



Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org



Defining Competency to Empower Blood and Marrow Transplant and Cellular Immunotherapy Quality Management Professionals in Healthcare

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Article history:

Received 7 March 2018

Accepted 8 August 2018

Key Words:

Quality management
Competency for quality professionals
Body of knowledge for the quality professional

A B S T R A C T

Blood and marrow transplant (BMT) programs worldwide frequently employ a quality management professional who is charged with securing quality and maintaining regulatory requirements. Although many BMT programs employ an individual to oversee quality management, there are no standard definitions of the education, training, and core competencies needed to successfully perform this role. The goal of this article is to propose the required qualifications and responsibilities of the BMT professional who oversees quality management and to elicit discussion to standardize such a role in BMT and cellular immunotherapy programs. Our results could serve as a model for quality managers in other complex healthcare environments. The recommendation and findings are primarily limited to cell therapy centers in North America.

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INTRODUCTION

Healthcare organizations can demonstrate value in the form of superior outcomes and lower costs for patients, payers, and accrediting organizations. In the United States the Center for Medicare & Medicaid Services has been driving this change with various items of legislation, such as the Medicare Access and Children's Health Insurance Program Reauthorization Acts of 2015 and 2018 and the Transforming Clinical Practice Initiative, among others. Blood and marrow transplant (BMT) programs worldwide frequently employ professionals charged with securing quality and maintaining accreditation through the Foundation for Accreditation of Cellular Therapy (FACT), European Society for Blood and Marrow Transplantation, The Joint Accreditation Committee ISCT-Europe & European Society for Blood and Marrow Transplantation (JACIE), American Association of Blood Banks, Associacao Brasileira de Hematologia, Hemoterapia e Terapia Celular, and others. The standards created by the accrediting agencies continue to evolve and promote ongoing commitment to robust quality programs and consistencies in clinical practice. Although many BMT programs employ quality management professionals to

achieve these goals, there are no standards regarding the education, training, and core competencies needed to successfully perform such a role.

To address the deficits in defined education and training requirements for professionals who oversee quality management, we conducted a comprehensive literature review and performed a survey to propose standard competencies for these professionals in BMT and cellular immunotherapy programs. In addition to defining competencies for quality professionals in BMT and cellular immunotherapy, the experiences and expertise gathered from the BMT and the cellular therapy clinical communities could be used to develop professionals who oversee quality in other clinical settings.

METHODS

Literature Review

A literature search was conducted to retrieve articles pertaining to the role of clinical quality professionals in healthcare, with a focus on BMT. The first search, conducted in June 2016, included articles in PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, and Google Scholar using the following search phrases: quality manager, FACT quality, FACT accreditation and quality, quality improvement and bone marrow transplant, and BMT quality. From this search 16 articles were reviewed. A second search in October 2016 using the same databases with the term "quality manager" alone and in conjunction with job description, requirements, criteria, responsibilities, and role yielded 3 additional articles.

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BMT Program Quality Professional Survey

A comprehensive electronic survey was created and distributed to BMT programs across the United States and Canada using quality management list servers. We received 43 responses, from a little over 200 BMT programs across United States and Canada. Smaller BMT programs were believed to be less likely to have a dedicated quality management professional in the clinical setting. The survey included measures of annual transplant volume, accreditation status, and quality structure and specific questions regarding the role of the clinical quality manager.

RESULTS

Literature Review

We conducted a literature review to define the qualifications and responsibilities of the clinical quality manager and outline the impact that FACT/JACIE accreditation confer on this role for BMT programs and healthcare organizations in general. Our search generated 19 articles for analysis [1-9].

The lack of a quality management program was 1 of the most common deficiencies noted during FACT clinical accreditation inspections [1,2]. In the early literature we noted that the impact of FACT/JACIE standards on quality measures, including survival, were inconclusive. In 2004 one institution took 14 months to implement JACIE standards at a cost 148,981 euros, which did not include accreditation fees. This institution hired a quality manager to meet the standards but noted a lack of evidence, suggesting that implementation of FACT/JACIE standards improved quality [3]. In 2011 a study of European centers that performed 107,904 adult and pediatric allogeneic and autologous transplants found that implementation of JACIE standards was associated with improved overall survival. Outcomes of patients who received a transplant after JACIE accreditation were improved compared with transplant at baseline (>3 years before application or no application), during preparation (3 years before application), or during application (time from application to accreditation) [4]. In a follow-up from 2014 of these same European centers, no statistical association was shown between JACIE accreditation and survival after autologous transplant; however, the presence of JACIE accreditation continued to show a statistically significant improvement in survival after allogeneic transplant [5]. However, in a study of 12,993 transplants performed at 162 centers in the United States, FACT accreditation alone was not associated with decreased mortality over a 3-year period [6].

The literature search yielded 3 narrative articles related to the role of the quality manager. Wilson [7] argued that quality management professionals must have sufficient relevant experience and credibility to gain influence and be effective in their role. A typical job description of a quality manager included policy development, data collection and analysis, communication and reporting, education and support, and administrative responsibilities [7]. From a business perspective, Addey [8] described the role of a quality manager to include the functions of a salesman, teacher, psychoanalyst, doctor, consultant,

detective, policeman, social worker, researcher, designer, strategist, lawyer, customer, and statistician. These terms exemplify the complexity of the quality manager's role. In the total quality management model, the quality manager not only focuses on quality improvement for patient care but considers employees as well. Patient care providers know the barriers involved in implementing quality improvements and are key stakeholders in any successful and sustainable change [9].

BMT Program Quality Professional Survey Results

Responses were gathered from 43 unique programs. Seventy percent of responding centers reported conducting at least 20 transplants per year. The full survey and results, including the names of each survey respondent and their volumes of transplant procedures, are presented in the Supplementary Data, which is available online. Our survey included questions on key responsibilities, improvements made by the quality professional, education, and types of standardized quality frameworks and/or process improvement methods that they use.

Over 70% of BMT programs surveyed indicated that their quality management professional fulfills the responsibilities listed in Table 1. Historically, the main responsibility has involved regulatory and policy management. Our survey results showed that the areas of responsibility have increased toward performance improvement and standardization oversight.

Survey participants also indicated areas where they contributed to improvements to secure quality compliance and maintain accreditation. Improvements undertaken by the BMT quality professional are listed in Table 2.

Regarding level of education, we surveyed quality professionals working on the clinical program side versus those working on the cellular therapy facility side. As shown in Table 3, a master's degree was the predominant level of education among these professionals, suggesting that this should be included as a requirement in a job description.

Finally, our survey asked quality professionals to select all standardized quality framework and/or process improvement methodologies that they use. As shown in Table 4, the most used methodology was root cause analysis, which is a well-known methodology in the healthcare setting that identifies causal factors and implements solutions to prevent similar incidents from happening again.

DISCUSSION

Today's healthcare landscape is rapidly headed toward quality-driven reimbursement, the establishment of performance metrics, publicly reported data for consumer use, and harmonization of informatics and systems among multiple healthcare networks. To meet these targets the BMT program structure can be leveraged as a model for quality management. Lessons learned from the BMT community can be integrated into other

Table 1
Specific Responsibilities Attributed to the BMT Quality Professional (37 Responders)

Area of Responsibility	Category	Respondents with the Responsibility(%)
Maintaining compliance with accreditation standards/preparing for accreditation surveys	Regulatory and policy management	100
Clinical program quality management		97
Policy and procedure development		97
Facilitation of process improvement projects	Performance improvement	91
Change management (assisting or directing the program in managing changes)		89
Data gathering and analysis		86
Quality committee facilitation/oversight	Standardization oversight	84
Creation of quality management framework for the program		78

Table 2
Improvements Attributed to the BMT Quality Professional Role (34 Respondents)

Improvement	Respondents Who Reported Making the Improvement (%)
Standard operating procedures	94
Workflow improvements	91
Achievement of accreditation	87
EHR documentation improvements	82
Regulatory compliance	81
CIBMTR form submission	74
Program improvement goals	72
Clinical outcomes	72
Patient satisfaction	62
CLABSI reduction	61
Program growth	58
Transplant-related mortality	47
Rate of <i>Clostridium difficile</i>	43
CPOE optimization	42
Cost savings	38
Staff satisfaction	38
Readmissions	36
Reimbursement	34
Workflow improvements between clinical and research	30

EHR indicates electronic health record; CIBMTR, Center for International Blood and Marrow Transplant Research; CLABSI, central line-associated bloodstream infection; CPOE, computerized physician order entry.

Table 3
Clinical Quality Manager Educational Level (37 Responders)

Highest Degree	Respondents Who Reported the Degree (%)
Associate's	0
Bachelor's*	31
Master's†	61
Other‡	14
Total	100

* 82% of bachelor's degrees reported were in nursing.

† 39% of Master's degrees reported were in nursing. The remaining 61% included engineering, administration, public health, science, and business administration.

‡ This included 3 doctorates.

Table 4
Process Improvement Methodologies Used by BMT Clinical Programs (44 Responders)

Improvement Methodology	Percentage Reporting Using the Methodology	Description
Root-cause analysis	83	Method for problem-solving used for identifying the factor that causes problems.
PDCA/PDSA	46	Plan-Do-Check-Act/Plan-Do-Study-Act.
LEAN	42	Customer-centric methodology used to continuously improve any process through the elimination of waste. It is based on the ideas of continuous incremental improvement and respect for people.
Six sigma	24	Disciplined, data-driven approach and methodology for eliminating defects in any process from manufacturing to transactional and from product to service.
IHI	17	Institute for Healthcare Improvement.
FMEA	17	Failure Mode and Effects Analysis: Highly structured, systematic technique for failure analysis. Involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes and their causes and effects.
DMAIC	15	Define, Measure, Analyze, Improve, and Control: Data-driven improvement cycle used for improving, optimizing, and stabilizing business processes and designs.
DMADV		Define, Measure, Analyze, Design, Verify: Six sigma framework that is focused primarily on the development of a new service, product, or process as opposed to improving a previously existing one.
Other (examples shared: SBAR, apparent cause analysis)	12	SBAR = Situation, Background, Assessment, Recommendation. Apparent Cause Analysis = used on less significant events (limited investigation compared with root cause analysis, which is more in-depth).
AHRQ Tools	7	Agency for Healthcare Research and Quality: Provides practical healthcare information, research findings, and proposed quality indicators, among others.

Lean is a set of operating philosophies and methods that help create a maximum value and serves the patients by reducing waste and waits in every process.

Table 5
Recommended Body of Knowledge for the Quality Professional

Subject Area	Description
Process improvement	Lead process improvement initiatives, process discovery, and sustainable implementation into operations through standardized workflows and clinical pathways.
Change management	Act as lead strategic change agent who drives an innovative culture of efficient improvements. Direct facilitation, support, and coaching for value streams.
Data analysis and stewardship	Support the link between quality and value, with data being the key ingredient. Accurate and discrete data points from the source drives impactful measurements of resources, EHR meaningful use analysis, and focused clinical practice improvement activities.
Accreditation and compliance	Meet third-party regulations while innovatively uniting the program's processes and need for growth with accrediting bodies' requests.
Informatics	Because the healthcare environment relies heavily on the EHRs and computerized physician order entry, information technology professionals must understand the various systems and clinical processes and translate physician needs into actionable items.

healthcare sectors. Our experience points to 3 positions followed by the BMT community: the ability to transform standards and regulations into positive outcomes, a focus on meaningful outcomes to patient care that can be measured and monitored, and the use of collaborative and coordinated teamwork. Quality professionals should guide providers toward standardization and meeting requirements as they best serve the patients and patientcare teams, interpreting regulation requirements in a way that efficiently supports and improves clinical care. It is also imperative for quality professionals to take leadership in acquiring clean data, after reaching clinical and process consensus among clinicians, so that improvements on patient care can be documented (Table 5).

Table 6
Recommended Program Roles of Quality Professionals

Job Title	Responsibilities
Coordinator	<ol style="list-style-type: none"> 1. Establishes the baseline of a quality program: identifies the immediate needs for standard operating procedures. 2. Creates a process for developing standard operating procedures. 3. Gathers data elements for audits, and audits records under the supervision of a manager or director. 4. Strength: Baseline competency with identified opportunities for growth
Specialist	<ol style="list-style-type: none"> 1. Evaluates trend lines based on audits designed by the manager or director. 2. Proposes plans for improvement to the clinical teams based on data analysis. 3. Works with data managers to create process improvements. 4. Strength: Competent in 2 to 4 areas from Table 5, with identified opportunities for growth.
Manager	<ol style="list-style-type: none"> 1. Creates a quality management plan. 2. Oversees the entire quality program and drives standardization. 3. In partnership with the clinical team, defines the roles and responsibilities of team members. 4. Establishes a baseline for education and competencies required for each role. 5. Focuses on process improvement before defining standard operating procedures. 6. Strength: Fully competent with the body of knowledge (Table 5). Working to mentor quality professionals.
Director	<ol style="list-style-type: none"> 1. With organizational policies and procedures as the foundation, helps develop clinical standardization and ensures translation into daily operations. 2. Develops and monitors performance and outcome measures. 3. Leads initiatives that advance quality and reduce costs by minimizing variation, reducing redundancies and streamlining processes. 4. Drives performance improvement by becoming the translator of the clinic needs, informatics, and process improvement. 5. Strength: Expert level in all domains, listed in Table 5.

Teamwork is needed for securing a successful quality control/regulatory-compliant environment. The skills and knowledge of a matrix team of professionals are needed to integrate process improvements and standardization into clinical operations. BMT is a great example of a matrix team environment, with similarity to a minicancer center. The quality professional is expected to manage change while supporting team members to work at the top of their license. BMT is a team activity based on a complex process with multiple moving parts. Other complex healthcare environments, whether cancer centers or hospitals, would benefit from the successes implemented in the BMT matrix environment, because the roles within a BMT program are similar to larger environments (Table 6). The size of the program, the support provided by clinical program leadership, and the organization's understanding of quality and performance improvement can all affect the role of the quality professional. There must be champions from physician leadership or administration in the center infrastructure to assure the quality professional is provided the appropriate resources for success.

Based on experience, survey results, and discussions within the BMT C4QI (Bone Marrow Transplantation Comprehensive Cancer Center Consortium) quality group, the consensus seems to be that quality professionals, albeit initially hired to meet accreditation and compliance roles, are highly expected to be engaged in process improvement initiatives, change management, data analysis and stewardship, and informatics. These four areas are highly integrated and provide the opportunity, when combined with the need to fulfill the accreditation and compliance needs, to create a holistic quality management infrastructure for bone marrow transplant and cellular immunotherapy centers (Table 5). We took a step further from recommending body of knowledge areas for the quality professional by detailing roles and responsibilities of quality professionals (Table 6) with the understanding that the size of the clinical program most likely drives the number and role of the quality professionals hired.

One limitation of our research has been a US-centric perspective. The authors are currently collaborating with European Union colleagues to administer this survey to European programs and hope to publish the results in a subsequent article.

In conclusion, within healthcare, many professional roles have a well-defined pathway for training and competency. This includes physicians, nurses, advanced practice providers, and pharmacists. However, for the quality professional, including the BMT and cellular immunotherapy program quality management professional, the pathway is often not clearly defined. Although quality management professionals evolve from various educational and professional backgrounds, there are clear gaps in standard definitions, competencies, training, and career paths for these individuals. The guidelines and structure for standardization of the quality management role within BMT and cellular immunotherapy programs provided here may be used as a framework for quality management professionals within other healthcare environments.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found on line at <https://doi.org/10.1016/j.bbmt.2018.08.017>.

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