JACIE and Quality Management in HSCT: Implications for Nursing

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Abstract

Laboratory medicine, along with the airline industry, has a long history of utilising quality management systems. It took until 1999 for the Joint Accreditation Committee of the International Society for Cellular Therapy (ISCT) and the European Group for Blood and Marrow Transplantation (EBMT), known as JACIE, to be established as an accreditation system in the field of haematopoietic stem cell transplantation (HSCT). The aim was to create a standardised system of accreditation to be officially recognised across Europe, and it was based on the accreditation standards established by the US-based Foundation for the Accreditation of Cellular Therapy (FACT).

Since the concept of JACIE was originally launched, many European centres have applied for initial accreditation with other centres gaining reaccreditation for the second, third or fourth time. Transplant units, outside of Europe, have accepted the importance of the JACIE Standards, with units in South Africa, Singapore and Saudi Arabia also gaining accreditation.

There is evidence that both donor and patient care have improved within the accredited centres (Passweg et al., Bone Marrow Transplant 47:906–923; 2012: Demiriz IS, Tekgunduz E, Altuntas F (2012) What is the most appropriate source for hematopoietic stem cell transplantation?).

Peripheral Stem Cell/Bone Marrow/Cord Blood Bone Marrow Res. (2012):Article ID 834040 (online)). However, there is a lack of published evidence demonstrating that this improvement directly results from better nursing care. Therefore, the authors conducted a survey of nursing members of the European Blood and Marrow Transplantation Nurses Group (EBMT (NG)) to identify how nurses working in the area of HSCT felt that JACIE impacted in the care they delivered and the general implications of JACIE for nurses.

Aleksandra Babic and Iris Bargalló Arraut are acknowledged for participating in first edition.

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M. Kenyon, A. Babic (eds.), *The European Blood and Marrow Transplantation Textbook for Nurses*,
https://doi.org/10.1007/978-3-031-23394-4_1

Keywords

FACT-JACIE International Standards · Nurses implications · Quality management · Standard operating procedures

1.1 Background to JACIE

The 1990s saw an increase in the number of transplant teams performing haematopoietic stem cell transplantation (HSCT) (Passweg et al. 2012a, b). The procedure that was initially considered experimental during the 1960s/1970s was becoming an established treatment for many blood cancers, solid tumours and acquired or congenital disorders of the haematopoietic system within adult and paediatric populations. Towards the end of the 1990s, the source of haematopoietic stem cells was collectable from the marrow, peripheral blood and cord blood and from autologous, sibling and unrelated donations (Demiriz et al. 2012).

In 1998 two leading European scientific organisations, The International Society for Cellular Therapy (ISCT) Europe and the European Group for Blood and Marrow Transplantation (EBMT), formed a joint committee to be known as the Joint Accreditation Committee for ISCT and EBMT (JACIE) (Cornish 2008). The purpose of this new committee was to establish a system to allow transplant teams to self-assess against a group of standards (Cornish 2008), provide an inspection process and recognise compliance with the standards by awarding accreditation to those teams who worked within the field of HSCT. A pilot study of the JACIE inspection and accreditation process was carried out in Spain 2000–2002. This enabled JACIE to assess sections of the standards that gave rise to common difficulty experienced by the transplant teams and to assess what assistance, if any, would be required by the centres for them to obtain accreditation. The results of this pilot study underlined the need to implement national and international regulations (Pamphilon et al. 2008) within each European country. In January 2004, with the support from the European Union under the Public Health Programme (2003–2008), the JACIE accreditation process was launched (Pamphilon et al. 2008).

To enable a set of international standards for the provision of quality medical, nursing and laboratory practice in HSCT transplantation to be developed and recognised, JACIE collaborated with their American counterparts, the Foundation for the Accreditation of Cellular Therapy (*FACT*) (JACIE). The "FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration" are revised on a regular basis.

JACIE remains a non-profit organisation with all members being an expert within their specialty: clinical, collection or processing procedures of HSCT. Clinicians, nurses and quality managers who are experts in their field can volunteer to become JACIE inspectors, if they meet the criteria set. Potential inspectors must attend training, pass an exam and act as an observer within the inspection team as a trainee before their first official JACIE inspection. As the JACIE accreditation process has evolved, the inspection team membership has extended to include apheresis nurses and experienced quality managers recognising the multi-professional components of HSCT programmes. The accreditation process monitors an established quality management system (QMS); therefore, accredited centres are required to apply for reaccreditation every 4 years.

Since 2000, 508 transplant programmes and facilities in 34 countries in Europe and beyond have applied to JACIE and 790 inspections (first-time and reaccreditation) have been performed. Three hundred sixty-eight applicants have achieved accreditation at least once with practically all centres repeating the process after the first accreditation cycle (JACIE activity report 2021 https://www.ebmt.org/annual-report-2020/jacie-activity-report-2020).

In terms of activity, 2020 was severely affected by the Covid 19 pandemic. From mid-March 40 applications were received, 18 inspections were completed before on-site inspections were cancelled and 47 accreditations were awarded.

Although the initial aim of the accreditation scheme was a voluntary process, in many countries, health-care systems/commissioners or health insurance providers and tissue banking authorities increasingly view JACIE accreditation as important and demand accreditation to allow the procedure of HSCT to be performed.

Accreditation is the means by which a centre can demonstrate that it is performing to a required level of practice in accordance with agreed standards of excellence. Essentially it allows a centre to certify that it operates an effective QMS. Furthermore, due to the increased use of unrelated donors from different countries, interaction and collaboration between units are key elements for the success of stem cell transplantation. JACIE accreditation is a guarantee that the donor and the cellular product have been handled according to specific safety criteria.

A QMS is a mechanism to:

- Ensure that procedures are being performed in line with agreed standards, with full participation by all staff members. In a HSCT programme, this ensures that the clinical, collection and laboratory facilities are all working together to achieve excellent communication, effective common work practices, shared policies where appropriate, increases guarantees for improved patient outcomes and the use of international donor criteria for related donors (Gratwohl et al. 2014; Anthias et al. 2015, 2016). Nurses have successfully taken on the role of improving communications for donor mobilisation, collections and liaising with the staff of the processing facility.
- Track and monitor collected cell products for safety and viability from the time of donation to the administration procedure. Patients' medical records must include not only the information of date and time of the collection but also volume of collected product, type and volume of citrate and the product identification. A transport log will be required to ensure traceability of all products from collection to processing and then to clinical for administration.
- Identify errors and incidents that can be reviewed and corrective actions to be implemented and allow a plan of action to be put into place to minimise the error reoccurring.
- Formalise training and competencies.
- Clearly identify the roles and responsibilities of all staff working within the transplant team or with outside agencies (clinical, collection, processing and support services; intensive care, radiotherapy, cleaning and transport services, laboratories and donor panels).
- Review documentation for evidence that standards have achieved compliance on a regular basis.

1.2 Preparing for JACIE Accreditation

1.2.1 Considerations

JACIE Standards set a minimum criteria of resources required for a safe delivery of the cellular therapy service. The Standards required for example human resource in quality manager, data manager and clinical support staff such as dedicated pharmacist, dietitian and social worker as part of the infrastructure. Therefore it is important that the centre has formal arrangements in place to meet these specific Standards and sometimes this may require additional resources. Any arrangements should be formalised as part of the QMS to achieve accreditation.

A clinical transplantation program may apply for accreditation alone or in conjunction with associated collection and processing facilities. JACIE allows stand-alone accreditation for independent facilities. There will be many processing facilities that are independent from the clinical transplant teams and may be responsible for collections of apheresis products. In this situation, the processing facility and clinical facility have a choice of accreditation. They may decide to apply for separate or combined accreditation. However, in order to obtain JACIE accreditation, it is important that the QMS describes the communication processes between all facilities involved and provides the evidence that communications

exist, e.g. minutes of weekly, monthly and annual meetings must include the names of the attendees, sharing evidence of engraftment and adverse events. It is important to remember that a clinical facility must use an apheresis and processing facility that are JACIE accredited. Similarly, an apheresis facility must use a processing facility that is accredited before clinical and apheresis facilities can be awarded JACIE accreditation.

1.2.2 Implementing a Quality Management System

HSCT is a procedure with a high technological content, which requires extensive attention towards patients/donors who might introduce important problematic clinical factors and also towards sophisticated laboratory procedures related to the collection, manipulation, cryopreservation and transplantation of haematopoietic cellular therapy. The continuous improvement of stem cell technology requires that all procedures regarding HSCT be guaranteed through the definition of qualitative standards recognised by scientific associations and international organisations. For the collection, processing and transplantation of HSCs, there are standardised procedures, which require specific clinical, haematological and laboratory knowledge and strict quality controls concerning all processes from cellular collection and manipulation to the administration of the collected product. Stem cell collection, processing, storage and transplantation must be carried out in a highly regulated manner to guarantee both safety and clinical efficacy. Moreover, in recent years, immune effector cells (IECs) have been introduced into clinical practice, along with their challenges due to widely diverse manufacturing methods, clinical indications, and safety and toxicity profiles. (For further information please see the chapter 7.

Therefore, quality assurance is a very important topic at all levels of a haematopoietic cellular therapy and transplantation program, including robust nursing procedures, e.g. chemotherapy administration, use of stem cell mobilisation agents and collection of cellular material.

The implementation of a QMS arises from the need to develop an appropriate system to optimise the quality of the service offered by a stem cell transplantation unit, in a general context of health-care quality improvement. A QMS is a tool that can be used to rapidly identify errors or accidents and resolve them to minimise the risk of repetition. A QMS assists in training and clearly identifies the roles and responsibilities of all staff (Cornish 2008; Caunday et al. 2009).

In 1966, Avedis Donabedian wrote a paper entitled “Evaluating the Quality of Medical Care”, where the concepts of structure, process and outcome in health care were introduced. The structure includes not only the physical aspects in which care is given but also the resources and tools available to the health-care team, the leadership and the staff. The process is how the health-care system and the patient interact. The outcome includes the effect of care on diseases and their prevention, such as the mortality rate, the error rate and the quality of life (Samson et al. 2007).

During the 1950s, Edwards Deming introduced the plan-do-check-act (PDCA) cycle, an iterative four-step management method used for the implementation and improvements of processes and products, also known as plan-do-study-act (PDSA). He also stressed the importance of viewing problems in the context of a system and that most mistakes were not the fault of the worker (Samson et al. 2007).

The major objective of the JACIE Standards is to promote quality medical and laboratory practice in HSCT and other therapies using cellular products; therefore dedicated quality management standards are found within the FACT-JACIE manual (clinical facility B04, marrow collection facility CM04, apheresis collection facility C04, processing facility D04).

Quality management is the management of activities involved in quality assessment, assurance and control that try to improve the quality of patient care, products and services in cellular therapy activities.

A QMS could be implemented applying the PDCA cycle for the management and continuous improvement of processes and products.

- **PLAN** means to establish the objectives and processes necessary to the centre. This means define the scope of the QMS and identify which processes within the scope are most important, those staff who are involved in the important processes and involve them in defining the targets to be used to measure the quality of the process. Ensure all staffs know how they can contribute to achieve the performance required.

  One important aspect to consider when implementing a QMS is the organisation and interaction between the different facilities (clinical, collection and processing). The Program shall include an organisational chart of functions, considering clinical, collection and processing staff, in particular for those tasks that are critical to assuring product or service quality. Training plans should be defined and put in place. Documentation may be displayed in a variety of formats (job descriptions, training records, qualifications certificates, retraining).

  A document system should be implemented serving multiple purposes for the QM programme. They provide instructions on:
  - Activities, policies and processes controlling various steps within the activities.
  - Quality control and traceability of products, donor and patients.

  The Quality Management Manual should be one of the first documents developed when preparing for JACIE accreditation. The centre must have a standard operating procedure (SOP) outlining the method by which to create, approve, implement and update SOPs (known as the "SOP for SOPs"). Clinical and collection protocols or laboratory methods must be translated into written procedures, in paper form or an electronic version, and readily available to staff. The purpose of document control is to ensure the correct approved documents are in use.

Since the 6th edition of the FACT-JACIE Standards, more specific requirements for validation and qualification studies have been delineated, and the concept of risk assessment has been implemented.

Validation is documented evidence that the performance of a specific process meets the requirements for the intended application. For example, the procedure for thawing frozen cells should be evaluated, as there is a risk of contamination and loss of cells during the thawing process. A thawing control, on three procedures, could be performed to assess whether these criteria would validate the process.

Qualification is documented evidence that the equipment/facility/utility is meeting the user requirement specification, working correctly and leading to the expected results. For example, "the dry shipper used for the transportation of frozen haematopoietic stem cells should be validated for temperature control".

During the implementation phase, risk management should be an ongoing part of the quality management process, to minimise hazards for processes, patients and staff.

In the 8th edition of the Standards, more general standards were added to address risk management program requirements for Clinical Programs utilizing licensed (or equivalent regulatory approval) cellular therapy products.

Risk management is not a new knowledge, even in healthcare. Risk is defined as an *"effect of uncertainty on objectives"* (ISO 31000: 2009), and there are many different approaches to classify and manage risks. Moreover, a risk can have not only a negative impact as a threat, but also be an "opportunity" with a positive influence.

There are several methods for the assessment of the risk, such as Failure Mode and Effects Analysis (FMEA) or Failure Modes, Effects and Criticality Analysis (FMECA), methods of assessing potential failure mechanisms and their impact on system, identifying single failure points.

- ***DO*** means to implement the plan, execute the process and carry on the activities. Once the programme has been established and staff trained, the activities and the quality plan should be maintained, through the document system and the available resources. Policies and procedures could be revised, training programmes implemented and the outcome analysis of cellular therapy product efficacy reviewed to verify that the processes in use provide a safe and effective product.
- ***CHECK*** is to measure the results and compare them against the expected results or goals defined by the plan. Audits represent one of the principal activities in this step and should be documented, independent inspection and retrospective review of activities to determine if they are performed according to written procedure and specified endpoints. They should be conducted to ensure that the QMS is operating effectively and to identify trends and recurring problems in all aspects of the programme. Moreover, the transplant programme should manage errors, accidents, deviations, adverse reactions and complaints and monitor activities, processes and products using measurable indicators (Harolds 2015).
- Finally, **ACT** is to improve the QMS based on the results of the previous steps. Investigation of errors and indicators and the implementation of corrective or improvement strategies are undertaken and monitored with follow-up assessment to determine the effectiveness of the change.

Data shown by Gratwohl and colleagues (Gratwohl et al. 2014) demonstrate that the use of a clinical quality management system is associated with improved survival of patients undergoing allogeneic HSCT.

BMT is a rapidly evolving field, involving in recent years not only blood and marrow stem cells but also many other cellular, immune and cytotoxic therapies (for example CAR-T therapies). The application of JACIE Standards is an excellent example for clinical quality systems in other specialities (Snowden et al. 2017).

1.3 The JACIE Accreditation Process

1.3.1 Start Working with the Standards

The JACIE accreditation process begins when the transplant centre, with the support of the hospital management team (a key element in order to assure provision of the required resources to successfully implement the JACIE accreditation process), agrees to start working according to the JACIE Standards.

It is important to gather all the necessary information before commencing the JACIE accreditation pathway. First read the JACIE Standards, access the guides, manuals and supporting documentation from the EBMT website (www.ebmt.org/jacie-accreditation). Then begin to complete the JACIE Inspection Checklist as a self-evaluation tool. This document contains all the JACIE Standards and will help the centre establish their level of compliance against each standard and identify further work required to achieve accreditation. Furthermore, the checklist is the pivotal tool used continuously throughout the JACIE accreditation process, until JACIE accreditation has been awarded.

1.3.2 Application for JACIE Accreditation

When the applicant has established a mature QMS, i.e. has been in place and operational for at least a year, a self-assessment of the standards has been performed and shows a high percentage of compliance, the centre can formally apply for JACIE accreditation. The application form and inspection checklist should be completed in English and submitted to the JACIE Office where the JACIE team will review and approve the application form, finalising this part of the process with the signing the accreditation agreement by the centre.

After application being approved, the applicant will be required to provide the preaudit doc-

umentation to the JACIE Office. The JACIE team and the inspectors will determine that all required documentation has been correctly submitted. The documents can be provided in the language of the centre/applicant; however, in some exceptional cases, a translation in English of some key documents will be requested. The preaudit documentation includes relevant documentation for all areas of the Stem Cell Transplant Programme such as personnel documentation, donor consent information, labels and summary of QMS activities (Quality Management Plan, audit report, policies) and others.

1.3.3 Arranging the Inspection Date

The JACIE Office will begin the process to assign an inspection date and the inspection team once all the documentation and the agreement are completed and approved. The inspection team will typically consist of one inspector per facility to be inspected, plus a quality management inspector. For example, if the applicant has applied for adult clinical and bone marrow, apheresis and processing accreditation, the inspection team will consist of experts in each of the following areas: clinical, apheresis, processing and quality management (The clinical inspector will be responsible for clinical and marrow collection facilities). The inspectors are selected according to their area of expertise: clinical, apheresis, processing and quality management. For instance, a clinician will inspect the clinical facility. If a paediatric unit is part of the inspection, a paediatrician will be assigned. When there is more than one facility per area, for instance, two apheresis units, an extra collection inspector will be included in the inspection team.

The applicant will be invited to view the list of JACIE inspectors, found on the EBMT website, and inform the JACIE Office if there are any inspectors that they would prefer did *not* participate in their inspection, due to a conflict of interest. Although the aim is to perfom the inspection in the language of the centre, the inspectors work internationally and therefore it is not uncommon for some/part of the inspection to be carried out in English. If the inspection is carried out in English, the JACIE co-ordinators will work with the Center to organise facilitators for the inspection team as well as to offer a discount to the center for translating some of the documents.

1.3.4 The Inspection

The inspection will take place over a period of 1–2 days and is a thorough examination of all aspects of the programme. The inspector will use the inspection checklist previously completed by the applicant to evaluate the centre's compliance with the standards.

The inspection is usually divided in the following parts:

- Introductory meeting by the programme director and the inspection team with all the programme personnel.
- Tour of the facilities and observation of procedures (or mock procedures).
- Review of documentation.
- Interviews with personnel.
- Closing meeting with programme director.
- Closing meeting summarising the inspection results with the transplant team.

1.3.5 The Inspection Report

Following inspection, the inspectors submit their completed written report and inspection checklist to the JACIE Office. The inspection report is a fundamental part of the accreditation process. The report will be prepared and presented to the JACIE Accreditation Committee by the JACIE Co-ordinators.

The Accreditation Committee is a group of experts from all areas of Stem Cell Transplantation (Clinical, Collection, Processing and Quality Management) that discuss each individual report and determine any corrective actions required in order to achieve accreditation. Bear in mind that while the inspectors' task is to *identify* areas of

non-compliance, it is the JACIE Accreditation Committee who determines what, if any, corrective actions are required to be performed.

1.3.6 Corrections and Accreditation Award

A high percentage of all inspections reveal at least some deficiencies and the degree of deficiency identified will vary in seriousness. In most cases, documentary evidence of corrections can be submitted electronically. However, if the deficiencies are considered to represent a risk for patients, donors or personnel, a focused re-inspection will be required before accreditation can be awarded.

Centres are allowed a period up to 9 months to implement and submit evidence of the corrections to the JACIE Office. The same team of inspectors will review and assess the adequacy of the corrections provided by the centre. Once the inspectors are satisfied that all points have been resolved, with the approval of the JACIE Accreditation Committee, the applicant will be awarded accreditation for a 4-year period, subject to a document-based interim audit at the end of the second year.

1.3.7 Post JACIE Accreditation

The inspection is the most visible part of the JACIE accreditation process. The most challenging part, once accreditation has been awarded, is maintaining accreditation. At the second year of accreditation, the interim audit will be due, and if the system has not been maintained, the hard work invested in achieving accreditation will become void and centres risk having to return to the beginning of the process when applying for reaccreditation.

The JACIE Committee warns against failing to uphold standards or maintain the QMS between inspections. Those centres that fail to maintain their QMS due to lack of commitment or allow their system to deteriorate may discover that standards that were compliant at the initial inspection have become partially compliant or non-compliant during the next inspection. For instance, inspectors may identify failures to review documentation, perform audits and maintain competencies due to the lack of available evidence during the accreditation cycle.

The accreditation process described above corresponds to the JACIE accreditation based on an onsite inspection. JACIE also offers accreditation based on a remote inspection by adapting the current onsite inspection format. The format of the remote inspections is designed to mimic as much as possible the onsite accreditation process through video conferencing and supported by live streaming of the facilities and/or prerecorded video tour.

Further information regarding the JACIE Accreditation process is available in the document entitled "Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy: The JACIE Guide", available on the EBMT website (https://www.ebmt.org/sites/default/files/2021-03/The-JACIE-Guide.pdf).

1.4 JACIE Standards That Affect Nursing: Clinical and Collection

The JACIE Standards are divided into sections: clinical and donor (B), collection of marrow (CM), apheresis products (C) and laboratory (D). Many of these standards are shared across each facility as appropriate (Table 1.1) with Quality Management standards being found in all sections.

It is not possible to describe, within this chapter, all the actions and evidence required to fulfill a full compliance for all the standards published in the latest edition of the FACT-JACIE Standards; therefore in Tables 1.2, 1.3 and 1.4, there are examples of appropriate standards, compliance and comments that have implications for nurses.

It is important that the nursing team takes ownership of the relevant standards and works towards achieving full compliance whilst being aware of the other standards that have implications on nurses or nursing (Table 1.5).

Table 1.1 FACT-JACIE Hematopoietic Cellular Therapy Accreditation Standards (8th edition) QUALITY MANAGEMENT

CLINICAL PROGRAM STANDARDS	BONE MARROW FACILITY STANDARDS	COLLECTION FACILITY STANDARDS	PROCESSING FACILITY STANDARDS
PART B	PART CM	PARTC	PART D
B1 General	CM1 General	C1 General	D1 General
B2 Clinical Unit	CM2 Clinical Unit	C2 Apheresis Collection Facility	D2 Processing Facility
B3 Personnel	CM3 Personnel	C3 Personnel	D3 Personnel
B4 Quality Management	B4 Quality Management	C4 Quality Management	D4 Quality Management
B5 Policies and Standard Operating Procedures	CM5 Policies and Standard Operating Procedures	C5 Policies and Standard Operating Procedures	D5 Policies and Standard Operating Procedures
B6 Allogeneic and Autologous Donor Selection, Evaluation, and Management	CM6 Allogeneic and Autologous Donor Selection Evaluation and Management	C6 Allogeneic and Autologous Donor Selection, Evaluation and Management	D6 Equipment, Supplies, and Reagents
B7 Recipient Care	CM7 Coding and Labeling of Cellular Therapy Products	C7 Coding and Labeling of Cellular Therapy Products	D7 Coding and Labeling of Cellular Therapy Products
B8 Clinical Research	CM8 Process Control	C8 Process Controls	D8 Process Controls
B9 Data Management	CM9 Storage	C9 Cellular Therapy Product Storage	D9 Cellular Therapy Product Storage
B10 Records	CM10 Cellular Therapy Product Transportation And Shipping	C10 Cellular Therapy Product Transportation and Shipping	D10 Cellular Therapy Product Transportation and Shipping
	CM11 Records	C11 Records	D11 Receipt Of Cellular Therapy Products
	CM12 Direct Distribution to Clinical Program	C12 Direct Distribution to Clinical Program	D12 Disposal
			D13 Records

Table 1.2 Examples of "non-compliant" clinical standards (FACT-JACIE Hematopoietic Cellular Therapy Accreditation Standards: (in previous editions of the JACIE standards))

B.3.7 C3	STAFFING NURSES	COMPLIANCE	COMMENT	COMMENT
	Standard		6th Ed. JACIE Standards	7th Edition Standards
C3.4.1	The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.	Partially compliant	No back up plan to continue the service in the rare event that a member of a small team requires long-term absence from work.	Continues to be an issue in 27% (3 out 11) initial collection reports
B.3.7.1	The Clinical Program shall have nurses formally trained and experienced in the management of patients receiving cellular therapy.	Partially compliant	No evidence of formal training in the transplant setting	Resolved in all 8 initial and 34 clinical re-accreditation reports
B.3.7.2	Clinical Programs treating paediatric patients shall have nurses formally trained and experienced in the management of paediatric patients receiving cellular therapy.	Partially compliant	Nurses are paediatric qualified but lack evidence of formal training in the transplant setting	Resolved in all 8 initial and 34 clinical re-accreditation reports

(continued)

Table 1.2 (continued)

B.3.7 C3	STAFFING NURSES	COMPLIANCE	COMMENT	COMMENT
B.3.7.3	*Nurses shall have received specific training and maintain* competence *in the transplant-related skills that they routinely practice* including:			
B.3.7.3.3	Administration of blood products, growth factors, cellular therapy products, and other supportive therapies.	Partially compliant	Hospital policy does not include the administration of cellular products; therefore a policy for the administration of cellular products is required. This policy can then be used for training and competency testing	Resolved in all 8 initial and 34 clinical re-accreditation reports
B.3.7.3.6	Palliative and end-of-life care.	Non-compliant	No training	Resolved in all 8 initial and 34 clinical re-accreditation reports
B.3.7.4	There shall be written policies for all relevant nursing procedures, including, but not limited to:			
B.3.7.4.1	Care of immunocompromised patients.	Partially compliant	Hospital policy used does not include the severely compromised transplant patient, therefore a policy or SOP required	Resolved in all 8 initial and 34 clinical re-accreditation reports
B.3.7.4.3	Administration of cellular therapy products.	Partially compliant	Policy/SOP does not include administration of donor lymphocytes	15% (5 out of 34 re-accreditation reports) either had no formal training in the administration of transplants (including DMSO containing products or Immune Effector Cells OR no special documentation of the infusion process)
B.3.7.6	There shall be a nurse/patient ratio satisfactory to manage the severity of the patients' clinical status.	Partially compliant	During the discussions with nursing staff there appears to be an informal policy in place to increase the number of nursing staff when required. A formal policy should be written	Resolved in all 8 initial and 34 clinical re-accreditation reports

Table 1.3 Examples of "non-compliant" quality management standards for clinical and apheresis facilities (FACT-JACIE Hematopoietic Cellular Therapy Accreditation Standards (in previous editions of the JACIE standards))

B.4	QUALITY MANAGEMENT	COMPLIANCE	COMMENT	
	Standard		6th Ed. JACIE Standards	7th Ed. JACIE Standards
B.4.4	The Quality Management Plan shall include, or summarise and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Clinical Program. Personnel requirements shall include at a minimum:			
B.4.4.1 C.4.4.1	A current job description for all staff.	Partially compliant	Job description not available for all nursing grades/role	Lack of evidence continues to be an issue in 9% of the re-accreditation reports (3 out of 34 reports). Not an issue in the 6 initial reports.
B.4.4.2 C.4.4.2	A system to document the following for all staff:			
B.4.4.2.2 C.4.4.2.2	New employee orientation.	Partially compliant	Orientation program in place but no evidence that nurse Smyth (only worked on the ward for 3 months) has participated in the orientation program	Lack of evidence continues to be an issue in 6% of the re-accreditation reports (2 out of 34 reports) not an issue in the 6 initial reports.
B.4.4.2.3 C.4.4.2.3	Initial training and retraining when appropriate for all procedures performed.	Partially compliant	No evidence of re-training for nurse X who has returned from long-term absence.	Not yet fully resolved in either the re-accreditation or initial reports. (1 out of 34 re-accreditation reports and 1 out of 6 initial reports lacked evidence).
B.4.4.2.5 C.4.4.2.5	Continued competency at least annually.	Partially compliant	Not all nursing staff have evidence that competencies are performed annually	Lack of evidence continues to be an issue in 23% of the re-accreditation reports (8 out of 34 reports). Not an issue in the 6 initial reports.
B.4.4.2.6 C.4.4.2.6	Continuing education.	Partially compliant	Education program in place but no attendance list for each education activity	Not fully resolved. Lack of evidence continues in 6% of re-accreditation reports (2 out of 34 reports) and in 2% of initial reports (1 out of 6 reports)
B.4.8.3	Audits shall include, at a minimum:			
B.4.8.3.3	Annual audit of verification of chemotherapy drug and dose against the prescription ordering system and the protocol.	Non-compliant	Not performed	Lack of evidence or the standard is not performed continues to be an issue in 47% of the re-accreditation reports (16 out of 34 reports) and an issue in 50% of the initial reports. (3 out of 6 reports)

(continued)

Table 1.3 (continued)

B.4	QUALITY MANAGEMENT	COMPLIANCE	COMMENT	
B.4.11 C.4.11	The Quality Management Plan shall include, or summarise and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	Partially compliant	Policies and SOP are included with the QMP. Staffs do not complete the tracking forms	

Table 1.4 Examples of "non-compliant" policy and procedure standards for clinical and apheresis facilities (FACT-JACIE Hematopoietic Cellular Therapy Accreditation Standards: (in previous editions of the standards))

B.5. C5	POLICIES AND PROCEDURES	COMPLIANCE	COMMENT	
			6th Ed. JACIE standards	7th Ed. JACIE standards
B.5.1 C.5.1	The Clinical Program shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in B4. These documents shall include all elements required by these standards and shall address at a minimum:			
C5.1.6	Administration of blood products	Non-compliant	Not an issue	17% (5 out of 29) re-accreditation reports and 54% (6 out of 11) initial reports were found non-compliant e.g. the policy not being available in the collection facility OR the policies/SOP's meet the JACIE standards but there is no reference to acceptable end-points and/or the range of expected results in the procedure
B.5.1.8	Administration of HPC and other cellular therapy products, including products under exceptional release	Partially compliant	The policy has not been updated to include cord blood	Resolved for both initial and re-accreditation reports
C6.1.7	Labeling (including associated forms and samples)	Partially compliant	Labeling procedure should show more details regarding roles of physician and nurse involved in labeling operations	Remains an issue in 54% initial reports (6 out of 11 reports)
C5.1.8				The processing facility is often responsible for labelling. (1) the SOP is not available in the collection facility. (2) the ISBT 128 standard terminologies for product code or Eurocode is not used.
C.5.1.14	Equipment operation, maintenance and monitoring including corrective actions in the event of failure.	Partially compliant	No evidence of maintenance reports	Resolved in the re-accreditation report.
				27% (3 out of 11) initial reports had no evidence or have no correction action documented in the event of equipment failure

Table 1.4 (continued)

B.5. C5	POLICIES AND PROCEDURES	COMPLIANCE	COMMENT	
C5.5.5	Staff training and, if appropriate, competency shall be documented before performing a new or revised standard operating procedure	Non-compliant	Lack of evidence	7% (2 out of 29) re-accreditation reports and 27% (3 out of 11) initial report had no documented evidence for this standard
B7	Recipient care			
B.7.4.4	Prior to administration of the preparative regimen, one (1) qualified person using a validated process or two (2) qualified people shall verify and document the drug and dose in the bag or pill against the orders and the protocol, and the identity of the patient to receive the therapy.	Non-compliant	No evidence of two persons verifying the drug.	Resolved in initial reports but remains a slight issue in 3% (2 out of 34) re-accreditation reports
B.7.6	There shall be a policy addressing safe administration of cellular therapy products.	Partially compliant	The policy has not been updated to include cord blood	15% (5 out of 34) re-accreditation reports **non-complaint** due to policy not being available in the outpatient facility or the policy not being detailed enough
B.7.6.4	Two (2) qualified persons shall verify the identity of the recipient and the product and the order for administration prior to the administration of the cellular therapy product.	Non-compliant	No evidence of two person verify the drug	Remains an issue for 33% (2 out of 6) initial reports
B.7.6.6	There shall be documentation in the recipient's medical record of the administered cellular therapy product unique identifier, initiation and completion times of administration, and any adverse events related to administration.	Partially compliant	No evidence of start and completion times of the infused product written in the recipient's medical notes	No issue for initial reports. In the re-accreditation reports there remains a slight issue in 6% (2 out of 34) reports not being compliant

Table 1.5 Examples of "non-compliant" process control standards for apheresis facilities (FACT-JACIE Hematopoietic Cellular Therapy Accreditation Standards: (in previous editions of the standards))

C.08	PROCESS CONTROLS	COMPLIANCE	COMMENT	
			6th Ed. JACIE Standards	7th Ed. JACIE standards
C8.1	Collection of cellular therapy products shall be performed according to written Standard Operating Procedures.	Non-compliant	Not an issues	10% (3 out of 29) re-accreditation reports were identified not to perform all the procedures mentioned in the SOP. e.g. calibration to be checked after every 5 procedures. 27% (3 out of 11) initial reports had no evidence that this standard was performed

(continued)

Table 1.5 (continued)

C.08	PROCESS CONTROLS	COMPLIANCE	COMMENT	
C8.2.2	Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination	Partially complaint	Not an issue	Lack of evidence that visual checks were performed were found in 14% (4 out of 29) re-accreditation and in 18% (2 out of 11) initial reports
C.8.10.1	Adequacy of central line placement shall be verified by the Apheresis Collection Facility prior to initiating the collection procedure.	Partially complaint	No evidence that this standard is performed	10% (3 out of 29) of re-accreditation reports could not demonstrate this standard was performed
C.8.11	Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.	Partially compliant	The responsibilities of administration of growth factors should be clearly defined in the appropriate policies especially for those donors where shared care is in place	Appears to have been resolved in both re-accreditation and initial reports. Although it was noted in one initial report that an allogeneic donor's results were not reviewed.
C.8.12.1	Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm that products meet predetermined release specifications.	Partially compliant	Criteria for HPC-A collection should be defined together with ranges of expected results concerning HPC product characteristics	Continues to be an issue in a minority of reports. 18% (2 out of 11) initial reports and 7% (2 out of 29) re-accreditation reports stated that the release criteria is not clearly defined in an SOP or there was no evidence of pre-determined release criteria from the collection facility to processing facility.

1.4.1 Staffing and Nursing (Table 1.2)

Senior staff should be aware that the patient's pathway, during the transplant process, can be unpredictable. There are episodes when the patient will experience complications of the treatment required for HSCT that will require a higher intensity of nursing care. During such episodes, the nursing management should have an established contingency plan to provide adequate nursing care for these patients. Possible options could be:

- Nursing staff within the team allowed to work extra shifts.
- The employment of additional nursing staff with relevant experience from the hospital pool of nurses or from nursing agencies.
- Transfer of the patient to a high dependency or intensive care setting.

Whatever the contingency plan, there should be evidence in place, such as a written policy for staffing. This policy should describe the plan of action to be taken for small teams, apheresis, quality management and data collection teams, in case of planned or unplanned long-term absence from work, therefore allowing the patient's or donor's pathway to continue without affecting the nursing or medical care given.

Not only should there be adequate nursing staff, the nurses should be qualified, trained and competent in the roles they perform.

JACIE can be a challenge and an opportunity for nurses in:

- Reviewing existing procedures.
  - Especially those that have been performed automatically in the same way despite being inefficient.
- In adopting measures for clinical risk management.
  - Paying more attention to long-term planning for continuing education of personnel, procedures and tools for monitoring, verifying and in achieving competence maintenance.
- Development and implementation of internal audits and quality indicators.

Furthermore, JACIE is an opportunity for nurse recognition within the organisation they work, in terms of contribution to the overall results achieved.

1.4.2 Training and Competencies (Tables 1.2 and 1.3)

All hospitals should have their own programme for training, annual review/appraisal and competencies. The structure already in place for recording the individual staff members training can also be used to record the JACIE Standards' requirements. A new system for training records for JACIE is not required if the following is undertaken.

- Basic training.
  - A route that leads to the skills acquisition in order to obtain new or improved "performance"
- Educational training:
  - The set of activities, including basic training, aimed to develop and enrich the staff on the technical, special, managerial and cultural side aspects of their role
- Competence:
  - The proven ability to use knowledge and skills
- Competency maintenance:
  - The minimum activity that is required to be performed by each operator in order to retain the assessments defined in the specific job description.
- Competency matrix:
  - The activities performed must be recorded in order to perform an annual assessment (quantitative and qualitative) for the activities that can be recognised.

It is important that training and competency programmes are structured and ongoing, with documented evidence of training topics and dates. Most importantly, an attendance register for training and competency sessions is required. Whilst initial supervised training is more easily documented, annual competency maintenance can be difficult to show (Table 1.3). Ongoing training for clinical personnel should reflect:

- Their experience
- Individual competencies and proficiencies
- Orientation for new staff
- Preceptorship

Training needs to be flexible to reflect staff requirements and should be performed in a timely manner to demonstrate annual updating.

When staff cannot attend a particular training session due to staffing issues, holidays or sickness, a self-teaching system, e.g. an electronic system that includes the presentation and self-assessment tool, may be an option to consider.

For those centres that apply for a combined adult and paediatric JACIE accreditation, it is important that training sessions should include relevant age-specific issues for each topic, especially if the two age group populations are nursed within the same ward environment. Where adult and paediatric patients are nursed on separate wards, training sessions may be separate for certain topics, but it is also important to share ses-

sions, where appropriate, to provide evidence that both population groups are an integrated part of a combined transplant facility.

The FACT-JACIE International Standards Accreditation requires that the clinical programme have access to personnel who are formally trained, experienced and competent in the management of patients receiving cellular therapy. Core competencies are specified within the standards, and evidence of training in these competencies must be documented. This may be achieved by evidence of in-service training, attendance at conferences, etc.

During September 2016, the EBMT (NG) in collaboration with JACIE and the EOC (Ente Ospedaliero Cantonale) launched the first video recorded course, aimed at physicians, nurses and technicians working within JACIE-accredited centres. The course focused on competency maintenance. Although this initial training course is no longer available, The EBMT (NG) has created and amassed a substantial amount of additional information useful to patients and practitioners. These guides, videos, presentations, E-learning programmes and online material that supports training and competency maintenance can be found in the EBMT (NG) document centre (www.ebmt/nursing/nurses-group-education).

1.4.3 Benefits of Quality Management (Table 1.3)

The key aim of the JACIE process is to implement a QMS into clinical practice. Despite the difficulties that maybe encountered, the process can be useful for integration of staff from all disciplines and professional collaboration. Staff education plays a key role in the implementation of the whole system and in particular for the quality management system (Piras et al. 2015). The majority of the quality standards are aimed at providing evidence that there are systematic processes in place. Furthermore, several of the standards relate to having systems in place to record initial qualification, training and competencies and minimal qualifications for the trainer. The hospital system can be utilised for these standards, and this evidence can be shown to the inspectors. However, not all hospital record systems register the training qualification required by a member of staff who has a training role.

1.4.4 Audits (Table 1.3)

Some nurses may be unfamiliar with this area. One approach is to view audits as assessing the care you give, reviewing the evidence and making changes to improve the patient's or donor's experience and/or nursing care given. After a predetermined period of time, it is necessary to reassess the changes made to measure any improvements resulting from those changes. This is referred to as "closing the audit loop". A nursing audit schedule works best when the nursing teams initiate the audit topics. It is important to include the audits required by JACIE, e.g. (1) the verification of the chemotherapy drug and dose against the prescription and the protocol and (2) the verification of the haematopoietic stem cell infusion.

It is important that the audit is performed by personnel that are not directly involved within the activity to be audited who has sufficient expertise in the subject manner to be able to identify problems and must also be a competent auditor (López-Villar and Dolva 2021).

1.4.5 Reporting Adverse Events (Table 1.3)

To enable adverse/serious events to be fully reported, it is important that a culture of "no blame" is present. The hospital should have an established reporting system in place, and it is important that the adverse events for transplantation and collection of cellular products including apheresis and marrow can be coded separately to other departmental adverse/serious events. This allows for clarity and a true record of the number of events recorded for the transplant programme. Each episode is reviewed and changes made if required. This is then followed

by an audit of the changes made to minimise a reoccurrence. Nurses working with patients and donors have a very important role in reporting adverse events.

It is important that all adverse/serious events are recorded in the quality meeting minutes, quarterly and annual reports and most importantly shared with all the sections involved in delivery of the transplant programme (clinical, collection and processing), as appropriate. For example, if a recipient has a reaction to a stem cell infusion or there is a deviation from the time specified for each infusion of thawed cells, these events should be reported and shared with the processing facility.

Where adverse/serious events have been shared across departments, the inspector will require evidence that the events were discussed, and if any changes were made to practice that this was recorded, policies were updated and the episode monitored.

1.4.6 Tracking of Collected Products (Table 1.3)

To enable the safe collection, storage (including temporary storage within the collection facilities) and distribution of collected products, it is important that each stage of the process is recorded. Therefore, collection, laboratory, transport and clinical staff should be involved in signing a transport log to accept the product and in some cases recording the temperature of the product. Policies should be in place to include what to do if there is a deviation in practice, e.g. temperature of the product falls outside the range of temperature agreed within the transport policy. It is important that policies and standard operating procedures that include responsibilities of more than one facility are shared and members of staff have ready access.

The donor and recipient's medical notes must be completed, as part of the tracking system, to record the collection or transfusion of the collected product. The cellular product identification, time and date should also be included in the medical notes.

1.4.7 Common Deficiencies That Have Occurred in Previous Editions of the FACT-JACIE Standards

During the annual meeting of the EBMT (2015), the results of a review of JACIE inspection reports against the 5th ed. of the JACIE Standards were presented (JACIE Quality Management 2015). The aim of the review was to identify common deficiencies within the standards. Of reports issued against the 5th ed. of the FACT-JACIE Standards, 95% (145/152) had been reviewed.

Standards relating to clinical personnel were rated as the group of standards with the highest number of deficiencies. This was due to the lack of evidence:

- In training and competencies for physicians.
- Relating to donor and recipient informed consent.
- Of diagnosis and management of graft versus host disease, both acute and chronic.

Other clinical standards that highlighted lack of evidence were related to the administration of the preparative chemotherapy regimen and the administration of the transplanted product. The inspectors could not find evidence that two personnel had checked the identity of the recipient against the dose of the material to be infused.

There were issues with quality management standards for clinical, collection and processing. Third-party agreements/service-level agreements failed to state the responsibilities of each facility involved within the process, e.g. who was responsible for transportation of the collected cellular product either from the collection facility to processing or transportation from processing to the clinical facility. For those clinical facilities that provide shared care for donors prior to collection of cellular material, it is important that third-party agreements/service-level agreements also include the responsibilities for the administration of mobilisation products. These responsibilities should be described within the appropriate standard operating procedure/policy (SOP), and it is

important that all parties involved with the shared care have access to the SOP.

Labelling of collected products was a common issue, either non-compliance with the International Society of Blood Transfusion (ISBT128) standards for labelling or personnel failed to complete all the data fields on the label. Often the volume and name of the citrate used and start and completion time of the collection were missing.

At the time of revising this chapter, FACT-JACIE accreditation is being awarded against the 7th and 8th Edition of the FACT-JACIE Standards. Although a thorough review of common deficiencies has not been performed against these editions, it is hoped that the common deficiencies described in the above section will help as a guideline to those applying for JACIE accreditation for the first time.

1.5 JACIE: Implications on Nursing—The Nurse's Perspective

Research demonstrates that patient outcomes and donor care are improved (Anthias et al. 2016; Gratwohl et al. 2011) when treatment is delivered within a JACIE-accredited centre. Therefore, it could be assumed that the JACIE accreditation process has had implications on nursing practice. A literature search was performed (using PubMed and Google search engine with the following parameters: quality management, standard operating procedures, nurse education, JACIE accreditation and audit), but no results were found reflecting the dearth of nursing research on implications of JACIE for nursing. Therefore, in 2016 a simple survey was sent to the members of the European Group for Blood and Marrow Transplantation Nurses Group (EBMT (NG)) via email. The aim of the survey was to establish what implications the JACIE process had for nurses in their daily practice.

The survey was repeated in 2021, to establish if views of nurses working within an established JACIE framework had changed. Initially the second survey, using the "SurveyMonkey" platform, was sent to 1130 EBMT (NG) members via email. (1125 emails were delivered. 21.42% (241/1125) of members opened the survey. Only 55/241 participated in the survey.) To improve the response rate of 4.9% (55/1125) the survey was then included on the EBMT web site, social media accounts such as Twitter and the September 2021 EBMT Newsletter, using the same email addresses, and the deadline for completion was extended.

1.6 Results

In the original survey a total of 322 EBMT (NG) members were contacted via email with a response rate of 9.62% (31 replies) from 12 countries. One reply was rejected due to the transplant centre not working towards JACIE accreditation, therefore 30 replies from 11 countries were evaluated. The response rate for the second survey after extending the deadline (see Sect. 1.5) allowed the authors to review 70 responder's comments. A response rate of 6.2% (70/1125).

The role, seniority and the involvement of the nurse, in the JACIE process, could have an influence on how each respondent responded.

In both surveys the majority of the respondents were classified as senior nurses (97% in the first survey compared with 94% in the second survey):

First survey 2016	Position	Second survey 2021
7	Ward Managers	5
14[a]	Clinical Nurse Specialists (CNS)	31
5	Quality Managers	8
3	Nurse Coordinators	Not mentioned
1	Junior Nurse	3
0	Did not complete 23	

[a] One CNS role includes data manager and one CNS is responsible for JACIE

In the first survey there was one nurse consultant responsible for SOPs in clinical and processing facility.

The majority of nurses, in both surveys, worked within the clinical area 93.3% (28/30),[1] and 95% (48/51) in the second survey (Nineteen nurses in the second survey declined to respond to this question—maybe they saw their role as managerial).

The apheresis facility was represented by 3.3% (1/30) and 5% (3/51) in the second survey.

The processing facility was represented in the first survey only, by 3.3% (1/30).

1.6.1 Does the JACIE Process Have any Implications for Nurses?

Although both surveys showed an overwhelming response 90% (27/30) and 77% (41/53—17 nurses declined to reply to this question) that the JACIE process has implications for nurses on their daily working practice. This means 10% (3/30) and 22.6% (12/53) of nurses thought JACIE had no implications on their daily working practice. It is difficult for the authors to argue that this is based on European nurses' experience due to the poor response rate in both surveys.

1.6.2 Conclusion of the Surveys

Although there was a very low response to the surveys (9.62% and 6.2%), the results represent the views of senior nurses (97% and 94% respectively).

After reviewing the 45[2] comments from the 30 respondents from the initial survey, the authors would like to suggest that the JACIE accreditation process has had a positive impact on nurses. Only 9% of comments could be classified as having a negative impact on the nurse due to extra workload.

The second survey revealed that 37% (14/38) of the responders work within a centre that had achieved JACIE Accreditation for a fourth time. Only 4 of the 70 responders had participated in both surveys: one responder agreed her/his view of the JACIE accreditation process having implications upon nurses had changed. (Unfortunately no comment was made to explain the change in opinion.) From the 25 comments reviewed from the 70 responders the authors would like to suggest that only 20% of comments relate to improvements within the quality management system giving raise to improved patient and donor care.

Therefore, it is suggested that a further in depth study is required within the BMT nursing community to fully understand the implications for nurses between the initial JACIE and re-accreditation phases whilst maintaining and improving the quality system that is now, or should be, embedded into daily practice. The study could be based on the Donabedian model looking at structure, process and outcomes.

The JACIE Standards are reviewed every 4 years, allowing them to be adapted to the rapidly developing field of HSCT. For example the recent editions of the standards have specifically identified standards relating to Immune Effector Cells. Of these 69 standards there are only 2 standards that directly involve the nurse and this is for specific nurse training involved with caring for those patients receiving Immune Effect Cells. (Please see relevant chapter relating to Immune Effector cells) Nurses are required to maintain compliance with the QMS and JACIE Standards and must familiarise themselves with the changes that occur in each edition of the JACIE Standards. Each edition will present fresh challenges to achieve the standards especially given the present day competing pressures on resource and finance. It is noteworthy that none of the surveyed nurses mentioned this aspect as a concern for nurses in their practice. As nurses working within FACT-JACIE-accredited centres, it is important to provide evidence of our continued monitoring of practice and processes through the QMS and not regard the JACIE accreditation process as a tick box exercise.

[1] Two clinical nurses worked in a second area (one in apheresis and one in processing facility).

[2] See Appendix for a full list of citations written by the respondents to both surveys.

1.7 Discussion Points

1. As stated earlier, the majority of responders in both surveys are classed as "senior nurses". Should we be asking ourselves is there a reason why "junior nurses", within the specialty, did not get involved with the surveys? Could it be the opportunity for junior nurses to become engaged with the EBMT (NG) and/or with the JACIE Accreditation process is rare due to the criteria for EBMT centre membership (www.ebmt.org/membership).

   Criteria of EBMT centre membership (2022)

   (a) Full Centre Membership Fees in 2022 were €900 per year, and include a team of 3 physicians (including the Principal Investigator), **1 Principal Nurse**, 1 Data manager, 1 Quality manager, 1 Lab technician, 1 Pharmacist and 1 Transplant coordinator per centre. The principle nurse, included in the centre membership is probably a senior nurse within the team.

   (b) Extra nurse members can be included within the centre membership at an extra fee €40 per year.

   (c) An individual membership can be applied for. The applicant must hold a PhD, nursing degree or any other relevant degree to be assessed on a case-by-case basis and demonstrate an expertise in stem cell transplantation, cellular therapy or other relevant fields. This should be proven by 2 years working experience in activities related to the aims of EBMT. Two EBMT members should support the application.

2. The other interesting observation in the results of the second survey is how many responders did not complete all ten questions,, within the survey, especially the following question: *"Describe briefly how the JACIE process has had implications/affected your daily practice"*.

   An amazing 57% (40/70) of responders did not respond to this question. Without performing another survey to these responders we can only surmise why they did not respond. Could it be that senior nurses (maybe more than we think) do not understand the aim of the JACIE Accreditation process or is it they are not fully involved with the JACIE accreditation process?

   The senior nurses who did respond to this question, focussed their comments on how their work was now focussed on following protocols, rather than focussing on the overall quality improvement the JACIE process was having, or maybe not, on their transplant program, patients and donor care.

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   The senior nurses who did respond to this question, focussed their comments on how their work was now focussed on following protocols, rather than focussing on the overall quality improvement the JACIE process was having, or maybe not, on their transplant program, patients and donor care.

   The majority of respondents 95% (38/40), to the question we are discussing, were not involved with the original survey in 2016. Does this tell us something regarding the turnover of staff within the speciality or does it suggest the responders were too junior during the first survey to respond and are now employed in a more senior role, finding themselves involved with EBMT (NG) and hopefully the JACIE process. If so, does this reflect there is only JACIE awareness in senior nursing staff (CNS/Ward managers) and not at ward level.

3. The low response rate and the survey results, to both surveys, may suggest nurses do not think the JACIE process is relevant to their daily practice or nurses think the aim of JACIE is to follow standard operating procedures rather than developing and addressing quality issues. If either, or both, of these suggestions

are correct the EBMT (NG) and JACIE may have to consider improving education, training and developing nursing based evidence for JACIE to allow nurses to fully understand the aims of the JACI process.

Since the introduction of JACIE accreditation, nurses have submitted oral and poster presentations at the annual EBMT (NG) conference on the topic "Preparing for JACIE". The small response to our EBMT (NG) surveys and a literature search that could not identify published articles on the topic of "JACIE and implications for nurses" could suggest the JACIE accreditation process has not impacted greatly on nurses.

One of the five Deming principles (Health Catalyst 2014) that help health-care process improvements:

> *Quality improvement is a science of process management. If you cannot measure it you cannot prove it, therefore quality improvement must be data driven.*

As specialised nurses, working in the field of HSCT, we should be asking ourselves why are we not publishing our data or audit findings. Using the development of the apheresis collection services across Europe as an example, many teams will be nurse led. When the collection of HSCs became an established practice, the number of nursing teams increased, training became more formalised and apheresis nurse forums were established to try and reinforce policies and procedures. A QMS was introduced in the form of JACIE accreditation with risk management and audit became integral to the apheresis nurse role.

Deming also states: "If nurses are going to manage care, they require the right data delivered in the right format at the right time and in the right place". Therefore, nurses with the HSCT programme should take ownership, perform audits, assess the results, make changes to patient care and reassess. These experiences and findings should be shared and published.

If the reluctance to publish is a lack of ownership of quality management, or nurses perceive quality management as the responsibility of the quality manager, then they must be reminded that JACIE has a significant impact upon each and every role and that they must be aware and fully participate in the process. Audit, review of policies and procedures, competencies and risk assessment will become a key part of the nursing routine for the QMS to be maintained and to evolve.

Acknowledgements The authors would like to thank the JACIE Office for the use of materials, Tuula Rintala (whom during the initial revision of this chapter held the following positions: Collection and Quality Management Nurse JACIE Inspector, Chairperson JACIE Inspectors Committee and member of the JACIE Accreditation Committee and at a later stage held the position of Quality of Care and Advocacy for JACIE) and Eoin McGarth (whom during the initial revision of the chapter held the position of Advocacy and Quality of Care Director for JACIE) for their help and advice.

Appendix: Citations Classified in the Role of the Nurse (Survey 2016)

1. Staff nurse/junior nurse: citation classed as positive (only one citation)
   (a) As nurses, we have checked procedures to enable the team to demonstrate our work on education and patient care.
2. Ward manager's citations
   Citations classed as positive:
   (a) Improved structure to create procedures.
   (b) A more uniformed way of working.
   (c) (Almost) everything we do is now described in the policies, and everybody performs the procedure the same way, which is better for the patient.
   (d) Communication processes have improved between the different professionals (e.g. nurses, physicians) improving the way we are working together.
   (e) We now have the knowledge to implement the method and the instruments of risk management.
   (f) There have been improvements on patient care, central venous catheter management, team work and communication and safety of the patients.

(g) A tool that can be used to helped introduce new staff to the daily routine of transplant care.

Citations classed as neither negative nor positive:

(a) Started to use many procedures.
(b) We regularly update the quality documentation.
(c) Description of working processes.
(d) It's an Issue of quality management.

3. Clinical nurse specialist's citations

Citations classed as positive:

(a) Now we are JACIE accredited and working within an established programme, it was well worth it and, we feel confident about our quality standards and programme.
(b) Quality is always a priority in every aspect of the transplant process.
(c) Maintain patient records more accurately.
(d) We have started the donor care programme according the JACIE.

Citations classed as neither negative nor positive

(a) Preparation of QMS and developing SOPs × four citations.
(b) Increased number of protocols and procedures to follow and manage, requiring additional management hours to administrate.
(c) We had to prepare and update all SOP documents from the nursing field.
(d) As a centre preparing for our first accreditation, we are preparing documents, SOP and the nurses' education programme.
(e) Perhaps not implications, many checklists and SOPs have been revised or developed which has developed our work.
(f) I personally worked on the SOPs and routines in HSCT.
(g) I was required to present results at the clinical audit meetings and answer questions.

Citations classed as negative:

(a) Initially the documentation and developing the programme took many years and was hard work
(b) As our quality manager is from a laboratory background, I had to incorporate clinical quality lead into my CNS role, and this has added to my workload.
(c) Finding time for many meetings related to quality and JACIE was difficult due to other demands.
(d) Unfortunately no impact on daily practice.

4. Quality manager's citations

Citations classed as positive:

(a) There is a greater awareness of the routines.
(b) An improved structure.
(c) Patient safety is highlighted
(d) All nurses are working in a more quality assured way, by only using adequate and current documents and working procedures.
(e) The internal audits, which we have performed for several years, whilst working with JACIE, have led to improvements in quality assurance.
(f) Before JACIE accreditation, we actually did not have strict medical SOPs for treatment of our paediatric transplant patients.
(g) Since first accreditation as a separate paediatric centre, we have broadened our cooperation with the adult clinic, apheresis and stem cell lab. Since then SOPs are more in common. "Nurses are now involved and appreciate being involved in the review meeting for patient outcome".

Citations classed as neither negative nor positive:

(a) More SOPs to write
(b) Increased audits
(c) Working with documents and internal audits
(d) Updating SOPS, ensuring staff, including the multidisciplinary team, understand the importance of following the SOP

5. Nurse coordinator's and nurse consultant's citations

Citations classed as positive:

(a) Separate donor and recipient management.

(b) JACIE is a good working tool, especially for new colleagues.

Citations classed as neither negative nor positive:

(a) More attention in the control of the working activities.
(b) More attention in the registration of processes.
(c) More attention in the nurse training and evaluation of competency.
(d) My mission is to work for the HSCT programme of quality programme improvement process as required by the accreditation body JACIE.

6. Citations from the second survey 2021. (Not grouped into role of the nurse)
   (a) Raised awareness of quality and governance. Understanding a structured approach to assessing performance
   (b) It is a guide for my daily practice
   (c) All staff far more aware of Quality Improvement
   (d) Improved documentation and recording of competencies
   (e) Awareness Quality education
   (f) Improved patient care
   (g) Improves many practices
   (h) Following guidelines
   (i) Controlling all existing documents concerning care treatments in stem cell program
   (j) Protocols, corrective actions, quality control and patient satisfaction
   (k) JACIE processes need more carefulness than some other assistance processes
   (l) Guidelines in what to do and screen in follow-up
   (m) We review our daily activity to confirm that it is within JACIE standards
   (n) It has implications from a workload perspective and also ensures standards are regulated.
   (o) Has allowed me to improve the way I organise my daily work schedule
   (p) Increased quality of care, integration of EBP, harmonization of care, learning activity for new collections via SOPs
   (q) The accreditation process requires a vast amount of work, which is jointly completed and kept up to date by the core quality team. I have weekly meetings with the QM and Lead Consultant to ensure standards are maintained, updates and recommendations are reviewed.
   (r) Not applicable
   (s) We work better because we follow the JACIE standards of working
   (t) Organised activities, SOPs, continuous educational programmes
   (u) Protocols exist to increase the safety and quality of patient care
   (v) SOPs must comply with JACIE
   (w) Working mainly on quality. The staff members are more quality oriented. Quality is part of everything we do.
   (x) SOPs based on scientific evidence, awareness of incidents and areas of improvement
   (y) Better procedures and guidelines
   (z) Very quality driven.
   (aa) Use of SOPs/document controlled forms/training records
   (bb) Need to ensure competencies etc. up to date
   (cc) We are toward the first accreditation so we try to train nurses and work following the Standard
   (dd) All areas are regularly accredited and with internal audits prepared

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Further Reading

Benchmarking: https://www.nature.com/articles/s41409-019-0718-7.

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