special communication

JACIE Accreditation in 2008: demonstrating excellence in stem cell transplantation

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JACIE was initiated as a small pilot project in Spain in 2000 and launched as a formal Europe-wide inspection program in January 2004. Since 2000, over 150 applications for accreditation have been received by the JACIE Office and more than 130 inspections have been completed in European centers and facilities. Almost all of these were found to be functioning at a high level of excellence, with the majority having only minor deficiencies in compliance with the standards. In one-third of centers there were more significant deficiencies. The most common deficiencies were in quality management. Following correction of deficiencies 86 centers have to date achieved full accreditation and many more are nearing the completion of the process. Implementation of JACIE involves a significant investment of time and resources by applicant centers. The majority require at least 18 months to prepare for accreditation and 85% have needed to employ a quality manager and/or data manager on an ongoing basis. However, all centers felt their program had benefited from the implementation of JACIE. JACIE is also working closely with other international organisations related to cellular therapy as part of the Alliance for the Harmonisation of Cell Therapy Accreditation (AHCTA), which is examining the differences in existing standards and aiming to develop international standards for all aspects of stem cell transplantation. In particular the requirements for safety of imported tissues and cells has emphasised the need for global harmonisation. The recent implementation of Directive 2004/23/EC and the associated Commission Directives 2006/17/EC and 2006/86/EC has provided an impetus for the implementation of JACIE in European Union (EU) member states. It will be important in the future to examine how JACIE can co-operate with the EU Competent Authorities (CA) to ease the burden of the inspection process for haemopoietic stem cell (HSC) transplant programs.

The Joint Accreditation Committee of ISCT-EBMT (JACIE) is a non-profit body first established in 1998 for the assessment and accreditation of hematopoietic stem cell (HSC) transplantation programs.[1] The Committee was founded by the European Group for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT), the two leading scientific organizations involved with HSC transplantation in Europe. JACIE modelled itself on the US-based Foundation for the Accreditation of Cellular Therapy (FACT), established in 1996 by the ISCT and the American Society for Blood and Marrow Transplantation (ASBMT).[2] JACIE works closely with FACT through a joint committee structure to establish standards for the provision of quality medical and laboratory practice in HSC transplantation. JACIE conducts inspections, accredits transplant programs and encourages health institutions and facilities performing HSC transplantation to voluntarily meet these standards to demonstrate their high levels of quality of care.

The primary aim of JACIE is to improve the quality of HSC transplantation in Europe by providing a means whereby clinical transplant centers, HSC collection facilities and processing facilities can demonstrate excellence. This is supported by its co-ordinating role in the provision of training courses in quality management for applicant centers and training courses for inspectors. An additional and wider aim is to ensure harmonisation between JACIE standards and other national/international standards, including the EU Tissues & Cells Directive 2004/23/EC[3] and the related implement-

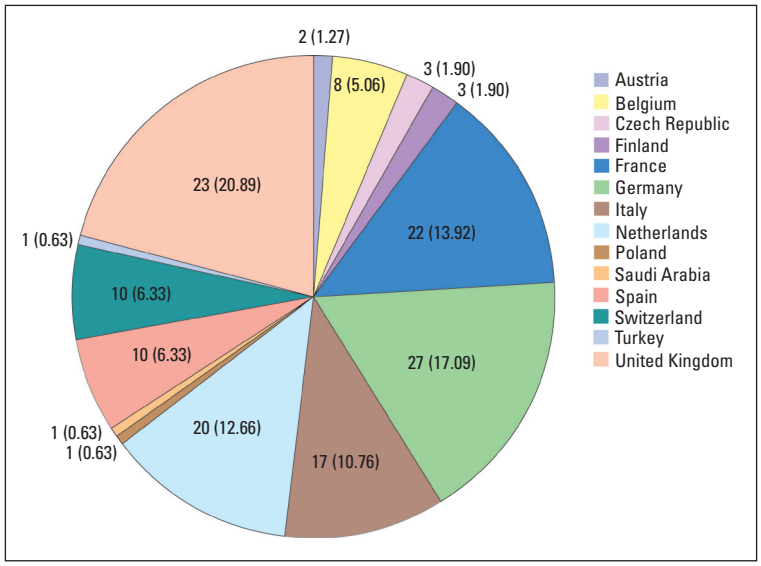

Figure 1. Initial applications to JACIE by country between 2000-2008.

REF	STANDARD	KEY	APPLICANT	APPLICANT'S COM
	Does the Clinical Program use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program?	I	N/A	
B1.3	Does the Clinical Program abide by all applicable laws and regulations?	I	No	
B1.3.1	Is the Clinical Program registered and/or accredited as required by the appropriate governmental authorities for the activities performed?	I	Yes	
B1.4	If applying for initial accreditation, does the Clinical Program have a dedicated transplant team including a Clinical Program Director(s) and at least one other physician trained and/or experienced in cell therapy and/or HPC transplantation that has been in place for at least twelve (12) months preceding application for accreditation?	I	Yes	
	Is the Clinical Program is requesting accreditation for allogeneic HPC transplantation	I	Yes	
B1.5	If requesting accreditation for allogeneic HPC transplantation, has the Clinical Program performed allogeneic HPC transplants for the minimum number of new patients annually?	I	Yes	
B1.5.1	If the Clinical Program utilizes more than one clinical site, has the Program performed allogeneic HPC transplants for the minimum number of new patients at each site annually?	I		
B1.5.2	If the Clinical Program cares for pediatric and adult patients at the same site, has the Program performed allogeneic HPC transplants for the minimum number of new patients in each age population annually?	I	Select answer from pull-down menu	
B1.6	If the Clinical Program is requesting accreditation for only autologous transplantation, has the Program performed HPC transplants for the minimum number of new patients annually?	I		
B1.6.1	If the Clinical Program utilizes more than one clinical site, has			

Figure 2. Extract from the inspection checklist. Both applicants and inspectors complete all sections of this document. Individual responses are then automatically coded green ('yes' response), blue ('non-applicable' response) and red ('no' response). Blue and red responses prompt the addition of additional information/explanation

ing directives 2006/17/EC[4] and 2006/86/EC.[5] The increasing use of unrelated donor cells for transplants highlights the need for further work in this area.

HSC transplant programs become accredited following on-line submission of documentation and an on-site visit by a team of trained inspectors. Centers may apply for accreditation as complete programs comprising a clinical program, a collection facility and a processing laboratory or, for example, as a single collection or processing facility serving one or more clinical programs.

JACIE accreditation is voluntary, but provides a means whereby transplant facilities can demonstrate that they are working within a quality system covering all aspects of the transplantation process and thus show compliance with the requirements of insurance companies or national and/or international regulatory authorities.

The JACIE program was run as a pilot program in Spain between 2000 and 2002 and formally launched on an international basis in January 2004 with support from the European Union under the Public Health Program (2003-2008) (http://ec.europa.eu/health/ph_projects/2003/action2/action2_2003_05_en.htm). Between January 2000 and November 2008, 139 centers or facilities have been inspected for the first time and 16 have been re-inspected. The number of applications/inspections per country is Austria 2/3, Belgium 8/3, Czech Republic 3/1, Finland 3/3, France 22/20, Germany 27/20, Italy 17/11, The Netherlands 20/16, Poland 1/0, Saudi Arabia 1/1, Spain 10/7, Switzerland 10/16, Turkey 1/1, and the United Kingdom 33/37 (Figure 1 shows initial applications by country). This experience has enabled JACIE to identify areas of common difficulty for applicant centers, to assess what assistance centers need in order to achieve accreditation, and has also raised some general issues relating to national and international regulation.

The FACT-JACIE Standards

The 4th edition of the joint FACT-JACIE standards covers all aspects of clinical transplant programs, collection facilities (bone marrow [BM] and peripheral blood progenitor cell [PBPC] collection) and processing of HPC, as shown in Table 1. These superseded the 3rd edition at the start of November 2008. The 4th edition will be the standard against which programs are inspected from 1st February 2009.[6] The updated standards are applicable to cellular therapy products (CTP) but where applicable only to hemopoietic progenitor cells (HPC), this is specifically referenced. The standards also apply to the use of therapeutic cells (TC) derived from blood or marrow, including donor lymphocytes. Important changes in the 4th edition are as follows:

1. Quality Management (QM): the standards have been realigned to reduce redundant references to QM topics and have been organized in each section on a topical basis. Standards pertaining to operational quality control have been relocated to the relevant operational sections
2. Standard Operating Procedure (SOP) review: the requirement has been changed from annual to biannual (or upon the introduction of changes in procedures, whichever is sooner).

Table 1. Analysis of Most Common Deficiencies

Clinical program	Collection facility	Processing facility
Donors	QM plan	QM plan
• Missing or inconsistent donor information e.g. vaccinations, travel, pregnancies and blood transfusion histories • Lack of written information e.g. on collection procedures	• No QM plan • Present but with significant omissions e.g. lack of validation procedures	• Lack of integration with the facilities activities • No validation or qualification studies • System for audits inadequate
*IDMs	Policies and procedures	Policies and procedures
• Medical history doesn't include the correct questions • Specific tests omitted • Tests not done within 30 days of HPC transplant	• Present but inadequate • No range of expected outcomes/ results • No procedures for recording deviation • No reference section	• Present but inadequate • No range of expected outcomes/ results • No procedures for recording deviations • No reference section
Data management	Review of new/revised documents	Process control
• Incomplete or incorrect forms • Lack of engraftment data • Clinical status at HPC transplant not recorded • Chemo: lack of prescription	• Failure to undertake or document review	• No written request for processing • No review of processing records • ABO, Rh tests not done
Adverse events, errors and clinical incidents	Collection procedures	Labelling
• Not reported or recorded • Lack of regular audit • No corrective actions	• Insufficient number of BM procedures • Lack of written order for collection • No interim donor checks	• Incorrect product name used • Information missing from labels e.g. date/time allocated, volume etc. • No unique alphanumeric identifier
Outpatient facilities	Engraftment data	Engraftment data
• Lack of space • Inadequate separation of patients with significant infections	• Failure to document and review time to engraftment	• Failure to document and review time to engraftment

*IDMs – infectious disease markers e.g. HIV – 1/2

3. The donor selection, evaluation, and management sections in the clinical program and collection facility sections have been modified to reflect the way that these responsibilities are divided between clinical programs and collection facilities. The collection facility standards focus more on donor evaluation and management, with less emphasis on donor selection activities. In some situations the collection facility is primarily responsible for donor selection activities, and the standards now state that in these situations, collection facilities are required to comply with the applicable clinical program standards.
4. Early discharge from the transplant center. It was agreed by the FACT-JACIE Standards Committee that it is against the spirit of the standards to inspect and accredit the center performing the transplant procedure as the "transplant center" without considering post-transplant care. With this in mind the 4th edition of the standards states that Clinical Programs shall ensure planned discharges are to facilities adequate for post-transplant care. This means that it is the responsibility of the transplant center to ensure compliance with items such as the provision of isolation facilities, staffing and training and policies and procedures. JACIE will require documentation of compliance and this might in the future include inspection of the hospital providing post-transplant care.
5. Appendices have been revised to clarify requirements and simplify the standards. Those that are external tables and forms have been removed and replaced with a reference table indicating the websites where the current versions can be found. This is in response to situations in which external tables and forms are updated within months of publication of FACT-JACIE standards, which causes the appendices to become out of date be-

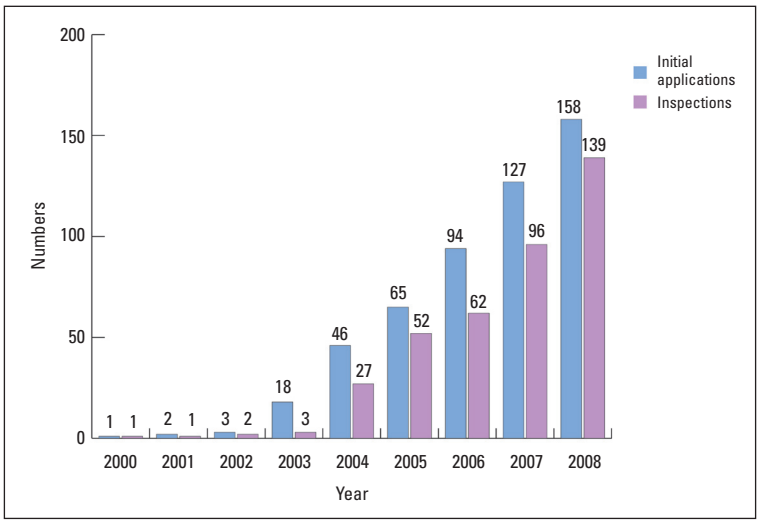

Figure 3. Cumulative numbers of initial applications and total inspections between 2000-2008.

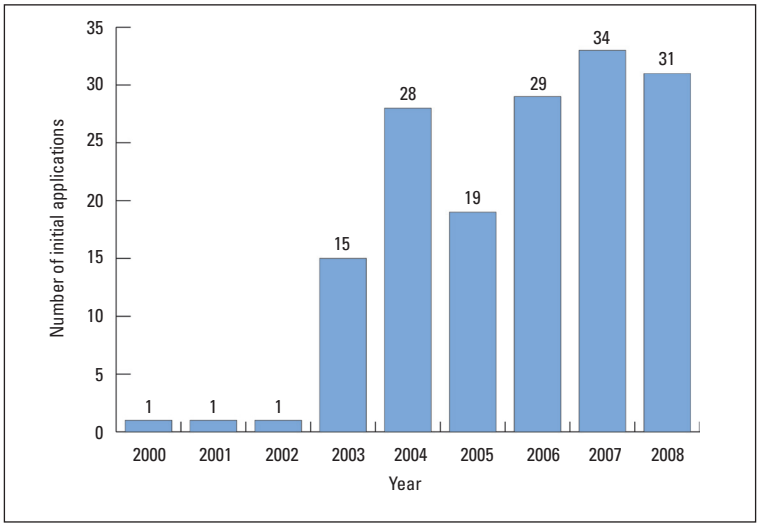

Figure 4. Initial applications for inspection by year between 2000-2008.

fore the next edition is published.

6. Expanded requirements: an effort has been made to simplify the standards since they are intended to define minimum standards rather than best practice. Some requirements have been expanded and specific examples include:
   - Written agreements – the responsibility of ensuring external entities comply with Standards and governmental laws and regulations is placed on the clinical program/collection facility/processing facility as appropriate.
   - Disaster plans – explicitly states in standard the requirement to include the response of the clinical program/collection facility/processing facility as appropriate.
   - Concurrent plasma and samples are required to have the same identifier as the cellular therapy product.
7. Terminology: in several cases the use of specific terminology was clarified to reduce misinterpretations commonly found during the inspection and accreditation process and also to account for international variations. Specific examples include:
   - Change from HPC to CTP where applicable. In instances where only HPC applies it is specifically referenced.
   - Board eligibility/certification references changed to 'specialist certification' to accommodate international education.
   - References to specific governmental agencies and accrediting bodies, e.g. the United States Food and Drug Administration (FDA) etc have been changed to 'appropriate governmental authorities' or 'certified as required by governmental authorities' as appropriate.
   - Validation has been redefined to include only processes (including intended uses of equipment) and qualification to include only equipment, supplies, and reagents (in alignment with FDA interpretation).

There are also a number of specific sectional changes which are not described here

The complete standards and the accompanying guidance manual are available on the FACT and JACIE websites. They are broadly consistent with the requirements of the Tissues and Cells Directive (2004/23/EC) and accompanying Commission Directives (see above) as regards donation, procurement and processing of stem cells, but in addition, cover the clinical transplant program. Accreditation of clinical programs includes the clinical use of cord blood (CB) stem cells but the JACIE program does not accredit CB collection and banking facilities as this process is currently carried out by FACT against the Netcord-FACT Standards.[7]

The FACT-JACIE Manual and Inspection Checklist

The manual contains the standards together with detailed guidance on the interpretation and measures required to demonstrate compliance. Each standard is followed by specific questions relating to that standard and these questions form the basis of the inspection checklist, which must be completed prior to inspection by the applicant center and verified by the inspector during the

inspection. The checklist has recently changed format from Microsoft Word to Microsoft Excel to facilitate the completion of the checklist by both the applicant and the inspector and to make analysis of the answers easier by using automatic colour-coding and including filters (Figure 2).

The Accreditation Process

Preparation by Center

The center implements measures as described in the FACT-JACIE accreditation manual, and then applies for inspection by submitting basic information about the program/facility and a number of supporting documents including a self-assessment checklist. The application information and checklist must be submitted in English but all other documentation, including SOPs is accepted in the language of the center.

Inspection

An on-site visit is carried out by a team of trained inspectors, usually one per facility (clinical / collection / processing). Inspectors are medical, scientific or other professional persons working in HSC transplantation, with specific qualifications and experience for inspecting clinical, collection and/or processing facilities. Inspectors must attend a JACIE-sponsored training course and pass an examination. Where a clinical program performs adult and paediatric transplants, an adult and a paediatric inspector will attend. Inspectors may also be from another country but should be either native or fluent speakers of the relevant language. An inspection visit usually lasts 1.5 days and involves discussion with staff during their work, review of documents /records and completion of a detailed checklist relating to the standards.

The report is prepared in English, notes any areas of non-compliance with the standards and is reviewed by the JACIE Office and Accreditation Committee, the latter established in 2006. This report indicates all non-compliances with specific standards and makes specific recommendations for corrections and improvements. The distinction between minor deficiencies and more significant deficiencies is not strictly defined, but in general terms, specific deficiencies in documentation are considered minor while more general problems with documentation or problems with processes or facilities are considered significant. The center is allowed up to 9 months to correct deficiencies, depending on the amount of work required.

Center Response

The center must indicate acceptance of the findings and then in due course submit documentary evidence to confirm corrections or amendments. The original inspectors review the documentation. Review by the inspectors rather than by the Accreditation Committee is required because of language issues. In some cases a full or limited re-inspection may be required to show that deficiencies have been corrected. The inspectors confirm to the JACIE Office that all necessary corrections have been made or indicate that there are still outstanding areas for completion.

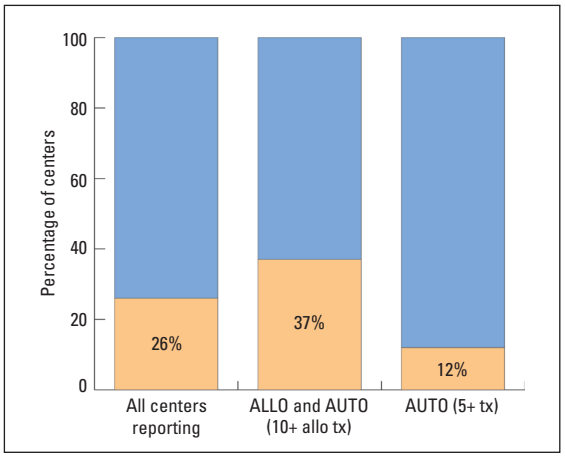

Figure 5. Provisional data showing the proportion of centers reporting transplants to the 2007 EBMT Activity Survey that have applied for JACIE accreditation and meet the minimum transplant requirements.

Accreditation

The JACIE Office and Accreditation Committee reviews all the reports and relevant documentation and if satisfied that all deficiencies have been corrected, make a recommendation to the JACIE Board that the center be awarded accreditation. If approved, accreditation is awarded, valid for 4 years, subject to an annual report from the center noting any significant changes in personnel or procedures and including annual activity figures and an interim audit at the end of the second year of accreditation.

Summary of JACIE Inspection Activity

To date, 156 facilities have formally applied for accreditation. Ninety-nine centers applied for accreditation for a combination of clinical, collection and processing facilities; 20 centers applied for clinical only; 1 for bone marrow harvest only; 12 centers applied for clinical and collection only; 4 for apheresis collection only; 8 centers applied for collection and processing only; and 12 for processing only. Between January 2000 and November 2008 139 centers were inspected (Figure 3) including

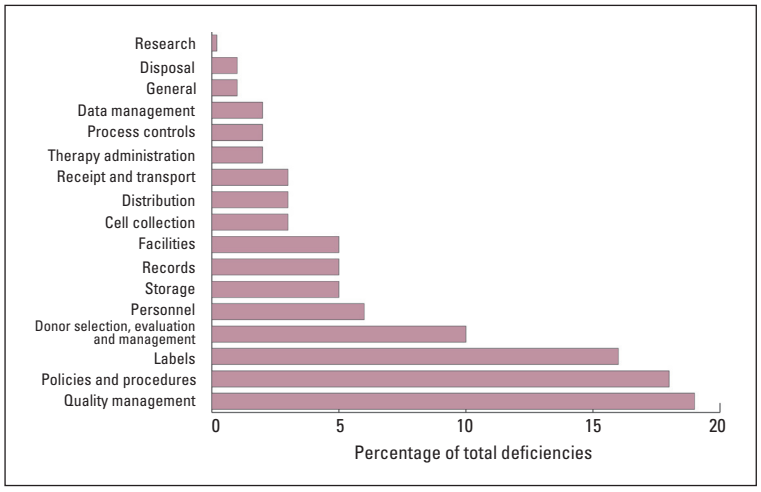

Figure 6. Deficiencies categorized from 1732 inspections carried out between 2004 and 2007. Problems with the quality management program, SOPs, labelling, and donor assessment/management are found most frequently.

both first-time and reaccreditation inspections. The number of first-time or initial applications rose to 33 in 2007 and 31 applications have been received to date in 2008 (Figure 4) although the overall number of applications is higher as a result of requests for reaccreditation. Figure 5 shows the overall proportion of transplant centers reporting to the EBMT that are now JACIE registered.

Common Deficiencies

The most common deficiencies were in documentation, labelling and in the quality management program. This is consistent with the initial experience of the FACT accreditation program in the United States and is described in more detail in the next section. Minor failures of compliance were frequent, usually involving problems with documentation. Examples include:

- SOPs not containing key references
- Pregnancy assessment not documented during donor evaluation

More significant failures of compliance were less common. Examples include:

- Program not functioning as a single program (e.g. SOPs not uniform across different clinical sites, for example where allogeneic and autologous patients, or adult and paediatric patients were treated on different sites)
- Outpatient facilities inadequate (e.g. no provision for isolation of infectious patients)
- Inadequate quality management program
- No continuous temperature monitoring of freezers in processing facility
- Temperature not monitored during transport of HSC from processing facility to clinical unit
- Engraftment data not monitored by processing facility

Some of these significant deficiencies arose from lack of resources, e.g. size of laboratory inadequate for workload or lack of an experienced quality manager.

Analysis of Deficiencies

Deficiencies in the quality management program were by far the most common cause of failure of compliance with the standards and, including problems with policies and procedures (SOPs), accounted for 37% (636 of 1732) of total cited deficiencies (Figure 6). Deficiencies included:

- Problems with the formatting and content of SOPs, example:
  - missing examples of worksheets/forms/labels
  - missing references (where relevant)
  - failure to include range of expected results (where relevant)
- Lack of procedure for documenting deviations from SOPs
- Lack of regular review process for SOPs
- No SOPs for critical procedures e.g. bone marrow collection
- Inadequate document control procedure
- Lack of validation of equipment /procedures in collection and processing facilities
- Inadequate audit activity e.g.
  - no SOP for audit,
  - no written program for planned audits
  - no documentation of results of audits
  - no formal process for disseminating results
- Inadequate adverse event (AE) reporting/reviewing.

Centers often used a hospital-based incident reporting system, but in many cases it appeared from the number of reported AEs that this was not adequate to meet the needs of the HSCT program. Often it was not clear that all AEs were reviewed by the program director and/or that a report was issued to the patient's physician.

Other significant problems included those related to donor selection and testing, labelling and process control. The commonest problems as documented for the clinical program, collection and processing facilities are summarised in Table 1. A list of common deficiencies is available on the JACIE website.

Centers often have problems in designing JACIE-compliant labels. This has been addressed by the International Cellular Therapy Coding and Labeling Advisory Group which has published terminology

and designed suitable labels for CTPs which are based on the ISBT 128 standard for stem cell component identification. An implementation plan has also been published by this group. Further information is available at http://iccbba.org/cellulartherapy_home.html. A Workshop of the EU Normalisation Committee (CEN) has agreed to recommend a modified version of the ISBT 128 system to the EU Directorate General for Public and Consumer Health (DG SANCO).

Current status of centers including time taken for correction /accreditation

Eighty-two centers have been awarded accreditation at least once. Of these, 58 are currently accredited including 4 reaccreditations and 7 of the remaining 10 centers whose accreditation has expired have presented themselves for reaccreditation (of the remaining 3 centers, one center has ceased transplantation and the other two centers have not yet requested reaccreditation). These 7 centers are among the 48 programs that are either awaiting reports, correcting deficiencies or who have presented evidence of corrections for assessment. One center abandoned the accreditation process but subsequently reapplied alongside a clinical unit.

The time taken by centers to present documentary evidence of corrections of deficiencies in 2007 varied from 18 to 297 days with an average of 130 days. In general the maximum amount of time allowed to correct deficiencies is 9 months (from the time the center receives the Accreditation Committee's report.)

Experience of centers implementing JACIE

It was anticipated that implementation of the JACIE standards would pose some difficulties for applicant centers, particularly in relation to establishing a QM system and accompanying documentation. While QM is well established in laboratory practice, and most processing facilities will already have an established QM program, QM programs were rarely in place in clinical units. It was also anticipated that there would be resource implications in terms of staff time because of the amount of detailed documentation that is required to demonstrate compliance with the standards.

We undertook two surveys designed to assess the difficulties experienced by centers in preparing for accreditation. The results of these surveys have been published in detail before.[8] Briefly, in the first survey we found that, in most centers, at least 18 months was needed for preparation. Twenty-two centers had additional staff other than the Program Director to manage project implementation, but these staff were only part-time in 13 centers and only 11 had any experience in quality management. The area of greatest difficulty for most centers was in the clinical program. Most difficulty was found in implementing the QM system, adverse event reporting system and other documentation. Some centers already had written policies and SOPs, an audit system and an adverse event reporting system, but in all cases further development was needed to bring theses aspects of QM up to the required standard.

The results of the survey were consistent with the findings of the inspectors that the most common deficiencies were inadequacies in the QM system. Our findings also indicated that these arise from lack of trained staff and absence of QM culture, particularly in the clinical setting. There is clearly an important need for training of clinical staff (doctors and nurses) in quality management. It is also important for centers to have a designated quality manager who has appropriate experience in quality management systems.

In a second survey all responding centers indicated that they had benefited from implementing the JACIE standards. The areas of greatest perceived benefit were in procedure and practices, staff motivation, control of adverse events, and co-ordination between different areas of the program. Significant benefits were also perceived in patient satisfaction, facilities, patient care and safety and training of new and existing staff. The areas where little or no benefit was noted were in costs, compliance with requirements of health insurers/social security and in government recognition. It was evident that implementation and maintenance of a quality system increases the running costs of a program. Eighty-one percent of the centers reported that implementation of the QM system had highlighted a need for changes in the implementation of the transplant program and all felt that accreditation was worth the effort invested

Implications of the EU Directive 2004/23/EC and supporting Commission Directives

The requirements of Directive 2004/23/EC became law in EU member States on April 7th, 2006. The implementation of the parent Directive is supported by two Commission Directives (2006/17/EC and 2006/86/EC) which set out the detailed technical requirements. They cover (i) donation, procurement and testing, and (ii) coding, processing, preservation, storage and distribution and were published on February 8th 2006 and 24th October 2006, respectively. The current JACIE standards conform to the requirements of the Directive as regards donation, procurement and processing of stem cells, although JACIE is more detailed in many areas and JACIE standards also cover clinical transplant programs. However in some areas more ex-

plicit wording of the JACIE standards is required to fulfil the requirements of the Directive and appropriate changes were incorporated into the 3rd and 4th editions of the FACT-JACIE standards.

While support for accreditation among the professional transplant community is high, there are varying levels of engagement with JACIE by the regulatory authorities in different countries. It has proven very difficult to build up a standard picture of official support across the EU due to significant differences in regulatory structures, varying readiness to implement the Directive and political issues. However, it can be said that in a number of countries there has been support from the regulatory authorities, both direct and indirect, for the JACIE accreditation system. This is the case in Austria, Belgium, France, Italy, The Netherlands, and the United Kingdom. In Spain, the National Transplant Organization (ONT) has signed a formal agreement with JACIE and national scientific societies which gives official support to voluntary accreditation by transplant units and will recognise accredited programs as meeting quality and safety requirements. (http://www.ont.es/contenido.jsp?id_nodo=306&&&keyword=&auditoria=F)

Outside the EU, a Swiss law on regulating transplants enacted in July 2007 directly cites JACIE in relation to HSC transplants and JACIE is cited as part of the law on compulsory health insurance requiring HSC centers to be certified by the Swiss Transplant Workgroup on Blood And Marrow Transplantation (STABMT) in accordance with JACIE Standards. All 10 HSC centers in the country have undergone inspection and the majority are now accredited.

Global harmonization of standards

JACIE, FACT, Netcord, AABB (formerly the American Association of Blood Banks) and the World Marrow Donor Association (WMDA) are working together to promote consistent interpretation of the requirements of the standards and guidance produced by each organization. A detailed comparison of the requirements of the EU Directives with the FACT-JACIE, Netcord-FACT, AABB and WMDA standards in being undertaken. It is a fundamental aim of JACIE to ensure that the FACT- JACIE standards as far as possible are harmonised with other applicable national and international requirements, including those of the EU. This is particularly important to prevent difficulties in importing and exporting tissues across international boundaries, which could occur if there were to be differences in the standards adopted in different countries.

One of the results of this collaborative approach has been the establishment of the Alliance for the Harmonisation of Cellular Therapy Accreditation (AHCTA)[9] whose members include AABB, American Society for Blood & Marrow Transplantation (ASBMT); European Group for Blood & Marrow Transplantation (EBMT); Foundation for the Accreditation of Cellular Therapy (FACT); International NETCORD Foundation; International Society for Cellular Therapy (Europe) (ISCT); Joint Accreditation Committee ISCT-EBMT (JACIE); and WMDA. AHCTA has developed a position paper on issues arising out of the import and export of HSC, together with a brief definition of the minimal standards that might be used to assess the provenance of imported HSC. The documents are accessible at www.ahcta.org. Within the EU discussions are now beginning on the establishment of a register of HSC collection centers and how this might be supported and hosted.

Conclusions

The FACT-JACIE accreditation system is now firmly established in Europe and the experience of centers that have been inspected is that implementation of the JACIE standards has led to significant improvements in different aspects of their transplant programs. JACIE has further assisted with a number of training courses for preparing centers for accreditation and has recently published a practical guide to quality management in transplant units. JACIE has also developed a close working relationship with other organizations involved in cellular therapy, which will form the basis for a new global approach to harmonisation of standards and accreditation systems worldwide. This collaboration represents an innovative and proactive approach to solving the problems of international exchange of tissues and cells as these relate to the stem cell transplant community.

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