

From the President's Desk

The 5th edition of the FACT-JACIE standards was released for public consultation until July 14th, 2011. FACT and JACIE representatives teamed up to revise the current standards, with the goal of evolving with new clinical practice in hematopoietic stem cell transplantation, preparing the way for the inclusion of new forms of cell therapies, making the standards easier to understand and implement for applicants, and to provide an improved and universal framework for excellence in stem cell transplantation. The process of revising the existing standards started during a meeting of the FACT-JACIE steering committee held in Barcelona in June 2010 and ended up after many teleconferences at a second meeting held during the joint ASBMT-CIBMTR Tandem BMT meeting in Honolulu in February 2011. Let me take here the opportunity to thank JACIE Medical Director, Dr. Derwood Pamphilon for co-chairing the process with his colleague Phyllis Warkentin from FACT and to also thank John Snowden, Jörg Hälter and Ineke Slaper-Cortenbach for their contribution as chairs of the Clinical, Collection and Processing Committees respectively, as well as our 15 other colleagues who participated in the work of the above cited committees on behalf of JACIE. Beyond the huge effort produced by these expert people in the field of accreditation, it is now very important that professionals in the field of stem cell transplantation actively contribute to the final edition of the standards, and to their future implementation.

It is expected that the final version of the 5th edition of the standards will be published in March 2012, and become effective by the end of May 2012.



Christian Chabannon
President, JACIE

Quality Management Committee

Following the launch of the JACIE Quality Management Committee (QMC) at the EBMT Congress in Paris in April 2011, the Committee had its first formal meeting on the 1st July 2011 at the wonderful Centre Régional Léon-Bérard (CLB) in Lyon, France.

Most of the Committee members including Pierre, Phuong, and Bianca had already worked together during the QM meeting at previous EBMT congresses. The committee has since been further strengthened by Renza Monteleone, from Reggio Calabria, Italy who brings her own valuable experience and the Italian perspective to the group.

The Committee's main objective for this meeting was to review feedback from the last Quality Management Programme presented at the EBMT Congress in Paris in 2011, to draft the programme for Geneva 2012 and to identify possible projects for the coming year. Regarding the Geneva programme, we aim to be able to offer interesting and practical content aimed at both those new to QM and accreditation and those with more experience and knowledge. Further details will be made available in the Autumn.

In addition, the committee also:

- Discussed the quality management section of the draft 5th edition of the FACT-JACIE standard and manual.
- Agreed to revise and update the "Quality Management Guide" to bring it into line with the 5th edition of the FACT-JACIE standards in 2012.
- Agreed to develop a plan to identify and share Quality Indicators with other SCT centres.
- To work on a publications related to quality management for the period 2012/13.

The Committee would like to extend it's thanks to Pierre Donot for hosting the meeting and to the warm welcome given by the CLB staff to the committee members.

Kirtash Patel, QMC Secretary

Accreditation Statistics

Total centres registered:
239

Inspections in preparation:
First time:
37

Reaccreditation:
20

Total completed inspections:
First time:
183

Reaccreditation:
47

Accreditations:
104

Facilities correcting deficiencies:
23

Number of countries registered:
17

Recent JACIE surveys

In March 2011, JACIE surveyed centres who were actively performing transplantation but who had not applied to JACIE for accreditation. The list of transplanting centres was taken from the 2009 EBMT Activity Survey kindly provided by Helen Baldomero (Basel, Switzerland). Of 421 centres surveyed, 98 responded (22%). The bulk of respondents came from Western Europe but other countries were also represented including Australia, Czech Republic, Finland, Greece, Hungary, Lebanon, Lithuania, Malaysia, New Zealand, Pakistan, Serbia, Slovakia and Slovenia.

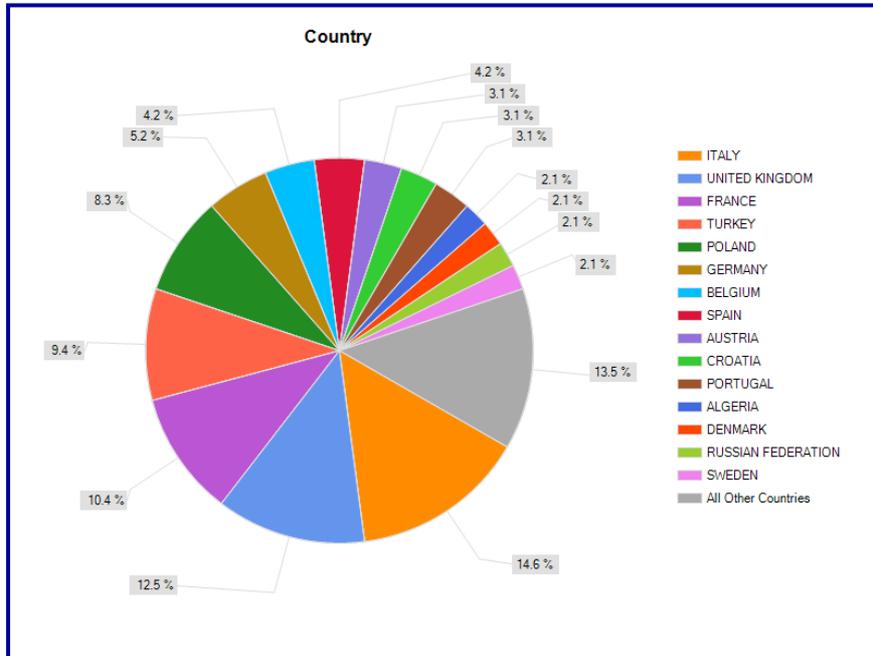


Fig 1. Countries of origin

Over 74% of the respondents said that they intend to apply for accreditation.

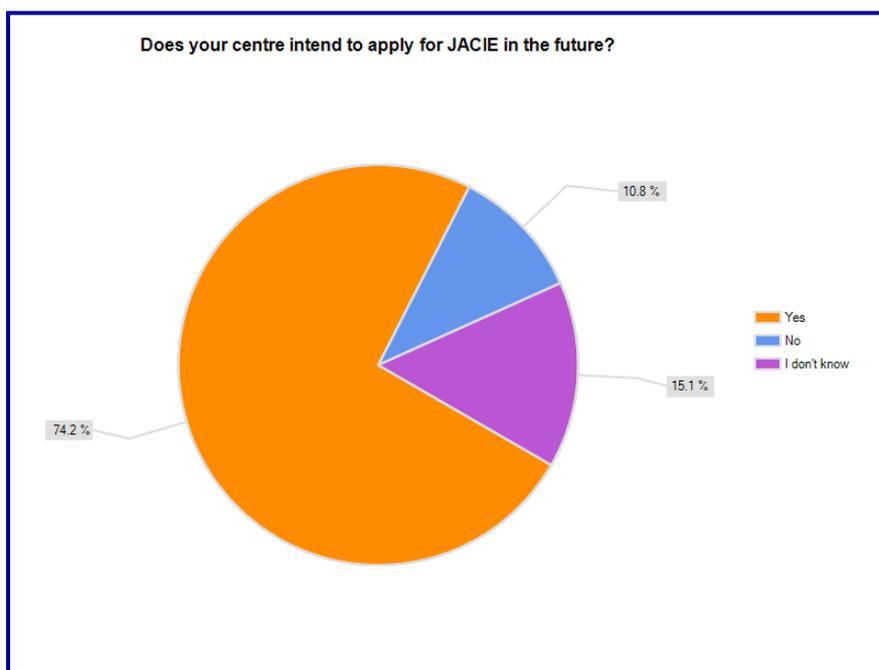


Fig 2. Intention to apply for accreditation

TOP TIPS

In this issue our TOP TIPS are for those -

Data management

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

Select the applicable consecutive records from the complete patient log for the most recent year for audit, and list these patients by unique patient identifier.

For each of these patient records, complete the applicable Minimum Essential Data-A (MED-A) forms.

Data reported to the EBMT Registry can be extracted and presented in the MED-A format in PDFs by following the instructions on the EBMT website.

Alternatively, blank forms can be downloaded from the same web page and completed by hand.

If you need any assistance with preparing these forms please contact the EBMT Registry Office directly.

Mark or flag the source documents in the primary patient record for each data point on the MEDA form to facilitate verification by the on-site inspector.

For these centres intending to apply in the future, the survey asked for the main motivation for accreditation. Increasing quality was cited as the main motivation indicating how accreditation is seen as a means rather than as an objective in itself. Other more minor motivations came from external requests for accreditation such as health insurers and pharmaceutical companies.

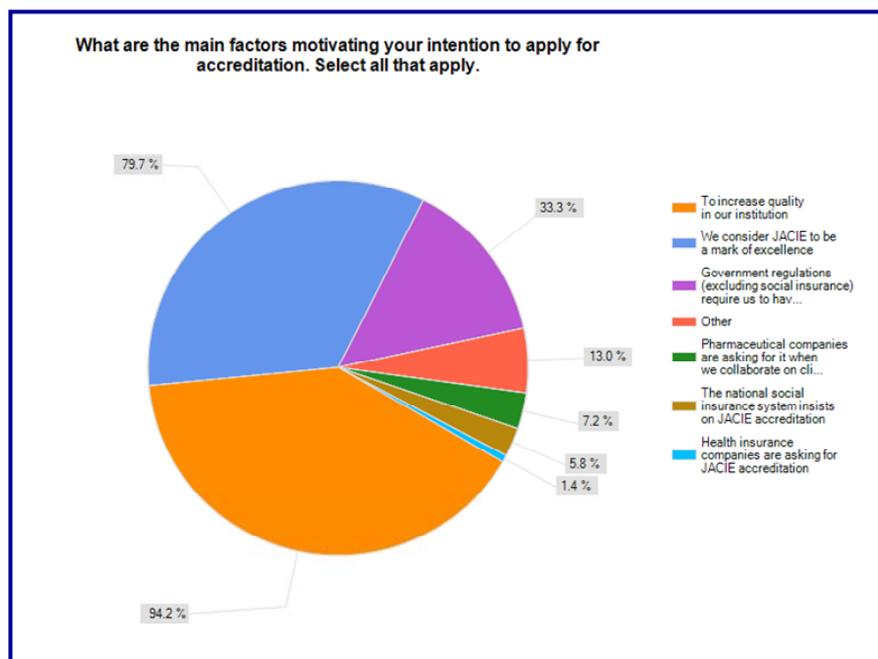


Fig 3. Motivation to apply for accreditation

Centres face a number of challenges which are sure to be familiar to programmes that have already embarked on accreditation. The lack of resources (funding and staff) and support from their institutions were the main problems cited. Interestingly, the fact that the Standards are only available in English was identified as a problem by only 6% of the respondents even though they came from a very wide variety of language backgrounds. This may be that the main contacts in centres are physicians who are comfortable with working in English but which may not be the case for nursing and technical staff.

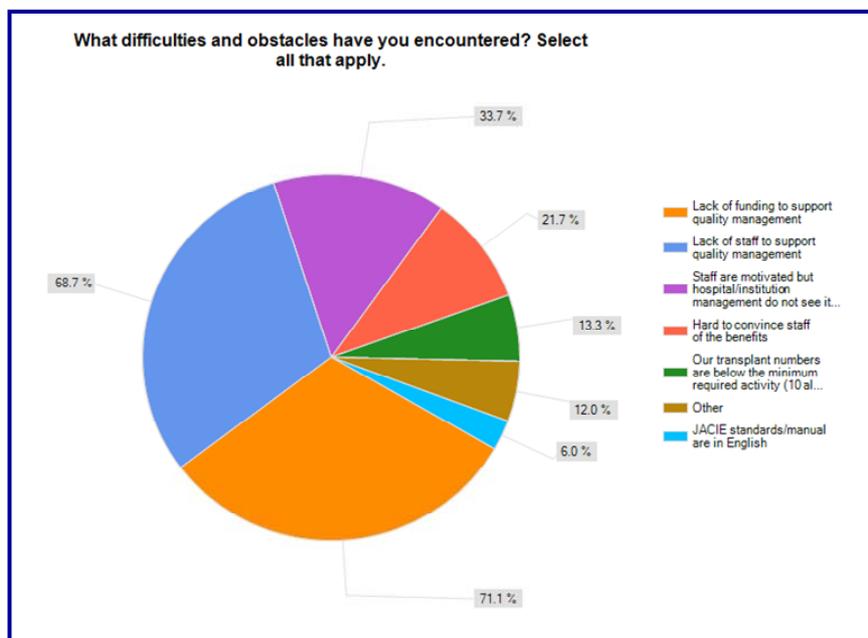


Fig 4. Obstacles encountered

Summary

The survey shows that JACIE is an objective among transplanting centres and that the challenges they face are similar to those already faced by centres that have already applied for accreditation. The data also indicates that accreditation is high among the short-, medium-, and long-term objectives of the centres which indicates continuity for JACIE accreditation in the future.

JACIE 2011 Training Courses

JACIE Centre Preparation

13-14 September 2011
Barcelona, Spain
Don't miss out!

JACIE Inspector Training Course

15 – 16 September 2011
Barcelona, Spain
Don't miss out!

JACIE-Kerteza Internal Audits

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

JACIE-Kerteza Internal Audits

14-15 November 2011
Barcelona, Spain

JACIE – GETH Inspector Training Course

24-25 November 2011
Barcelona, Spain
(open to Spain only)

PDWP-JACIE Centre Preparation

15-16 December 2011
Barcelona, Spain

Inspection Reports: key points to keep in mind

The inspection report is the key document at the centre of the accreditation process. It is very important that it is complete and clearly reflects what the inspector observed. Here are some key points to keep in mind:

- Consequences of late submitted or incorrectly completed Summary Report or Checklist.
 - a) Slows down the accreditation process
 - b) Creates more work for the inspector and the JACIE Team
 - c) Centre has to wait longer for the report
- Remember to complete all sections of the summary report and checklist. The following sections are often overlooked by the inspectors:
 - Summary report*
 - a) Distances between facilities, Transplant numbers, those individual interviewed .
 - b) General description of the facility.
 - c) Name and Position of persons interviewed.
 - Checklist*
 - a) Explanation of why something is non-compliant
 - b) label check sheets including shipping labels.
- If an inspector finds deficiencies in the facility they are inspecting e.g. QMP, audits or consent, they should check with their inspector colleagues if these deficiencies were found elsewhere.
- When completing the Summary report, remember to mention the good practice of the programme as well as areas for improvement, without repeating the list of deficiencies.

Carole Charley and Ivana Ferrero, JACIE Inspection Report Assessors.

Important dates for your diary

JACIE Centre Preparation Course.
13th & 14th September 2011 Barcelona, Spain
FEE: 1250€ (accommodation included)
LANGUAGE: ENGLISH
Limited number of places available

JACIE Internal Audits Course.
14th & 15th November 2011 Barcelona, Spain
FEE: 849€* (accommodation not included)
LANGUAGE: ENGLISH
Limited number of places available
***New and lower Fee!**

PDWP Centre Preparation Course. 15th & 16th December 2011 Barcelona, Spain
FEE: 165€ (accommodation not included)
LANGUAGE: ENGLISH
Limited number of places available

JACIE Inspector Training Course.
15th & 16th September 2011 Barcelona, Spain
FEE: No Fee (accommodation not included)
LANGUAGE: ENGLISH
Limited number of places available

GETH Inspector Training Course.
24th & 25th November 2011 Barcelona, Spain
FEE: No Fee (accommodation not included)
LANGUAGE: SPANISH
Limited number of places available

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

2012 Events: final details will be announced in due course.

- **Internal Audits Course:** 11th and 12th June 2012.
- **Centre Preparation Course:** 2nd and 3rd October 2012.
- **Inspector Training Course:** 4th and 5th October 2012.
- **Advanced QM Course:** 21st, 22nd and 23rd November 2012.

JACIE Staff

At the beginning of June, our colleague Catherine Foggo had her baby, Sebastian. Both mother and son are very well and we take the opportunity to congratulate the new family. We wish the new parents and Sebastian all the best for the future.



Catherine Foggo

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