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### 1. Objective

Give an introduction to the JACIE standards and JACIE accreditation process.

### 2. Background

JACIE is a joint partnership between EBMT and ISCT (International Society of Cellular Therapy) and was established in 1998. It was largely modelled 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. JACIE continues to develop and maintain global standards for the provision of quality medical and laboratory practice in cellular therapy. Based on these Standards, JACIE offers accreditation to transplant programmes in order to encourage health institutions and facilities to establish and maintain quality management systems impacting on all aspects of their activities and to engage in continuous improvement.

The executive body responsible for JACIE activities is the JACIE Committee, composed of a Chair, two EBMT representatives, two ISCT representatives and the EBMT Medical Officer. The Committee has also invited the Chairs of the Accreditation and Inspector Committees to attend. Ultimately, the JACIE Committee is accountable to the EBMT Board.

From the early days of JACIE the transplant community has been keen to evaluate the impact of quality management system within the clinical environment and specifically the impact on patient outcomes – a key clinical outcome measure. Data from the EBMT Registry showed a correlation between participation in the JACIE accreditation process and survival, with improvements in overall survival and relapse-free survival after allogeneic transplant.<sup>1,2</sup> The measured impact was systematic and clinically relevant with an overall improvement of 10–15%. A similar but non-significant positive impact was seen in autologous transplantation, most likely as a result of the shorter post transplantation follow-up period experienced by most autologous patients. The association of outcome with JACIE accreditation was independent of disease, patient risk profile, conditioning, GNI/capita of the country and calendar year of the HSCT procedure. The study data suggested that JACIE accreditation was the single most important factor contributing to the substantial improvement in clinical outcome over time.

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<sup>1</sup> 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;29:JCO.2010.30.4121.

<sup>2</sup> Gratwohl A, Brand R, McGrath E, van Biezen A, Sureda A, Ljungman P, et al. Use of the quality management system “JACIE” and outcome after hematopoietic stem cell transplantation. *Haematologica.* 2014;99:908–15.

### 3. JACIE Standards

The JACIE Standards are a collaboration between FACT (Foundation in Accreditation for Cellular Therapy) and JACIE. The Standards are reviewed every four years by the Standards Committee and Subcommittees with equal representation from both organisations. The Subcommittees represent the different sections of the Standards, namely: Clinical, Collection (Bone Marrow and Apheresis), Processing and Quality Management.

The Standards are set out to align with the complex, multi-step processes within each Facility and the Quality Management subsections within each of the main Facility sections reflect that quality management activity is common across all three Facilities. The Standards also set out the relationship between the FACT-JACIE accreditation conditions and the national, country-specific regulatory requirements. The tension between national and global Standards is mitigated by a close collaboration between JACIE and the national haematological societies as well as public consultation prior to Standards being approved by the FACT and JACIE Boards.

### 4. JACIE Accreditation Process

The JACIE accreditation process is a staged process comprising five distinct steps (Figure 1):

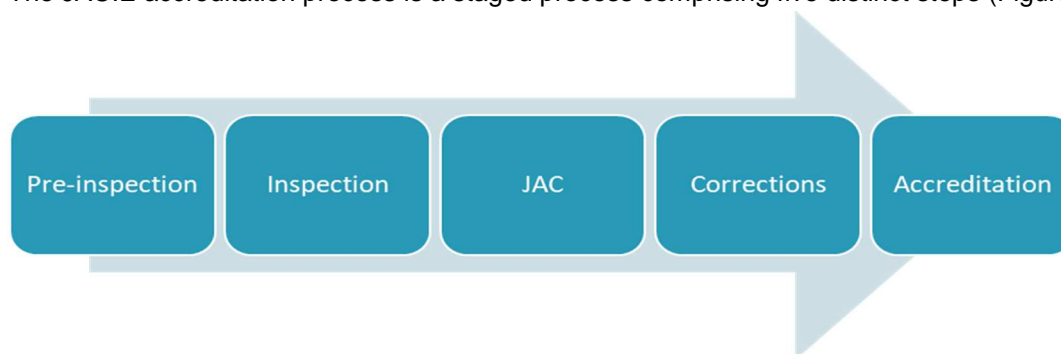


Figure 1: Five steps of the JACIE accreditation process

The pre-inspection stage is the initial phase after a Transplant Centre/ Facility applies to JACIE. During this phase, the Centre / Facility will be required to submit a self-assessment checklist as well as a pre-defined set of documents. These are assessed by the JACIE office team, and if complete, the JACIE office will initiate the inspection process. The JACIE office will act as the facilitator between the Transplant Centre / Facility, Inspectors and the Accreditation Committee for logistics, timelines and documentation flow. All decisions on compliance and accreditation are taken by the Inspectors and the Accreditation Committee.

The duration and method of JACIE inspections vary according to the preference of the applicant Centre / Facility and the type of accreditation being applied for. First-time accreditation inspections are carried out on-site over 2 days. Reaccreditation inspections can be offered virtually over 3 half days, or on-site over 2 days. Reaccreditation inspections including first-time IEC activity can be carried out remotely over 3 half days along with a focussed one-day on-site inspection, or fully on-site over 2 days. The team will typically include a separate inspector for Clinical, Collection, Processing and Quality Management, but the number of inspectors will depend on the number of sites and Quality Management Systems within a Programme, and whether the inspection includes both paediatric and adult transplant facilities. One of the inspectors also carries out the role of Team Leader. At the end of the inspection, the team submits a report to the JACIE office.

The inspection report is initially reviewed by the JACIE office to ensure that all Standards have been assessed and are consistent across the different sections, where appropriate. The report is then

reviewed by the JACIE Accreditation Committee (JAC) whose members are experienced inspectors with expertise in all of the sections of the Standards. The JAC will decide on the level of compliance against the Standards based on the information provided in the report by the Inspectors and set the time given to the Centre to correct any deficiencies.

Subsequently the JAC report and annotated checklist are sent back to the Transplant Centre / Facility who has to provide evidence of correction of any deficiencies within the allocated time period. This evidence is then reviewed by the initial inspection team and once it considers that all of the deficiencies have been corrected, the final report will be approved by the Chair of the Accreditation Committee and the Centre / Facility will be notified of its accreditation. This accreditation is valid for four years following an on-site inspection (commencing from the date that accreditation is awarded), after which the Centre is required to reapply to maintain accreditation.

It is important to note that, unlike many Competent Authorities' processes, the JACIE accreditation process involves volunteer inspectors who have other time commitments and this is reflected in the time to completion of some of the JACIE accreditation process steps. As the pre-inspection stage can take up to six months, and the JAC can allocate up to 12 months to address the deficiencies identified by the inspection team, it is not unusual for the end-to-end accreditation process to take 12 -18 months, particularly for an initial accreditation.

It is usual that a reaccreditation process proceeds more quickly, as the facilities, infrastructure and QMS have already been assessed as adequate. The challenges with reaccreditation usually occur, if there have been changes in the facilities (e.g. new ward/laboratory) or staff (e.g. changes to quality manager, significant staff turnover).

The JACIE inspection model based on onsite inspections was understandably exposed during the COVID pandemic and inspections had to be paused for a significant period of time. As a result, JACIE had to develop a virtual inspection model in order to restart the inspections during the pandemic as well as build in resilience for the future. The onsite tour and staff interviews were replaced with pre-recorded videos of the facilities with virtual interviews with facility staff in combination with the document review. During these inspections the full checklist is reviewed resulting in a full four-year period of accreditation

## 5. Inspectors

JACIE inspectors are volunteers who work in the field of stem cell transplantation in clinical, quality management (QM), nursing or scientific roles. There are specific entry requirements for would-be inspectors and defined job descriptions for the different inspector roles (Clinical, Collection, Processing and QM). Some inspectors may be qualified to inspect more than one area. For example, a clinician might be qualified to inspect both clinical and collection facilities. All inspectors are asked to commit to 1-2 inspections per year.

The JACIE approach to using volunteer subject matter experts has been vital to the transplant community accepting and embracing the inspection process, as the inspectors are part of the community and peers of the clinicians and Allied Health Professionals (AHPs) working within the Centres. This has also allowed the transplant community to use JACIE to educate Centres on quality management system working and best practice within the field of cell therapy. This in turn has helped to standardise practice and support an ethos of continuous improvement within transplant programmes. The initial inspector training is in two stages. The first part includes online webinars on the inspection process and covers the FACT-JACIE Standards in detail. The trainees need to demonstrate their knowledge on their specific area of the Standards in an online exam. Once the trainee has passed the exam, they can start the second part of the training which consists of face-to-face training to learn about the practicalities of the inspection process and inspection techniques including interview techniques

and report writing. Upon completion of the training but before participating in an inspection independently, the trainee will participate in an inspection as an Observer.

Inspectors are offered ongoing training as part of the EBMT Annual Meeting as well as regular webinars on technical and topical issues. In addition, the inspectors complete an online exam against each new edition of JACIE Standards to retain competency.

Challenges for JACIE include the heterogeneity of the inspector pool and ensuring consistency, both across the inspections and in the interpretation of Standards. Ongoing development of the Inspector pool through educational events and information sharing is one of the approaches JACIE takes to address these challenges. Additionally, the role of the Team Leader is crucial in providing 'real-time' feedback and support for the members of the inspection team. The JACIE Office team also has access to the JAC Chair to provide guidance on challenges encountered through Centres' and Inspectors' disparate interpretation of Standards.