

SPECIAL REPORT

Ten years after the first inspection of a candidate European centre, an EBMT registry analysis suggests that clinical outcome is improved when hematopoietic SCT is performed in a JACIE accredited program

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In 2010, JACIE, the Joint Accreditation Committee of ISCT (International Society for Cell Therapy) Europe and EBMT (European group for Blood and Marrow Transplantation) celebrated the tenth anniversary of the first inspection of a European hematopoietic SCT program. JACIE standards establish the criteria for a comprehensive quality management program that covers all three major domains of activity that are necessary for the delivery of HSCT: clinical, collection and processing, as well as their interactions with ancillary and supportive activities. Although more than 200 European programs have applied for JACIE accreditation, and more than 100 have been granted accreditation, a recent retrospective analysis of the large-size EBMT registry of autologous and allogeneic hematopoietic HSCT demonstrates that one of the factors affecting the overall survival of recipients of allogeneic transplantation is the status of the transplant program regarding JACIE accreditation. This provides one of the first demonstrations that introduction of a quality management system contributes to the overall survival of patients treated with a highly specific medical procedure, and represents a milestone in the implementation of JACIE.

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JACIE (Joint Accreditation Committee of ISCT Europe and EBMT) was started in Europe at the end of the 1990's, with the support of the European group for Blood and Marrow Transplantation (EBMT), and the European branch of the International Society for Cell Therapy (ISCT). JACIE pursues the same objectives as FACT (Foundation for the Accreditation of Cell Therapy), the accreditation program for hematopoietic SCT (HSCT) activities in North America; both aim at promoting excellence,¹ harmonization and improving results of HSCT. FACT-JACIE standards establish criteria for a comprehensive quality management program that covers all three major domains of activity in HSCT—clinical, collection and processing, as well as their interactions with ancillary and support activities. The fourth version of the FACT-JACIE standards was released in 2008. The fifth version is currently being prepared for release in early 2012.

Reasons for implementing FACT-JACIE standards include the complexity and diversity of the therapeutic procedure, the production of cell-based medicinal products by academic facilities rather than by pharmaceutical companies, the necessary collaboration between various hospital-based infrastructures and healthcare professionals, the non-conventional use of cytotoxic and immunosuppressive drugs,² and the increasing use of unrelated donors with international exchanges.^{3–7} Recognizing the complex nature and multi-disciplinary approach necessary for HSCT led JACIE to accredit 'programs' rather than infrastructures, a significant difference to authorizations issued by competent authorities to 'facilities'.

The first inspection of a candidate program, that was later granted accreditation, took place in 2000. Since then, 218 European professionals have been trained as inspectors, of whom 150 have participated in at least one inspection. A total of 216 HSCT programs have applied from 17 European countries (See Figure 1). In all, 191 programs have been inspected, including 157 first inspections and 34 second inspections for re-accreditation; 133 programs have been accredited at least once, of which 102

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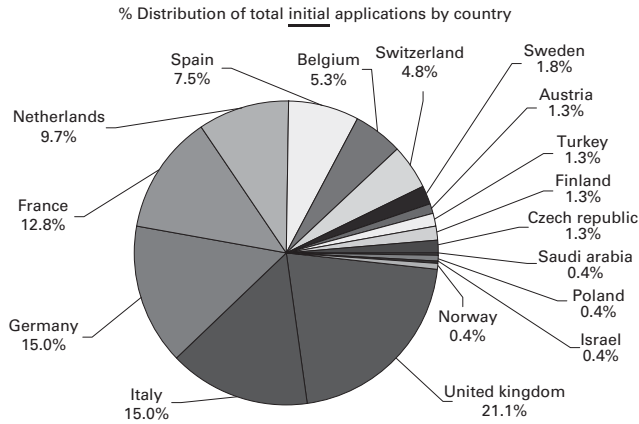


Figure 1 Proportion of initial JACIE applications for accreditation in European countries.

are currently accredited. This is a remarkable achievement in the context of the linguistically, culturally and regulatory diverse environment of Europe.

However, the question remains whether JACIE improves patient outcome. The literature contains little evidence to justify costs associated with quality management: human resources, documents, communication^{1,8}... A retrospective analysis of the EBMT registry was recently conducted on more than 100 000 HSCT performed between 1999 and 2007 at 421 different HSCT programs. The hypothesis was that introduction of JACIE should lead to a stepwise improvement in outcome, from *baseline* (>3 years before application or no application), to *preparation* (3 years before application), to *application* (time from application to accreditation), to *after JACIE accreditation*, with a greater magnitude than expected by time alone.⁹ Confounding factors: EBMT risk factor for individual patients, centre size, per-capita income in different countries,^{10,11} were included in the analysis, to eliminate potential biases. Results provided support for the hypothesis: a significant 14% increase in overall survival was observed for patients with chronic leukemias who received an allogeneic HSCT in a JACIE-accredited program, as compared with those treated in a non-accredited program. Although mainly applicable to recipients of allogeneic transplantation, improvement in overall and disease-free survival was also apparent for recipients of high-dose chemotherapy supported with autologous HSCT. The major caveat associated with this study is the small number of HSCT procedures performed in JACIE accredited centres, which reflects both the relatively recent establishment of the accreditation process, and the small proportion of accredited programs among centres that report their activity to EBMT. Nevertheless, this study provides one of the first demonstrations that introduction of a quality management system may be a factor in improving patient's overall survival, and so represents a milestone in the implementation of JACIE.

A 14% improvement in survival is of the same order of magnitude as that associated with major innovations in the field: the design of new immunosuppressive regimens for GVHD prophylaxis,¹² substitution of aphereses for BM as a source of transplantable cells,¹³ introduction of cord

blood units as an alternative source of hematopoietic stem cells,¹⁴ or the design of non-myelo-ablative conditioning regimens that favor the use of immunosuppressive rather than cytotoxic agents.¹⁵

JACIE does not substitute for legal requirements: on the contrary, a key criterion in FACT-JACIE standards is that all active facilities comply with national, European and international regulations. However, JACIE is unique in its coverage of clinical and technical/biological activities: the EBMT registry analysis supports the postulate that this approach is clinically relevant and useful. It thus provides a rationale for hospitals to invest resources in voluntary accreditation, in addition to resources that they devote to maintain mandatory authorizations for their activities. For the JACIE board and executive committee, the clinical benefit associated with accreditation is a strong incentive to increase the proportion of European accredited programs.

Conflict of interest

The authors declare no conflict of interest.

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