transplantation for acute myeloid leukemia in first complete remission: systematic review and meta-analysis of prospective clinical trials. *Jama* 2009 Jun 10;301(22):2349-61.
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5. Gratwohl A, Brand R, Niederwieser D, Baldomero H, Chabannon C, Cornelissen J, et al. Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation. *J Clin Oncol* 2011 Apr 11.
6. Gratwohl A, Baldomero H, Schwendener A, Gratwohl M, Apperley J, Frauendorfer K, et al. The EBMT activity survey 2008: impact of team size, team density and new trends. *Bone Marrow Transplant* 2011 Feb;46(2):174-91.
7. Horan JT, Logan BR, Agovi-Johnson MA, Lazarus HM, Bacigalupo AA, Ballen KK, et al. Reducing the risk for transplantation-related mortality after allogeneic hematopoietic cell transplantation: how much progress has been made? *J Clin Oncol* 2010 Mar 1;29(7):805-13.

Accreditation Statistics

Total centres registered:
233

Inspections in preparation:
First time:
40
Reaccreditation:
22

Total completed inspections:
First time:
174
Reaccreditation:
43

Accreditations:
97

Facilities correcting deficiencies:
25

Number of countries registered:
17

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EBMT Congress, 2011 Overview

The quality management (QM) and JACIE sessions attracted excellent attendances. There were 381 pre-registered participants for the QM sessions, testimony to the continued growth in interest in this area. Interest was particularly high in all aspects related to the 5th edition of the Standards.

At the stand, Eoin and Iris from the JACIE Office answered questions from centres and inspectors. Aside from speaking to people from European countries, we had interesting discussions with representatives of centres from Israel, Iran, South Africa, Colombia and Jordan.

The slides from the following sessions are available at www.jacie.org:

- 5th edition of the FACT-JACIE standards. Changes & developments. D. Pamphilon (Bristol, UK)
- An update on EFI accreditation. G. Fischer (Vienna, AT)
- Data from the first annual European report on biosurvey for cell and tissue transplantation. I. Siska (Brussels, BE)

We are preparing the QM slides for distribution via the web site. Keep an eye open for future updates.

Public consultation: draft 5th edition of FACT-JACIE Standards

The Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee of ISCT-EBMT (JACIE) have published the draft 5th Edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration and its accompanying Accreditation Manual for inspection and public comment for a 90-day period. Comments will be accepted from April 18, 2011 through July 14, 2011.

We would like to invite you to comment and feedback on the proposed text. In order to have International Standards that are applicable to all centres, it is vital that a large, diverse group of those who are involved in Cellular Therapy review and contribute to the Standards. Your feedback is essential and greatly appreciated.

The instructions for contributing are available at www.jacie.org.

The final Standards will be published on March 1, 2012 and will become effective on May 30, 2012

FACT and JACIE announce interim cellular therapy standard

FACT and JACIE announce the publication of an interim standard to the fourth edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration.

Standard B3.1.1 now requires that Program Directors have at least achieved specialist certification, and does not require that board certification be renewed or kept current. The use of the term "achieve" is believed to be compatible with international requirements, and programs are reminded that they must still comply with any applicable laws and regulations requiring recertification.

The interim standard will be effective on May 1, 2011. The following documents have been updated on the JACIE website:

- 4th Ed. Standards v. 4.1
- 4th Ed. Accreditation Manual v. 4.3
- JACIE Inspection Checklist 4th ed. ver.6

Quality and Patient Outcome

We would also like to take this opportunity to inform you that the article Gratwohl, A. et al. *Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation* recently appeared in the *Journal of Clinical Oncology*. The article supports the hypothesis that introduction of a comprehensive clinical quality management system is associated with improved outcome of patients after HSCT.

Journal of clinical oncology : official journal of the American Society of Clinical Oncology 1-7(2011).doi:10.1200/JCO.2010.30.4121

TOP TIPS

In this issue our TOP TIPS are for those -

Preparing the Pre-Inspection documentation

Check that you have the most recent version of the pre-audit document folders by going to the Document Centre at www.jacie.org

Download and read carefully the Inspection Guide. This document explains how to prepare your pre-audit documentation

Read the instructions inside the folders carefully in order to understand which documentation is required

Save and organize the documentation in the corresponding folder

In the 'Applicant's Comments' column of the Inspection Checklist, specify the documents or other relevant information that demonstrate compliance with the requirements

Double-check that you have all the documentation required correctly saved in the Pre-audit Documentation Folders

Contact the JACIE Office if you have any questions or queries

Quality Management Committee

The Quality Management Committee was presented at the EBMT Congress in Paris. As a less formal group in the past, the Committee has worked on the quality management content of the EBMT Congress over the past three years. Now they are formally set up as a Committee, they will look to expand their activities beyond simply the congress. Current ideas include establishing some common quality indicators, publishing articles, updating the quality management guide, supporting the establishment of national or regional networks and developing sample materials. If you have any suggestions or ideas for projects, please email jacie@ebmt.org.

The members of the Committee are:

- Chair: Pierre Donot (Lyon, F)
- Secretary: Kirtash Patel (London, UK)

Members:

- Huynh Phoung (Brussels, B)
- Renza Monteleone (Reggio Calabria, IT)
- Nina Som (Bristol, UK)
- Bianca Wauben (Maastricht, NL)

All of the members are experience quality managers working in accredited centres. There is also a good geographical distribution ensuring a variety of experience.

Important dates for your diary

JACIE would like to highlight two **FREE*** up-and-coming JACIE courses in Rotterdam, The Netherlands, that could be suitable to you or a member of your team

**Participants would need make their own travel and accommodation arrangements and cover their own cost*

JACIE Inspector Training Course, 16th & 17th May 2011 Rotterdam, The Netherlands

"Being a JACIE Inspector gives me the opportunity to see other centres and to raise quality awareness" – JACIE Inspector

JACIE requires that all Inspectors attend a JACIE-approved training course in order to ensure uniformity and consistency in interpretation of the Standards and performance of the inspection.

The course includes assessing a quality management system, interpretation of the Standards and how to prepare and perform an inspection. The inspection is an excellent learning mechanism, both for the centre and the inspector as you will have a unique opportunity to see how other centres solve problems and observe their procedures up close and to transfer your own experience.

FACT JACIE Workshop, 18th May 2011, Rotterdam, The Netherlands

An ideal opportunity for an introduction to JACIE and the Inspection process!

This training workshop is designed to explain the requirements of the FACT-JACIE Cellular Therapy Standards and how to apply them in real-world scenarios. FACT and JACIE representatives will be in attendance to clarify the intent of the FACT-JACIE Standards, provide inspectors tips for conducting inspections, and assist programs in preparing their programs for the on-site inspection.

The morning sessions will include a FACT track and a JACIE track during which the respective organizations will provide information regarding their inspection and accreditation processes. Everyone will join in the afternoon for the Standards track, including interactive exercises and practical application of the requirements.

For more information including how to register for these courses, please visit http://www.jacie.org/portal/en/public/events_listing

JACIE Meeting- Milan, Italy

The European Institute of Oncology in Milan, Italy, is organizing a JACIE meeting on the theme "L'accreditamento JACIE: l'ottimizzazione dell'iter" on **23rd - 24th October 2011**. This meeting is open to physicians, nurses, biologists, data managers and technicians. This year there is a pre-meeting day for nurses which will focus on clinical issues. The following day will look at different Italian approaches to complying with JACIE Standards.

The program is available at www.jacie.org. The language of the meeting will be Italian.

JACIE 2011 Training Courses

JACIE Inspector Training

16-17 May 2011
Rotterdam, The Netherlands

Don't miss out!

FACT-JACIE Workshop

18 May 2011
Rotterdam, The Netherlands

Don't miss out!

JACIE Centre Preparation

13-14 September 2011

Barcelona, Spain

JACIE Inspector Training

15-16 September 2011

Barcelona, Spain

JACIE-Kerteza Internal Audits

24-25 October 2011
United Kingdom
(open to UK only)

JACIE-Kerteza Internal Audits

14-15 November 2011
Barcelona, Spain

PDWP-JACIE Centre Preparation

15-16 December 2011
Barcelona, Spain