Chapter 14

The Accreditation Process

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The complexity of haematopoietic cell transplantation (HCT) as a medical technology and the frequent need for close interaction and interdependence between different services, teams and external providers (donor registries, typing laboratories, etc.) distinguish it from many other medical fields [3]. At around the turn of the millennium, recognition of these challenges led to efforts by the HCT community to standardize processes based on consensus to better manage quality, including the inherent risks of HCT [2]. Ever since, HCT has continued to be a pioneer in setting agreed clinical quality standards [5, 8] and subsequent external inspection and certification via the process of accreditation (via JACIE). An accredited programme can therefore demonstrate that it is performing at a required level of practice in accordance with agreed standards of excellence, including operating an effective quality management system (QMS). Such a hallmark of quality provides reassurance to healthcare professionals, health service payers and, most importantly, patients and their families.

The accreditation process is divided into three phases. The first phase is a pre-inspection phase where the applicant submits the relevant documentation and the inspectors review it in advance of the inspection. The second phase is an inspection phase, where the inspectors assess on-site if the documentation from the pre-inspection phase meets the reality of the day-to-day work in the centre through interviews with key personnel, tour of the facilities and review of additional documentation. Inspectors document findings and observations in the inspection report which is reviewed by the accreditation committee which decides on the next steps

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for the centre to achieve the accreditation. The third phase is a post-inspection phase, where the applicant submits evidence of corrections for the deficiencies identified in the report. The programme achieves compliance once the inspectors assess the evidence of corrections, the standards are compliant and the accreditation committee gives the approval. After achieving the accreditation, the main challenge for the programme is to maintain all the aspects, including the QMS, making it more robust and adhering to the new editions of the FACT-JACIE standards and manual.

Why Seek Accreditation?

Accreditation is the means by which a centre can demonstrate that it is performing a required level of practice in accordance with agreed standards of excellence and certify that it operates an effective QMS.

A quality management system is a mechanism to ensure that procedures are being carried out in line with agreed standards with full participation by all staff members. In an HCT programme, this ensures that the clinical, collection and laboratory units are all working together to archive excellent communication, effective common work practices and reassurance for patients. It is a means of rapidly identifying errors or accidents and resolving them so that the possibility of repetition of the problem is minimized. It assists in training and clearly identifies the roles and the responsibilities of all the staff.

Once the required level of quality has been achieved through modifications to practice, the remaining challenge is to maintain this standard of practice. With a working quality management system in place and adequate resources, the fundamental elements necessary to sustain the programme are continued staff commitment and vigilance.

Initial evidence of a positive relationship between the implementation of a QMS and an outcome of HCT in Europe was published in 2011 [6]. In this paper, patients' outcomes were systematically better when the HCT centre was at a more advanced phase of JACIE accreditation and independent of year of transplantation and other risk factors. Another analysis [7] was performed on a large cohort of patients who received either an allogeneic or an autologous HCT between 1996 and 2006 and reported to the EBMT database. The authors showed that the decrease of overall mortality in allogeneic HCT procedures over the 14-year observation period was significantly faster in JACIE-accredited centres, thus resulting in a higher relapse-free survival and overall survival at 72 months from transplant. Such improvement was not shown in autologous transplantation. Similar results published in an American study [10] showed that centres accredited by both FACT and Clinical Trial Network (CTN) demonstrated significantly better results for more complex HSCT such as HLA-mismatched transplants. These data reinforce the concept that clinical improvement is driven by the implementation of a quality management system embedded in external accreditation standards, especially in the context of more complex procedures. This process also results in a wider standardization of

procedures across different countries and geographic areas, thereby contributing to providing patients with similar treatment expectations even when accessing different health management systems. A comprehensive review summarized these developments [13]. Other studies have assessed the impact of accreditation on quality and organizational aspects of transplantation programmes [1, 4, 11].

Where to Start?

Before starting with accreditation process, the HCT programme needs to be formally recognized by the institutional authorities and by competent authorities if needed. This is an important step to be entitled to assign duties and responsibilities to the key persons of the HCT programme.

The accreditation process starts with a centre's aspiration to achieve certification and subsequent plan (see Fig. 14.1).

Planning The first step is preparing a timetable (see Table 14.1) triggered on the goal to reach JACIE accreditation. The introduction of JACIE standards is embedded in an accompanying quality management system, the type of which is at the discretion of the single HCT programme [14].

Implementation of an action plan and its monitoring The second step is the preparation of an action plan detailing all the operative activities, their timeframe, the key persons, and responsibilities involved and the final objectives to be reached. Where there is a QMS already implemented by the hosting institution, the preparation of the plan of action for achieving accreditation should be organized in close collaboration with the quality office of the institution.

Fig. 14.1 Aspects to consider prior to starting the accreditation process

Table 14.1 Timetable

Time	Activity	Responsibility	Indicators
Before starting accreditation process	Formalization of the transplant programme	HCT programme director(s) Hospital Management	Formal institution of the HCT programme and leadership assignment
1–2 months	Preparation of the action plan	HCT programme director(s) Quality officers Working groups	Analysis of activities and processes in the light of JACIE requirements Meeting minutes of the working groups (clinical, collection and processing facilities) Finalized action plan for JACIE accreditation
12–18 months	Implementation of the action plan and its monitoring	Quality officers Working groups	Meeting minutes of the working groups Writing of the quality system documentation Staff education Audits for monitoring action plan implementation Action plan adjustments if needed
1–2 months	JACIE application	Hospital director HCT programme directors Quality officers	Upload of checklist, application form and requested documentation
3–5 months	JACIE inspection & report	HCT programme team and hospital key persons JACIE inspectors	JACIE report and checklist post inspection
3–9 months	CAPA plan post-inspection	Quality officers Working groups	Analysis of JACIE report and inspectors' checklist post inspection CAPA implementation Upload of checklist with CAPA evidences
1 month	JACIE accreditation	JACIE accreditation committee	HCT programme accreditation award

The analysis of the HCT programme processes and activities and the organization of the QMS documentation already available are the starting points to prepare a good action plan. The analytical comparison between the documentation already present and requirements of the FACT-JACIE standards enables evaluation of how much commitment must be expected in terms of personnel and working time to complete the preparation of documentation required by FACT-JACIE standards.

The action plan must also include education on FACT-JACIE standards of HCT programme staff, possibly before starting with document preparation, to enable personnel to work on documentation and on the accreditation process (awareness and competence).

The action plan must be monitored during its application so that it can be corrected and amended if necessary (action plan adjustments). The monitoring can be carried out through regular and routine meetings of people responsible of the different working groups and/or through focussed audits (on quality system documentation or on processes).

Phases of the Accreditation Process

Accreditation is the means by which a centre can demonstrate that it is performing a required level of practice in accordance with agreed standards of excellence and certify that it operates an effective QMS. According to the International Society for Quality in Healthcare, accreditation is a process “in which trained external peer reviewers evaluate a health care organization’s compliance with pre-established performance standards ... Unlike licensure, accreditation focuses on continuous improvement strategies and achievement of optimal quality standards, rather than adherence to minimal standards intended to assure public safety” [12].

Programmes interested in achieving accreditation for hematopoietic cellular therapy product collection, processing and administration can contact relevant accreditation organizations, including the following:

- JACIE: www.ebmt.org/jacie-accreditation
- FACT: <http://www.factwebsite.org/>
- AABB: www.aabb.org

Although each accreditation organization has its own accreditation process and specifications, the following sections provide a general description of the different phases that the applicants are subject to. The accreditation process is divided into three main phases: pre-inspection, inspection and post-inspection.

Pre-inspection Phase

HCT programmes seeking accreditation are encouraged to start the accreditation process with the accreditation organization of their choice once their QMS has been in place at least for a year and there is sufficient evidence to prove compliance with the FACT-JACIE standards.

Out of the three phases of the accreditation process, the pre-inspection phase is a phase that often requires more efforts for all the involved parties: applicant and inspectors. The pre-inspection process starts when applicant submits the corresponding documentation to the accreditation organization for review and approval.

Following are the documents that are to be provided during the pre-inspection phase.

Application Form

Key information about the HCT programme seeking accreditation should be provided, including the following:

- General information: Name of the programme, contact details and invoicing information.
- Scope: Standards cover the entire HCT process, starting from the selection of the donor/patient to collection, processing, storage, and subsequent infusion and follow-up. Thus, programmes are encouraged to apply for the accreditation as a full programme, which includes the clinical unit (adult and/or paediatric), the administration of immune effector cells (IEC), the bone marrow and/or apheresis collection unit and the processing unit. However, stand-alone applications are accepted for processing units, for clinical units that work with accredited collection and processing units or for collection units that work with accredited processing units.
- Structure of the programme: Key personnel of each unit, organization of the HCT programme and distance among the units.
- Activity: Standards establish minimum activity numbers for the clinical and collection units.

The information provided by the HCT programme in the application form enables the accreditation organization to determine the eligibility for the accreditation process.

Self-Assessment Standards Checklist

Applicants need to self-assess their compliance with every one of the standards indicating if they comply or not with it and referencing supporting documentation as a proof of compliance. The information provided by the programme in the self-assessment checklist enables the applicant, the accreditation organization and the inspectors to determine the readiness of the centre for the accreditation process.

Once the application form and self-assessment checklist are reviewed and approved by the accreditation organization, the applicant provides an established set of pre-inspection documents.

Pre-inspection Documentation

This consists of selection of documents that the applicant needs to submit prior to the on-site inspection. This documentation allows the inspectors to understand the centre's activity, organization and to check compliance with some of the standards before the on-site visit. Depending on the accreditation organization (and subject to the language capabilities of the inspectors), the documentation can be submitted in

the language of the centre or only in English. Following are examples of the key documentation requested:

- Selection of key SOPs
- Evidence of staff training and qualifications records of key personnel
- Facility licences and authorizations
- Quality management plan (QMP), interchangeably referred to as the Quality Manual or Quality Handbook
- Documented evidence that the QMS is functioning
- Consent forms and related information
- Sample labels
- Plans or maps of the centre
- Sample agreements with third-party service providers

Examples of pre-audit documentation can be found at <https://www.ebmt.org/jacie-document-quicklist>.

Support prior to submitting the forms is available from the accreditation organization, i.e. the JACIE office. Once the application is submitted to the accreditation organization, each HCT programme is assigned to an accreditation coordinator to help and guide through the process. Also, the accreditation organizations have supporting guides to accompany centres during the process.

Completing the application form, self-assessment checklist and pre-audit documentation thoroughly and accurately leads to a more efficient on-site inspection.

During the pre-inspection phase, applicants will be requested to sign an accreditation agreement with the accreditation organization and will be invoiced with the corresponding accreditation fees.

Once all the pre-inspection information is submitted, the accreditation organization starts to assemble the inspection team for the on-site inspection. Each accreditation organization has their own pool of inspectors who are volunteers and experts in one or more of the areas covered by the FACT-JACIE standards. Inspection teams consist of at least one inspector per area to be inspected: clinical, collection and processing, one of whom is also a team leader. For example, if the applicant applies for adult clinical, collection (bone marrow and apheresis) and processing accreditation, the inspection team will consist of the following: a clinical inspector, an apheresis inspector and a processing inspector. Each inspector is responsible for assessing the standards under their area of expertise and it is the clinical inspector who is usually responsible for the marrow collection facilities. Some accreditation organizations also include a quality manager specialized inspector. When a quality manager inspector is included, they are responsible for assessing the QMS in relation to the quality-related standards in the HCT programme. During this process, both applicant and inspectors need to communicate to the accreditation organization any conflict of interest to exclude those inspectors from the inspection team. Furthermore, one of the inspectors also has the additional role of being the team leader. The responsibilities of the team leader include to provide a general overview of the interactions between the units of the programme and to become the main point of contact (among the inspectors, with the applicant and with the accreditation organization).

As soon as the inspection team is confirmed:

- Inspectors receive all the pre-audit information of the programme so that they can review and assess it prior to the inspection. During the review time, inspectors can ask for additional information and have a pre-inspection team meeting to share their preliminary assessment.
- Both applicants and inspectors start working on the inspection's agenda and the logistics of the inspection, which mainly revolves around the travel/accommodation arrangements.

Inspection Phase

The inspection phase is the most visible part of the accreditation process. Inspectors will travel to the HCT programme to verify that the information provided during the pre-inspection phase corresponds to the way they work and that it meets the requirements of the FACT-JACIE standards. The inspection is a thorough peer-reviewed examination of the aspects of the HCT programme and/or its component parts.

Inspections are conducted in the language of the centre or in English depending on the accreditation organization.

The on-site inspection consists of 1 or 2 days of inspection and comprises the following items:

- Opening meeting: This meeting is the opportunity for the applicant to present their programme and for the inspectors to introduce themselves, explain the purpose of the inspection and set a collaborative atmosphere for the inspection. It is attended by the personnel of the HCT programme.
- Review of documentation: Even though inspectors review documents from the HCT programme during the pre-inspection phase, at the time of the inspection, they dedicate a necessary amount of time to this task, looking for evidence of compliance with FACT-JACIE standards.
- Tour of the different units seeking accreditation: It allows inspectors not only to see the facilities but also to interact with the personnel working to better understand how they work on a day-to-day basis.
- Observation of a clinical/collection/processing procedure or a mock procedure: Specific observations of the procedures help inspectors to understand the process and traceability of the product.
- Interview with key personnel: It allows both applicant and inspectors to exchange key information for the accreditation. The purpose of the interview is not to assess the performance of the personnel, but it is to assess the compliance of the HCT programme with the FACT-JACIE standards.
- Closing meeting with the programme director followed by a meeting with all the programmes to highlight the observations and findings of the inspection: The

inspection team and the programme director will discuss any sensitive issues identified. Afterwards, the inspection team meets with all the personnel involved in the on-site inspection to explain the main findings and observations from each of the units inspected. The team leader takes the opportunity to explain the next steps in the process and highlights that inspectors write the report based on their observations, but it is the accreditation committee that makes a judgement on the compliance of the centre with the standards. This closing meeting helps applicants to manage the expectations about the inspection report.

After the on-site inspection, inspectors write the inspection report (see Fig. 14.2) identifying which standards are compliant and which ones need further adjustments. The inspection report is provided by the inspectors to the accreditation organization for review and it is presented to the accreditation committee (see Fig. 17.5) to decide the next steps for the HCT programme to achieve the accreditation. Once the report is finalized with the observations from the inspectors and the committee, it is provided to the applicant so that they can continue working towards achieving the certification for accreditation. The report is a fundamental part of the accreditation process.

The possible results of the accreditation report are as follows:

- All standards are compliant – In the rare case that a centre applying for accreditation complies with all the standards at the time of the inspection, the applicant will receive the accreditation without going through the post-inspection phase.
- Some standards are not compliant – The great majority of the reports reveal deficiencies and the centre needs to continue working to achieve compliance with all the standards during the post-inspection phase.

Fig. 14.2 Report pathway

Post-inspection Phase

Once the applicant receives the inspection report, they can start working correcting the deficiencies, implementing the corrective actions, and generating the supporting evidence. The degree of deficiencies identified will vary in seriousness. In most cases, it will be sufficient to provide documentary-based evidence, while in other cases, for example when the QMS is immature or facility structures are not adequate, a focussed reinspection will be necessary. Whether the centre submits documentary evidences or is subject to a focussed inspection, the same inspection team that participated in the inspection phase will assess the adequacy of the corrections. When those are assessed as compliant by the inspectors and are approved by the accreditation committee, the applicant is awarded with accreditation.

Some accreditation organizations are assessing how to offer a stepwise accreditation programme for programmes in low-to-middle income countries (LMICs). The main concept is to help centres to achieve full accreditation in different stages, which makes the accreditation goal more reachable. Programmes subject to the stepwise process must achieve the same level of compliance as programmes going through the full accreditation process, but they can do it more gradually over a longer period. This stepwise programme would allow LMIC to connect with an international network focussed on quality in HSCT and could also serve to stimulate local authorities to support accreditation in the interest of patients and donors.

Plan the Post-accreditation Period

Maintaining JACIE accreditation is probably as challenging as being awarded it first time. JACIE standards are not something that should be forgotten about until getting ready for the next accreditation cycle. The effort in the post-accreditation period is to maintain an up-to-date QMS, making the FACT-JACIE standards a part of the everyday life of the HCT programme.

Any system, without maintenance, is destined to deteriorate, including adherence to key aspects such as the QMS that depend on the possibility of changes in many aspects in the internal institutional and external health care systems. The continuous improvement of the QMS is not a simple update of the documented information over time but also means maintaining all elements and ensuring implementation on everyday working practices.

- *Documentation* including SOPs should continue to be updated and developed.
- *Audits* should continue to be planned and carried out.
- *Information* about JACIE developments should continue to circulate among the team.
- *Regular meetings* on the run up to the next inspection should continue.

- *Continuous education* of HCT programme staff should be planned and guaranteed to maintain competent personnel over time who are able to operate on programme processes.
- *Monitoring* the HCT programme activities and processes through suitable and relevant indicators (key performance data and outcome analysis) should be planned and performed at least annually.

Prompt and accurate *collection of occurrences* (this term refers to errors, accidents, deviations, adverse events, adverse reactions and complaints deviations) should be maintained and the need for CAPA plan should be investigated.

If you do not continue to develop and maintain JACIE, most of the hard work in achieving accreditation will become redundant and you will find yourself back at the beginning when applying for reaccreditation.

Key Agents

This peer-reviewed accreditation process is possible, thanks to volunteer professionals in the field of HSCT, who devote their valuable time and expertise to contribute, promote and implement quality in the transplant community: inspectors, accreditation committee members and cellular therapy standards committee.

Inspectors

Inspectors are involved in the three phases of the accreditation process (see Fig. 14.3); thus, they dedicate their efforts and knowledge to learn about the applicant and visit their programme to assess their compliance with the standards. As

Fig. 14.3 Accreditation process flow, documentation and key agents

previously mentioned, they are the eyes and ears of the accreditation committee and include all their findings in the inspection report. Inspectors are also involved in the review of the evidence of corrections during the post-inspection process, and thus they follow the progress of the programme from the application until they achieve certification of accreditation.

The entire process is usually performed in a collegial and positive atmosphere and is often a learning and rewarding experience for both inspectors and applicants. In addition, inspectors benefit from meeting and collaborating with colleagues while helping to implement and promote quality in the transplant community [9]. Accreditation organizations might offer specific benefits to their volunteer inspectors, such as discount in the application fees of the inspector's centre or educational events.

Professionals from HCT field interested in becoming inspectors should contact the accreditation organization to learn more about the requirements. Inspector requirements are based on professional experience, completion of an inspector training course and associated exam. Before becoming an inspector, candidates must participate in the observation of an inspection.

Accreditation Committee Members

Accreditation committee members are the main source of expert opinion and peer review. Membership is formed by experienced inspectors from all the areas, clinical, collection and processing, and some accreditation organizations also include quality managers members. The accreditation committee members meet regularly to discuss the inspection reports, determine the next steps for the centres to achieve compliance and decide on the accreditation of the centres.

Cellular Therapy Standards Committee Members

Members of the cellular therapy standards committee oversee establishing, maintaining and reviewing the standards. Members are usually experienced inspectors and members of the accreditation committee.

Standards are reviewed periodically and are subject to a public consultation process before the publication of the final version.

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