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Review

Worldwide Network for Blood and Marrow Transplantation Special Article on Key Elements in Quality and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy

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A B S T R A C T

Hematopoietic stem cell transplantation (HSCT) represents an example of a highly complex and costly medical procedure with major applications in hematology and oncology. It is associated with life-threatening complications and, consequently, increased demands on healthcare resources. Although improving quality is an integral component of healthcare strategic planning, drivers of quality may be variable, and there is logical debate as to what drives quality in HSCT. Moreover, HSCT programs differ in structure and availability of resources, which drive the type of transplantations provided and determine what is affordable and/or economically feasible. The complexity of HSCT procedures with involvement of different stakeholders necessitates not only regulatory frameworks, but also robust quality systems to ensure consistent standards, demonstrate transparency for regulators, and define what quality means within the HSCT program. In an era of escalating healthcare complexity and heightened fiscal responsibility, transparency and accountability, accreditation contributes to ensuring that care

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meets the highest standards and can serve as a risk mitigation strategy. Quality management has become an indispensable tool for the management of a complex medical intervention such as HSCT. It allows the transplantation team to monitor its activities and identify areas for continuous improvement. The Worldwide Network for Blood and Marrow Transplantation invited a group of international experts in HSCT and quality management to work on providing a summary document about the key elements in quality and accreditation in HSCT and highlight the foremost challenges of implementing them, with a special focus on low- and middle-income economies.

INTRODUCTION

The constant desire for optimal quality in healthcare is now considered an essential component of daily clinical and management operations. The World Health Organization defines quality of health care as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes" [1]. Quality itself is not a static concept; in its dynamic form, it becomes continuous improvement. Furthermore, quality assurance, concerned with compliance, should not be considered the same as quality improvement (QI), defined as the framework used to systematically improve care delivered to patients [2,3]. Improving healthcare quality by refining structures and processes will ensure safety, enhance efficiency, and improve patient outcomes [4]. In an era of escalating healthcare complexity and heightened fiscal responsibility, transparency, and accountability, accreditation contributes to ensuring that care meets the highest standards and can serve as a risk mitigation strategy as well as a management tool for identifying strengths and areas for improvement.

Hematopoietic stem cell transplantation (HSCT) represents an example of a highly sophisticated and costly medical procedure with major applications in hematology and oncology. It is performed in a challenging environment and is designed to treat adult and pediatric patients with life-threatening congenital or acquired disorders. The procedure is associated with substantial morbidity and mortality and, consequently, increased demands on healthcare resources. The availability of multiple stem cell sources from family members, international unrelated bone marrow donor registries, and cord blood banks adds another unique aspect to HSCT that necessitates not only regulatory frameworks, but also robust quality systems. Although health authorities and regulatory agencies have enforced increasingly stringent rules for inspection and accreditation of activities in the field, regulations differ from one country to another and mostly emphasize processing facilities as being ultimately responsible for the production and delivery of therapeutic progenitor cells [5–7].

In HSCT, structural data are largely those that describe characteristics of facilities and providers, process data describe the elements of treatment necessary to achieve optimal outcomes, and outcome data refer to patients' health status after intervention. This report addresses key elements of quality management (QM) and accreditation in an HSCT program [8].

PROGRAM STRUCTURE AND RESOURCES

HSCT programs differ in their structures according to transplant population, stem cell sources, indications for transplantation, and case complexities. Disease prevalences and availability of resources in different regions drive the types of interventions needed and determine what is affordable and/or economically feasible and sustainable [5]. Multiple structural and functional components must in place for HSCT to be done successfully and safely for patients and donors. Although the establishment of HSCT programs with centralized and dedicated patient care has evolved over time and with diverse models of care, program requirements are similar.

HSCT Program Structure and Quality

The main domains of a transplantation program include infrastructure, ancillary laboratory services including blood banking, ancillary clinical services, core personnel in the transplantation team, and QM. Each of these categories has different components that may vary according to a program's level of development and focus. Because allogeneic HSCT carries a significantly higher risk of morbidity and mortality compared with autologous HSCT, it requires a number of unique components to maximize safety and efficacy. The decision to start with an autologous or an allogeneic HSCT program or to expand the indications of HSCT and include cellular therapy depends on a center's experience, infrastructure, and supportive services. Selection and evaluation of candidates for HSCT or cellular therapy must be carried out according to a preestablished work plan designed by each institution; the use of standardized procedures reduces the risk of errors or omissions. Recommendations regarding choice of donor type, stem cell source, conditioning intensity and regimen, graft-versus-host disease (GVHD) prevention, and treatment of transplantation-related complications should follow the principles of evidence-based medicine and be performed under a coordinated care setup (Figure 1).

The Transplant Centre and Recipient Issues Standing Committee of the Worldwide Network for Blood and Marrow Transplantation (WBMT) developed a structured set of recommendations that guide the prioritization of minimum requirements for establishing a transplantation program and set a pathway for further expansion and development. As reported by Pasquini et al. 2020 [9], minimal requirements preferably include clinical, collection, and stem cell processing facilities that are supported by blood banks and have access to an HLA typing laboratory. Other fundamental requirements include access to critical care and emergency and multispecialty consultative services. Proper leadership, a dedicated, multidisciplinary team, and support within the institution are essential for implementation of a successful HSCT program. Delineation of quality control (QC) and QI measures should be essential requirements of HSCT programs to improve outcomes. Although not part of the minimum requirements, HSCT centers should adopt QM processes at the early stages of the programs. As centers expand their services and/or perform higher-risk procedures or newer approaches (eg, immune effector cellular therapies), increasing emphasis should be placed on QM and accreditation, because these services require specially trained staff to record and oversee results in their own programs and to share data and collaborate with relevant regional and international registries. This can certainly help develop standards of practice in line with accreditation requirements and ensure the team's compliance with recognized performance standards [5,9].

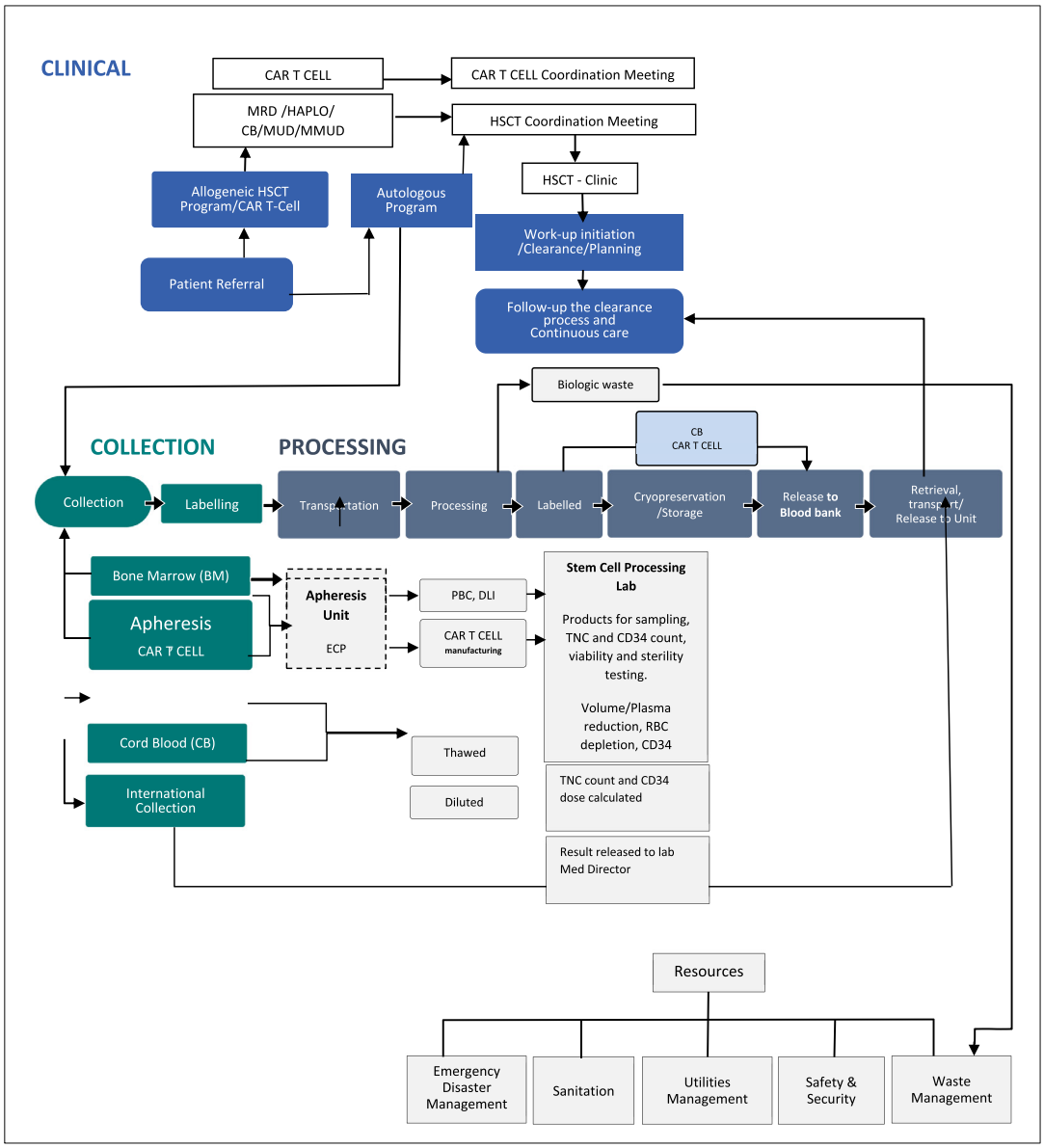

Figure 1. Example of a standard structure of an HSCT program. MRD, matched related donor; HAPLO, haploidentical; CB, cord blood; MUD, matched unrelated donor; MMUD, mismatched unrelated donor; PBC, peripheral blood collection; DLI, donor lymphocyte infusion; ECP, extracorporeal photopheresis; TNC, total nucleated cell; RBC, red blood cell.

An interesting review by Gratwohl et al. [6] in 2013 showed that the success of a program was directly correlated with country- and center-specific economy with significantly improved outcomes associated with the more affluent and fiscally strong centers. Unlike most of developed countries in Europe or North America where there are regulatory bodies such as JACIE (Joint Accreditation Committee for the International Society of Stem Cell Therapy), EBMT (European Society for Blood and Marrow Transplantation), and FACT (Foundation for the Accreditation of Cellular Therapy), in low- and middle-income economies (LMIEs), the absence of standard quality regulatory groups, lack of trained QM personnel, inadequate data management and standard operating procedures (SOPs), unavailability of blood products, transplantation-specific medications, and collection and processing laboratory infrastructures are major challenges.

The impact of more resources for the health care system in a given country and of the network infrastructure became visible only after the more complex allogeneic HSCT, with its higher non-relapse mortality over a long period. More resources are required to achieve sufficient expertise for the team and to maintain the pre-transplantation and post-transplantation networks for individual patients. This is also applicable for well-established HSCT programs even in higher-resourced countries; some programs are tackled by maintaining staff competency, accreditation standards, and cost efficiency practices and building team expertise in disease and complication management for optimal outcome and survival benchmarking.

WBMT Recommendation for Quality: Minimum Requirements and Beyond

Thoughtful and practical approaches were proposed by the WBMT to help growing HSCT programs overcome structural and other barriers and work progressively to meet the preferred quality requirements. In the earliest stages of development, the HSCT program primary focus should be on staff

competency and establishment of ongoing training for faculty and nursing staff parallel with development of SOPs that are available to the entire team. Simple growth or evolution into increasingly complex procedures will demand further structure development and planning, including consideration of data reporting and participation in collaborative or institutional-based clinical trials, all of which would require skilled clinical coordinators dedicated to research. Reporting of activities through national or international societies is also an essential part of a transplant program. Maintaining quality of an HSCT program requires additional human resources for staffing, information technology tools and error monitoring. For sustainability of a new or developing transplantation programs, the leadership, entrepreneurs (and/or venture capitalists) and governmental authorities should embrace that the importance of focusing on quality is essential given the high stakes of this tertiary care service.

One of the WBMT recommendation that should be emphasized when planning a startup program is a pairing or partnering strategy with experienced transplantation programs in other countries for continuous advice over a period of years [9,10]. It is of paramount importance for transplantation centers to identify the needed area(s) of expertise to seek appropriate pairing programs through either personal training or telemedicine. For example, more focused training would be needed for transplantation centers when implementing a new procedure (eg, cord blood or haploidentical HSCT) or expanding a new indication (eg, thalassemia). For centers with low-volume activity seeking to grow their transplantation capacity by adding hematologists or hematologist-oncologists with no experience in HSCT to their workforce, more rigorous education and training would be more desirable. In this case, large-volume transplantation centers with established training curriculums that provide broader training and exposure to the various areas, such as clinical care, stem cell processing, quality, and research are preferable choices for a twinning approach [10].

QUALITY MANAGEMENT SYSTEM

A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. In HSCT programs, a QMS helps coordinate and direct the clinical, collection, and laboratory program activities to meet patients' needs and regulatory requirements and improve effectiveness and efficiency [11]. Without a QMS, it is difficult for a transplantation program to monitor its own performance, ensure consistency of processes, identify areas for improvement, and demonstrate safe and effective operation to internal and external entities. On the other hand, scientific analyses searching for an impact of QMS on clinical outcomes remain scarce. A study reporting from 126 EBMT centers with >100,000 patients revealed that working toward implementation of a QMS triggers a dynamic process associated with a steeper reduction in mortality and significant improvement in survival after allogeneic HSCT [12,13]. A QMS should be designed to fit the actual organization of the HSCT program and the institution at large. Some HSCT programs operate within a hospital-wide QMS accredited by national or international bodies; integration of an HSCT QMS with its organization is imperative for better QC and ultimately improved outcomes. New or recently established programs are strongly encouraged to develop a QMS into their development plans at an early stage aimed at optimizing resource use and focusing on patient and donor safety. Developing a comprehensive QMS is often the most challenging and time-consuming exercise for HSCT programs, at least at the beginning because it often requires a cultural shift, especially for the clinical HSCT service owing to the involvement of many stakeholders and multidisciplinary teams in the care process. Typical HSCT-QMS components are listed in Table 1.

When implementing an HSCT-QMS for better commitment and motivation, it is essential to have a clear justification for the involved team in terms of benefits of QI, such as working patterns and facilities development, and ultimately for patients. Professional development, protection against potential legal prosecutions, and competitive advantages relative to other centers also may be drivers of culture change.

QMS and Accreditation

The adoption of a QMS as part of the accreditation process also firms up and solidifies collaboration between departments, services, and "third parties" (eg, national or regional blood services, unrelated donor collection centers and registries). Use of a QMS also may help meet legal and regulatory requirements of social and private health insurance systems and compliance with conduction of clinical trials, among others. A QMS is central to achieving JACIE or FACT accreditation, which is considered a benchmark indicator of quality by many external regulators and by manufacturers of chimeric antigen receptor T cells and other immune effector cellular therapies [11]. Consolidation of a QMS can generate significant changes in the attitude of stakeholders, as demonstrated by holding more frequent team meetings, logging incidents, and conducting frequent audits relevant to improving the quality of HSCT programs [14].

A recently reported survey of 9 Spanish JACIE-accredited centers conducted to evaluate the satisfaction of HSCT program members with their quality management plan (QMP) showed that in general, all stakeholders involved in the HSCT program considered the QMP to be rewarding and were familiarized with the implementation requirements of the program in their centers. However, the degree of collaboration and involvement in the maintenance of the QMP varied greatly among professionals. Even if it seems logical that the main burden of the tasks of QM should fall on the professionals specializing in QI, this is not sufficient to ensure that quality is ultimately attained [15]. Awareness that the workload associated with implementation of QMS cannot be fully delegated to quality managers must be strengthened. With a working QMS in place and adequate supporting resources, the additional fundamental elements necessary to sustain the program are continued broad staff commitment and surveillance.

ACCREDITATION

Unlike regulatory requirements, which are mostly governmental, accreditation is a voluntary process that indicates to the organization and the public that the program is competent

Table 1
Main Components of HSCT QMS

People and organization
Facilities, equipment, and materials
Contractual agreements
Document and recordkeeping
Product tracking and traceability
Audits and remedial actions
Validation and verification
Investigation and reporting of nonconformance, adverse events, complaints, and reactions

and credible in meeting established standards. Recent reviews evaluating the impact of accreditation programs on the quality of healthcare services have indicated that accreditation improves the process of care and overall clinical outcomes in both general and subspecialty accreditation programs [16]. HSCT is a complex and evolving medical specialty in which the transplanted stem cells are neither regulated nor manufactured as a medicinal product and that requires a multidisciplinary approach from various healthcare professionals. Thus, HSCT can serve as a model for assessing the value of QMS, defining infrastructure, equipment, eligibility for admission and discharge, responsibilities and training of staff, and required implementation of SOPs and continuous improvement strategies. In view of the above and to meet a professional responsibility to both patients and public health services, JACIE and FACT have developed an evolving set of similar standards that require an ongoing QMS [8]. JACIE was modeled on the US-based FACT, established in 1996 by the International Society for Cell and Gene Therapy and the American Society for Blood and Marrow Transplantation. In addition to providing training, educational activities, and guidelines that have been accepted in Europe, Canada, Australia, New Zealand and the US, FACT also offers a voluntary accreditation for HSCT programs and cord blood banks, with >90% of eligible US HSCT facilities and programs holding accreditation. Since its inception, JACIE has performed >760 inspections in 31 countries, representing approximately 50% of transplantation centers in the European Union. In recent years, evolving interest has been followed by successful accreditation in countries in central Europe as well as in Turkey, Saudi Arabia, Lebanon, South Africa, and Singapore. HSCT is a rapidly growing field that now involves not only blood and marrow stem cells, but also many other cellular, immune, and cytotoxic therapies and increasingly overlaps with other areas of "regenerative medicine." The FACT-JACIE standards also are evolving and are revised every 3 years; the development of each edition is based on a transparent, structured program of work involving international experts and public consultation [7,17].

Value and Challenges of Accreditation

The value of accreditation in HSCT is a talking point, given the effort and resources required to establish and maintain the required standards at each transplantation center. Whether prioritizing the investment of human resources in direct care to individual patients or in the maintenance of a QMS with indirect benefits to the patient community is a long-lasting debate across hospitals and department managers that may be fueled by the persistent shortcomings in QMS training and culture in the healthcare sector compared with other industries, such as the airline and banking industries. EBMT registry data have correlated the rollout of accreditation with improvements in patient survival and reductions in procedural mortality [12,13]. Evidence relating clinical trial participation and FACT accreditation in the United States also has indicated a generally positive impact [7,18]. Implementation of the standards and accreditation is also strongly associated with closer alignment with international consensus on recommendations for related donor care compared with nonaccredited centers [19]. Despite initial concerns that clinical quality standards and accreditation might just be a demanding paper exercise with significant costs and limited benefits [20,21], there has been relatively unimpeded adoption of JACIE standards by HSCT programs in countries with widely differing health services, regulations, laws, cultures, and languages, with data now available to support improvement in clinical outcomes, is testament to the success of this international approach (Table 2).

HSCT Accreditation in LMIEs

For many LMIEs, HSCT is prohibitively expensive and too complex, and is sometimes delivered only through private providers, with little or no access to the general population. Despite this, transplantation activity is increasing outside the high-income economies, owing in part to initiatives by the local medical community to adapt established medical practices to their own needs, including economic constraints. Therefore, it is important that QI and accreditation support the development the development of HSCT in LMIEs [5,7]. In response, JACIE developed a stepwise process based on minimum standards to certify quality assured HSCT services, particularly where they are provided to the broader population through public or not-for-profit healthcare providers [7,9]. The goal of the stepwise project is to break the same standards as applied to centers in developed countries into steps to make the process more accessible for centers with limited resources and experience. The first step focuses on patient and donor safety along with the fundamentals of quality as applied to a transplantation program while subsequent steps build on this base to achieve an active QMS.

The feasibility of this approach has been substantiated by the experience of the Latin American Bone Marrow Transplant group through strong and consistent collaboration with FACT and JACIE to develop quality programs for Latin America. These efforts culminated in the development of the FACT-JACIE International (FJI) stepwise certification program. The HSCT program at Hospital Privado Universitario de Córdoba, Argentina was recently certified under the FJI stepwise process. As reported by transplantation teams, the efforts made though the process of accreditation provide an important motivation for the teams to work in pursuit of the same goal of improving patient care and outcomes, and the certification will drive further improvements [22]. This demonstrates that achieving significant improvement in quality in HSCT can be achieved through changes in work culture and habits as by making costly investments in systems and facilities. Hopefully, the successful and inspiring story of this program will encourage other centers to become certified and expand the FJI stepwise program to other regions of the world.

Several factors are reported to influence successful implementation of hospital accreditation and drive QI [16,23], the most important of which is the reason for an institution to embark on an accreditation program. Some factors may include continuous QI, organizational development, fulfilling government regulations, advantage in market competition, public recognition, and accountability. Other factors that also may contribute to successful accreditation implementation and maintenance include available funding, leadership and stakeholder involvement, cultural acceptance, and integration of information and data.

QM AND IMPROVEMENT

QM is a holistic approach to managing quality output considering the people, processes, and products rather than independent factors with the objective of effective and efficient performance output. The concept of QM in the field of cellular therapy is relatively new compared with quality assurance and QC. The implementation of a QM program with its components including QC, quality assurance and assessment, and QI can advance the quality of service provided to patients and help stem cell and tissue banks address extrinsic threats and

Table 2
Data Supporting Clinical Benefits of FACT/JAICE Accreditation

Reference	Study Design and Objective	Results	Key Points
Gratwohl et al., 2011 [13]	Tested the hypothesis that the introduction of QMS through JACIE accreditation improved patient survival. Data on 41,623 allogeneic HSCTs (39%) and 66,281 autologous HSCTs (61%) for hematologic disorder performed (1999 and 2007) by 421 teams in Europe were used to assess the outcomes of patients who received HSCT at baseline (>3 years before application or no application), during preparation (3 years before application), during application (time from application to accreditation), and after JACIE accreditation. The analysis was clustered by team and stratified for year of HSCT, donor type, disease, conditioning, and gross national income per capita of the respective country.	Improvement was robust, as quantified for relapse-free survival after allogeneic HSCT compared with baseline by a hazard ratio (HR) of 0.96 (95% confidence interval [CI], 0.90-1.03; $P = .22$) for preparation, 0.95 (95% CI, 0.88-1.03; $P = .20$) for application, and 0.86 (95% CI, 0.78-0.95; $P = .01$) for the accreditation (test for trend, $P = .01$). Improvement from baseline was similar after autologous HSCT (HR for accreditation, 0.83; 95% CI, 0.74-0.93; $P < .01$).	Initial evidence of a positive relationship between the implementation of a QMS and outcome of HSCT in Europe. Patients' outcome was systematically better when the transplantation center was at a more advanced phase of JACIE accreditation, independent of year of transplantation and other risk factors.
Chabannon et al., 2012 [17]	Tested the hypothesis that introduction of JACIE should lead to a stepwise improvement in outcome, from baseline (3 years before application or no application), to preparation (3 years before application), to application (time from application to accreditation), to after JACIE accreditation, using EBMT registry data of 100,000 HSCTs (1999-2007) at 421 different programs.	A 14% increase in overall survival was observed for patients with chronic leukemias who underwent allogeneic HSCT in a JACIE-accredited program compared with those treated in a nonaccredited program. Improvements in overall survival and disease-free survival also were apparent in recipients of high-dose chemotherapy supported with autologous HSCT	An EBMT registry analysis suggests that clinical outcome is improved when hematopoietic SCT is performed in a JACIE accredited program
Gratwohl et al., 2014 [12]	Tested the hypothesis that working toward and achieving JACIE accreditation would accelerate improvement in outcomes over calendar time. Overall mortality of the entire cohort of 107,904 patients who underwent HSCT (41,623 allogeneic [39%], 66,281 autologous [61%]) between 1999 and 2006 decreased over the 14-year observation period by a factor of 0.63 per 10 years (HR, 0.63; 95% CI, 0.58-0.69).	Relapse-free survival (HR, 0.85; 95% CI, 0.75-0.95) and overall survival (HR, 0.86; 95% CI, 0.76-0.98) were significantly higher at 72 months for those patients who underwent HSCT in 162 JACIE-accredited centers. No significant effects were observed after autologous HSCT (HR, 1.06; 95% CI, 0.99-1.13).	Working towards implementation of a quality management system triggers a dynamic process associated with a steeper reduction in mortality over the years and a significantly improved survival after allogeneic stem cell transplantation.
Marmor et al., 2015 [18]	Retrospective review; relationship between FACT certification and survival. Using CIBMTR data (2008-2010), 3 center categories were created: non-FACT centers (24 centers), FACT-only certified centers (106 centers), and FACT and core clinical trial network (FACT/CTN) certified centers (32 centers). The cohort comprised 12,993 transplants conducted in 162 centers.	FACT/CTN centers had consistently superior results relative to non-FACT and FACT-only centers ($P < .05$), especially for more complex HSCT. However, non-FACT centers were comparable to FACT-only centers for matched related unrelated donor HSCT recipients.	Centers accredited by both FACT and the Clinical Trial Network demonstrated significantly better results for more complex HSCT.
Anthias et al., 2016 [19]	Tested the hypothesis that related donor care in FACT-JACIE accredited centers is more closely aligned with international consensus donor care recommendations than related donor care delivered in centers without accreditation. A survey of transplant program directors of EBMT member centers was conducted by the Donor Health and Safety Working Committee of the CIBMTR.	The response rate was 39% among 304 centers. Practice in accredited centers was much closer to recommended standards compared with nonaccredited centers. Specifically, a higher percentage of accredited centers used eligibility criteria to assess related donors (93% versus 78%; $P = .02$), and a lower percentage had a single physician simultaneously responsible for related donors and their recipients (14% vs 35%; $P = .008$).	Implementation of the standards and accreditation are strongly associated with closer alignment with international consensus donor care recommendations for related donors compared with centers without accreditation.
Snowden et al., 2017 [7]	Review of the evolution and current status of JACIE in relation to its international acceptance and validation as an effective means of QI with an impact on survival outcomes and future directions	Published data support positive improvements in clinical outcomes related to the accreditation process, also promoting a progressive standardization of HSCT practices across different countries. Developments in standards include standards for chimeric antigen receptor T cells and other immune effector cells, benchmarking of patient survival, and access of centers in LMIE countries to the stepwise accreditation.	The success of JACIE is an excellent example of clinical quality and accreditation systems in other specialties (need for QI acceptance by transplantation leaders, support by international societies, incorporation into national regulatory requirements). Controversial aspects, such as standardized performance benchmarking of survival outcomes and minimal center activity, can be presented as further means of QI.

CIBMTR indicates Center for International Blood and Marrow Transplantation Research.

Table 3
Important Elements of QM and QI [25–27]

QM	QI
Commitment of top management and active support of HSCT program director Formation of quality management team reporting to management Developing quality culture with awareness of goal and objective of HSCT quality program and accreditation Staff education and training (JAICE/FACT workshop, international HSCT conference) Developing and maintaining quality manual and SOPs Automation; good hospital information system Constant audits and follow-up on corrective action Risk assessment; rectification of errors and evaluation Performance measurement and key performance indicators	Service improvement: facilities, latest technology and machines, supplies, regular maintenance and standardization of equipment, implementing SOPs Process improvement: indicators, audit, risk assessment People improvement: regular staff competency checkup, circle discussions, team spirit, leadership, motivation, and rewards

intrinsic weaknesses, which could negatively affect services and products. In HSCT, different stakeholders have been identified as holding an interest in delivering top quality care: patients, referring physicians, payers, other community healthcare providers, and professional and patient organizations [24]. Given the complicated nature of QI and the numerous requirements for building and maintaining an effective, continuous QI program with sustained outcomes, it is no surprise that transplantation centers may feel overwhelmed. Sustaining successful QI in HSCT, whether the program is in early development or at an advanced stage, requires adaptive leadership, culture adjustment, and governance. Some important elements of QM and QI are summarized in Table 3. Continuous QI is a key component of a successful QM approach. The most important QI initiatives that transplantation programs can use as a metric to achieve the best outcomes include active involvement of frontline staff including nurses and physicians throughout the process. Quality outcomes should be transparent; decisions must be supported by quality research and staff, who should feel empowered to make decisions and ultimately be held accountable. Recognized barriers to successful implementation of a QM and QI include lack of or insufficient program resources, experience, inadequate financial support, and absence of leadership.

CONCLUSION

It remains challenging to define optimal quality in HSCT, but it seems evident that it is a complex management decision and a product of cooperative relationships between providers and patients in supportive environment of leadership, technology, and innovation. Our learning curve has led to significant decreases in the rates of transplantation-related morbidity and mortality over time. Although diagnostic and therapeutic innovations are essential to improve the outcomes of patients undergoing HSCT, proper application of standards of care through appropriate education and training of all involved staff and structured interactions across the different components of the program is another driver. QM has become an indispensable tool in the management of a complex medical intervention such as HSCT. It allows the transplantation team to monitor its activities and identify areas for continuous improvement. It aids communication both within the team and with external service providers and helps anticipate and respond to adverse events and facilitates implementation of process improvements needed to avoid repeated errors. The development of voluntary standards and sample processes by the professionals themselves has been the key factor driving the acceptance of these controls and keeping them relevant to day-to-day practice (Figure 2). New and recently established programs are strongly encouraged to incorporate QM into their plans at an early stage, with a focus on efficient use of resources and safe delivery of care to patients.

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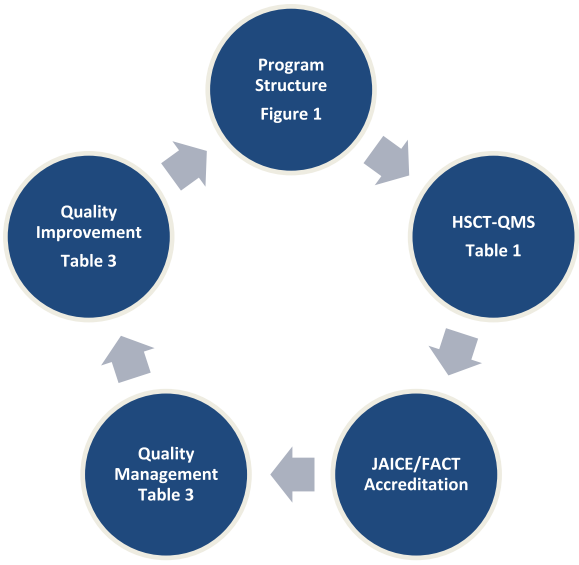

Figure 2. Key elements of quality in HSCT and cellular therapy.

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