

JACIE Newsletter



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Issue 5

From the President's Desk

As 2011 starts, it is my pleasure as President of the JACIE Executive Committee to wish a very Happy New Year to all professionals who contribute to a better outcome for patients receiving hematopoietic stem cell transplantation and cell therapies. Among those professionals, I would like to highlight the contribution of all of those who have made a success from the initiative led by Pr. Alois Gratwohl on behalf of EBMT and Pr. Gunnar Kvalheim on behalf of ISCT, more than 10 years ago: since the first inspection of a transplant program applying for JACIE accreditation in year 2000, the JACIE accreditation program has been organized and structured, including governance, and has reached financial balance, many inspectors have been trained and have participated in inspections of clinical, collection and processing activities and facilities, transplant programs have been accredited and some of them have been re-accredited. This is a remarkable achievement in the culturally diverse European environment. Last but not least a recent retrospective analysis of the EBMT registry supports the clinical usefulness of JACIE accreditation, with patients transplanted in JACIE accredited programs doing better in terms of outcome: while this preliminary indication deserves further scrutiny, it is a huge reward for all of those within our professional community who have worked towards meeting FACT-JACIE standards in their daily practice, for inspectors who – in addition to their local duties - have devoted time to document reviews and on-site inspections, for members of the accreditation committee and for our Medical director, currently Dr. Derwood Pamphilon.

This starting New Year also provides the opportunity to extend warm thanks to Pr. Jane Apperley who stepped down in October 2010, for her invaluable contribution to the development and activities of JACIE, as well as activities of EBMT in general; Jane will keep assisting the Executive Committee for one more year in the position of Past-President. I am very grateful to Pr. Alessandro Rambaldi who has accepted to step in as Vice-President for the next two years; Alessandro has already numerous duties, and will bring his expertise and judgment to help develop JACIE in coming years. And of course, I would like to thank all members of the JACIE office who daily contribute to the existence of JACIE. With such resource and commitment, I am confident that JACIE will be able to shape its future in a changing medical, scientific, regulatory and financial environment, and ultimately to help provide better care to our patients.

Again, Happy New Year to all of you, your families and friends.

Christian Chabannon
President, JACIE

A note from the new Vice-President

Since the modern era of transplant began over 40 years ago, new transplant procedures, stem cell sources, conditioning regimens and cellular therapies have become available and more patients are now eligible for these life saving therapeutic procedures. It is evident that the complexity of clinical and laboratory work is dramatically increasing and overall quality assurance must be implemented. For that reason, it was a great honour for me to accept the position of Vice President of JACIE in October 2010 following my nomination by the EBMT. My relationship with JACIE began more than 10 years ago when I became convinced that JACIE met three important needs: (1) to establish common international standards to regulate clinical activity in stem cell transplantation programs.; (2) to promote safety in the context of increasing numbers of transplants being performed with cells transported across international borders; (3) to establish a formal and independent accreditation process to validate quality management applied to an expensive clinical activity such as stem cell transplantation.

Accreditation Statistics

Total centres registered:
228

Inspections in preparation:
First time:
54

Reaccreditation:
29

Total completed inspections:
First time:
165
Reaccreditation:
36

Accreditations:
101

Facilities correcting deficiencies:
27

Number of countries registered:
17

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For me and my team in Bergamo, as for many others, the initial steps of JACIE accreditation were not easy. However, I am glad to say that JACIE has now become a clear part of our daily activity. This includes the routines of doctors, biologists, technicians and most importantly our nurses. Indeed, the continuous implementation of the standards is the basis of our strategy to meet our patients' clinical needs. I would therefore strongly recommend all transplant centres to commit themselves to implementing the standards and pursuing accreditation.

I believe the three reasons to support JACIE are as valid today as 10 years ago and I therefore look forward to working for JACIE in collaboration with my dedicated colleagues on the Executive Committee and the Board.



Alessandro Rambaldi
Vice-President, JACIE

AHCTA Survey on Training of HPC, Apheresis and HPC, Cord Blood Collection Staff

As part of an international collaborative project between AHCTA partners, we are asking you to complete this important survey. The survey will be used to help AHCTA (www.ahcta.org) develop consensus recommendations for training staff performing collections of apheresis and cord blood stem cell transplant products.

The expected outcome from this project will be an international overview of current training practices and a subsequent consensus document making recommendations for training and competency. The paper will be useful for allowing centres to compare or benchmark their practices with other centres and will offer good examples that could be adopted and implemented elsewhere.

You are kindly asked to provide one response from each facility - you may need to collaborate with your colleagues in this regard.

We appreciate your valuable contribution to this project. Please access the online survey at http://www.surveymonkey.com/s/AHCTA_Survey

5th edition FACT-JACIE Standards

The FACT-JACIE Cellular Therapy Standards Committee is nearing completion of the first draft of the 5th edition FACT-JACIE Cellular Therapy Standards. Important dates regarding the transition to this new edition are below:

Public Comment Period: April 2011

The draft of the 5th edition Cellular Therapy Standards will be released for public review and comment in mid-April 2011. All cellular therapy programs are strongly encouraged to participate in this process. It is your chance to have input on the standards that will be required of you! The public comment period will be open for 90 days.

5th Edition Publication Date: March 1, 2012

The final version of the 5th edition Cellular Therapy Standards will be officially published on March 1, 2012. This includes the Accreditation Manual and associated documents.

5th Edition Effective Date: May 30, 2012

The 5th edition Cellular Therapy Standards will be effective on May 30, 2012.

Inspectors Evaluation to be introduced

JACIE has amended the post-inspection process to include an evaluation by inspectors of inspections. The evaluation is an effective way for inspectors to provide feedback to the JACIE Office on inspections including areas that could be improved, problems that were faced and any other comments relevant to the onsite visit and its preparation.

Following an inspection, the JACIE Office will send a link to the inspectors for them to complete the short survey online. JACIE will respond to the inspectors on specific points raised.

Important dates for your diary

Training Courses and Events

Please visit our website for details of the 2011 Training Courses and Events
http://www.jacie.org/portal/en/public/events_listing

TOP TIPS

In this issue our TOP TIPS are for those -

Completing the Inspection Checklist

Check that you have the most recent version of the Checklist by going to the Document Centre at www.jacie.org

Complete the worksheets in the Excel file for the sections relevant to your programme e.g. Part B Clinical, Part C HPC, M if you collection Bone Marrow

Read the questions carefully – sometimes a centre answers 'No' when they should have answered 'Yes' because they misunderstood the question. If in doubt, contact the JACIE Office.

Use the Applicant's Comments column to include references to the documents (SOPs, forms, manuals etc.) that provide evidence demonstrating compliance. This will make the inspectors' job easier

Be careful using the 'Not applicable' or 'N/A' answer. Some questions are only not applicable when it is not performed in your centre e.g. you don't perform allogeneic transplantation or no children are treated in your programme. On the other hand, if you answer 'N/A' for donor evaluation, then explain where donor evaluation is performed e.g. associated collection unit. Also remember that in that case, the checklist for the collection unit should show 'Yes' for the same question.