THE CLINICAL NURSE LEADER ROLE IN ACCREDITATION OF A RURAL STEM CELL TRANSPLANT CENTER

by

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DEDICATION

This paper is dedicated to my daughter, Finley - my greatest accomplishment is being your mom; and to my husband Alex, for his unwavering love and support.

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ABSTRACT

In 2020 the National Cancer Institute's annual estimation of newly diagnosed cancer cases was reported at 1,806,590, with 606,520 people expected to die from cancer during the year. In 2017, cancer was the second leading cause of death in the United States. Autologous hematopoietic stem cell transplant is an intervention used to manage and cure hematologic malignancies, extend life, and improve quality of life. A microsystem assessment was completed for a rural stem cell transplant center located in the western United States to better understand factors associated with deficiencies cited during accreditation renewal process. A Clinical Nurse Leader, certified in oncology nursing, is uniquely positioned to act as an expert clinician within the stem cell transplant center and support attainment of accreditation renewal. Eight accreditation priorities were identified through the microsystem assessment that fall within the expertise of the Clinical Nurse Leader. A color-coded scorecard was investigated, and a draft tool was adapted to link CNL competencies with accreditation standards and deficiencies. The proposed scorecard will help monitor client-based improvement measures and guide accreditation success.

INTRODUCTION

According to the National Cancer Institute, it is estimated that there will be 1,806,590 new cancer cases diagnosed in the United States annually, while 606,520 people will die from cancer (2020). Cancer is the second leading cause of death in the United States (Centers for Disease Control and Prevention, 2017). The mission of Healthy People 2030 is "to promote, strengthen, and evaluate the nation's efforts to improve the health and well-being of all people," including patients with cancer (Office of Disease Prevention and Health Promotion [ODPHP], 2018). Two Healthy People 2030 objectives, one baseline and one research, target patients receiving cancer care: a) "increase the proportion of cancer survivors who are living longer than five years from 64.2 percent to 66.4 percent" (C11) (ODPHP, n.d.-a; and b) "increase the mental and physical health-related quality of life of cancer survivors" (C-R01) (ODPHP, n.d.-b).

Autologous hematopoietic stem cell transplant (HSCT) is an intervention used to manage and cure hematologic malignancies, extend life, and improve quality of life. In 2018, the Center for International Blood and Marrow Transplant Research (CIBMTR) reported 61,461 peripheral blood autologous HSCTs were performed in the United States between 2013 and 2017. Social determinants of health, including rurality, have potential negative impacts on patient access to treatment options. According to the CIBMTR, the majority of HSCTs were performed in major metropolitan centers.

The Foundation for the Accreditation of Cellular Therapies (FACT) guides organizations that provide stem cell transplant services (FACT, 2020b). The FACT examines clinical, collection, and processing facilities involved in a cellular therapy program and includes the review of an organization's application for accreditation renewal and a site visit. Accreditation

supports a program's commitment to quality and safety and certifies a facility meets or exceeds best practices and established standards of care regardless of geographic location.

Background

Microsystem Assessment:

A microsystem assessment allows for examination of clinical environments and each of its components to "identify specific activities, information, and knowledge that is needed to design and plan patient care and patient-centered services that meet patient expectations" (Godfrey et al., 2003, p. 159) and improve clinical outcomes. Godfrey et al. (2003) analyzed the clinical microsystem by describing the "'four P's'—the patients, people, processes, and patterns" (p. 159). The four P's framework has since been updated to the "five P's" to include "purpose".

To better understand the problems associated with accreditation deficiencies identified in a rural western stem cell transplant center, referred to in this paper as Facility X, a microsystem assessment was performed to clarify the following components: purpose, patients, professionals. processes, and patterns.

Purpose. The microsystem assessment was completed for a stem cell transplant center located within a cancer center that is part of a larger health care system situated in the metropolitan core of a geographically large area in a predominantly rural setting. The health care system is not-for-profit, led by a physician CEO, and governed by a board that is made up of community members, nurses, and physicians. The facility aims to be a national leader through the provision of the highest levels of service, value, safety, and quality care.

The cancer center (Facility X) is currently accredited by the FACT and the larger organization is Magnet-designated. The cancer center's mission is "to provide the best patient experience possible because we care about taking excellent care of our patients and each other" (Facility X, n.d.). The stem cell transplant center was established in 2004 and consists of a clinical site (medical oncology and inpatient cancer unit), collection site (infusion center), and processing site (facility laboratory). The foci of this project are the clinical and collection sites.

In March 2020 the facility received their reaccreditation report from the FACT that identified deficiencies and variances. The purpose of this microsystem assessment is to identify problem areas and opportunities for improvement to achieve accreditation renewal and maintenance.

Patients. Patients seen in the stem cell transplant center are under treatment for hematologic malignancies, including multiple myeloma (MM), lymphoma, and acute myeloid leukemia (AML). In 2019 eight patients were treated with autologous HSCT; in 2020 a total of 14 patients were treated; and as of March 2021, 16 patients had been referred to the center for transplant. In 2020, 73% of patients were treated for MM, 7% for non-Hodgkin's lymphoma diffuse large b-cell lymphoma (NHL-DLBCL), 7% plasma cell leukemia, 7% Hodgkin's lymphoma (HL), and 6% angioimmunoblastic peripheral T-cell lymphoma. The majority of patients are referred from within the larger health care system, but referrals are received from the greater northwest region as well.

Data collection on patient demographics is from 2002-2020. The patients treated in the program are from the following racial groups: 96% White, 2% American Indian/Alaska Native, 1% Black, and 1% other. Approximately 50.36% of patients are male, 49.64% are female. The

average age is 56 years old with ages ranging from 22-73 years old. Pediatric patients requiring stem cell transplantation require further expertise and must travel to a pediatric health care system located in a major metropolitan area. Patient hometowns are located in four western states, including Alaska. Patient data on occupation and educational level is not currently collected.

In 2020, six of the 14 HST patients were admitted to the hospital for at least one of the following reasons: no caregiver available, febrile neutropenia, small bowel inflammation, uncontrolled nausea, or pain. The average length of stay for patients admitted between 2002 and 2020 was 9.89 days. There were no microbial infections or central line associated blood stream infections between May 2019 and June 2020. In 2020 the average time to engraftment after reinfusion of cells was 10.8 days and the average time to a platelet count of greater than 50,000 was 15 days. Between 2018 and 2019 the one-year post-transplant mortality rate for treatment-related health complications for patients was 0%.

Professionals. The process of HSCT requires collaboration among physicians, nurses, pharmacy, laboratory, and other personnel. Interdisciplinary collaboration is a key component of the culture within the organization. The program and apheresis collection facility director is a medical oncology physician. Four BSN-prepared, Oncology Nurse Certified (OCN) specialists provide different aspects of care to the transplant patient. First, a Transplant Nurse Navigator guides the patient until day one of cell mobilization; second, the Transplant Nurse Coordinator supports the patient from cell mobilization through follow-up; third, the HSCT Infusion Nurses perform cell collection, high dose chemotherapy administration, cell reinfusion, and frequent assessments; and finally, the Quality Manager reviews documentation, patient data, and

adherence to accreditation standards to ensure that safe, quality care was provided throughout the process.

In summary, patients referred to the center are presented to the weekly multidisciplinary team tumor board for screening. If the patient is deemed eligible for transplant, they have a consultation with the medical director of the center that is coordinated by the Transplant Nurse Navigator. The Transplant Nurse Navigator notifies the financial counselor of the patient, obtains patient information, notifies the stem cell center team, schedules tests, and schedules the patient's initial appointments in addition to cell mobilization and line placement. Upon the start of mobilization, coordination of the patient's care is transferred from the Transplant Nurse Navigator to the Transplant Nurse Coordinator who meets the patient on their first day of cell mobilization prior to collection, completes patient education, meets with the patient multiple times a week during the entire process, and supports care coordination through follow-up post-transplant. The HSCT cell collection, high dose chemotherapy administration, and cell reinfusion is performed by Infusion Center registered nurses who have completed a chemotherapy and immunotherapy certificate course through the Oncology Nursing Society and are skilled in apheresis and HSCT. All HSCT infusion nurses complete a two-day course with a nurse educator from the apheresis machine manufacturer and experience an initial training and competency checkoff to the procedure with another HSCT nurse. Once approved for the role (or certified) an annual competency is required. The clinical and apheresis quality manager is a nurse clinician with responsibility for data management to ensure adherence to the FACT accreditation standards.

Processes. The processes involved with the stem cell transplant center are referenced in four of the facility's policies and procedures (Facility X, 2012; 2016a; 2016b; 2016c). Patients undergoing autologous HSCT utilizing peripheral blood progenitor cells (PBPCs) complete the process in the ambulatory setting unless they experience adverse effects requiring hospitalization. During screening for eligibility, the patient completes numerous laboratory and screening tests, has a consultation with the medical director of the program, and signs an informed consent with the physician. Treatment plans may vary according to the patient's diagnosis and comorbidities, but every treatment plan follows a similar process.

Prior to cell collection the patient receives a granulocyte stimulating factor drug to increase bone marrow peripheral stem cell production. Cell collection occurs over one to four days, depending on the patient's CD-34 cell count at the end of each collection day. At the beginning of each day of cell collection the patient is assessed by the physician and apheresis nurse who then document their assessments. Daily laboratory values are also collected. Cell collection must be completed by 1330 each day for the cells to be sent to the laboratory for processing and then shipped to a major medical center for analysis. Analysis is completed by the major medical center in another state and reported to the clinical site the following day. This analysis determines if a patient requires additional cell collection procedures.

Upon successful cell collection and after a treatment break the patient completes laboratory and screening tests and sees the physician. Within one week of test completion and the physician visit, patients undergo high dose chemotherapy to eradicate all malignant cells. This process requires close monitoring of patients due to their immunocompromised risk. High-dose chemotherapy administration requires the patient also receive additional hydration via an

ambulatory pump, a daily nursing assessment, and 24-hour access to an on-call medical oncology physician.

After administration of high-dose chemotherapy the patient receives their hematopoietic progenitor cells back via reinfusion. Reinfusion requires two qualified infusion nurses who thaw and administer the cells while monitoring the patient.

Following cell reinfusion, the patient requires close monitoring for the first 100 days. During this initial period, the patient is monitored for cell recovery and treatment side effects. Patients remain at high risk throughout this process due to their extreme immunocompromised state and resultant challenges performing activities of daily living. Patients who undergo stem cell transplants require re-immunization of all childhood and lifetime vaccinations This process of re-immunization begins no earlier than six months post-transplant. Following this initial period of patient recovery, patients are seen periodically for two to five years.

Patterns. The FACT accreditation committee identified several deficiencies and variances during their on-site inspection of Facility X in fall of 2019. The clinical and collection site had 21 citations and one variance (see Appendix A). The FACT noted that the quality manager of the center cannot have oversight of their own work. This creates the need for a nurse leader who can both perform the procedures, act as a leader to staff, and support adherence to accreditation standards for program quality and safety. The Clinical Nurse Leader (CNL) stem cell transplant coordinator is an oncology certified master's prepared nurse who will support change within the clinical and collection sites. As an oncology certified nurse, this novel approach will allow the CNL to act as an expert HSCT nurse who is also uniquely prepared to support facility accreditation. Quality and safety citation categories received by the clinical and collection sites

become facility priorities that fall under the purview and competencies of the CNL stem cell transplant coordinator. Priority areas for improvement include the following categories:

- Management of policies, procedures, Standard Operating Procedures, and guidelines
- Staff education and competencies
- Outcome analysis
- Auditing of required data
- Documentation and data collection
- Collection of feedback from donors and legal representatives
- Labelling of cellular therapy products
- Inventory control

Problem

As the microsystem assessment supports, the problem of deficiencies on the recent FACT accreditation renewal report (March 2020) identified multiple areas for improvement. To maintain accreditation and demonstrate continuous improvement the stem cell transplant center needs to ensure they are meeting and exceeding the FACT standards identified as lacking in the accreditation report.

Significance

As the only facility in the state and region that offers autologous HSCT, patient volumes at the project site have continued to grow over the past year, requiring additional staff time, education, and documentation. The microsystem assessment allows for the identification of opportunities for improvement through the incorporation of a CNL coordinator in the stem cell transplant center. The FACT notes that through accreditation organizations demonstrate they “have developed and implemented a foundation of high-quality practices that result in cell products and patient care that are sought after by physicians and patients” (2020a) regardless of rural or

metropolitan location. The larger organization of the stem cell transplant center aims to provide the highest level of quality care, patient safety, value, and service. To ensure positive patient outcomes continue to be achieved as the center grows, adherence to FACT standards is critical. Loss of accreditation and ability to offer these services would negatively impact the facility's ability to meet their mission. Poor documentation and care coordination can result in complications that require patient admission to the hospital and decreased quality of life. Patients who rely on these procedures would be forced to seek treatment from a different state and facility, requiring significant travel and financial impact. These consequences of poor program management and loss of accreditation would negatively impact the facility's reputation as a provider of the highest level of quality care. Significant revenue is associated with HSCT procedures thereby putting the organization at risk of great financial loss if accreditation and ability to offer these procedures is lost.

Purpose and Aims

The purpose of this project is to examine the role of CNL competencies that align with the stem cell transplant center's goal to maintain accreditation and commitment to continuous quality improvement.

The project will address the following aims:

1. Identify CNL competencies that specifically pertain to stem cell transplant program accreditation priorities.
2. Investigate and adapt a draft tool to guide accreditation success.

Definitions

For the purpose of this professional paper the following definitions will be used:

- Apheresis: a procedure that involves the removal of the blood from the body, separation into different components, removal of a particular component, and return of the remaining blood components to the body (Merriam-Webster, n.d.).
- Autologous hematopoietic stem cell transplantation (HSCT): involves the use of a patient's own hematopoietic cells to "rescue" their bone marrow after high dose chemotherapy treatment and can be used to manage several types of cancers (Holmberg et al., 2019).
- Clinical Nurse Leader: a nurse educated at the master's level who is educationally prepared to "practice across the continuum of care in any healthcare setting" (AACN, 2013, p. 4). The role was created to address a critical need to improve patient care outcomes quality initiatives (AACN, 2013).
- Accreditation: the confirmation of a facility's ability to meet standards established by specific boards and organizations. This involves submission of a self-evaluation, on-site visit, and ongoing review that confirms maintenance of standards. (FACT, n.d.-b).
- Balanced Scorecard: a tool that visually represents financial, customer, internal business processes, and learning and innovation perspectives within an organization (Agency for Healthcare Research and Quality, n.d.).

REVIEW OF THE LITERATURE

The Clinical Nurse Leader (CNL) role was created by the American Association of Colleges of Nursing (AACN) to address the need for quality improvement within healthcare systems. The CNL is prepared to improve the healthcare system through implementation of evidence-based practice, advocacy, quality management, and effective interdisciplinary team communication and collaboration. Extant literature supports the positive effect the CNL has upon various healthcare systems (Bender et al., 2017; Bender et al., 2019a; Bender et al., 2019b; Estrella et al., 2018; McGowan, 2016; Miltner et al., 2020; Noles et al., 2019; Ott et al., 2009; Phillips et al., 2012; Sotomayor & Rankin, 2017; Stanley et al., 2008). Researchers identified throughout this review of the literature have identified that CNLs influence the healthcare system through the dynamic nature of the role, possession of complex skills, and the delivery of tangible and intangible outcomes. The purpose of this project is to examine the role of CNL competencies that align with the stem cell transplant center's goal to maintain accreditation and commitment to continuous quality improvement. The remainder of this chapter will address the theoretical framework of the scholarly project, a review of current and historical literature, and the suggested method for performance measurement. The chapter will also identify potential gaps in current research pertaining to the CNL's role in continuous quality improvement and organizational accreditation.

Theoretical Framework

The Neuman Systems Model was the theoretical framework used as a foundation and guide for the project. The Neuman Systems Model is informed by general systems theory.

General systems theory is based on the interaction and relationships of multiple elements in a system. Neuman Systems Model builds upon general systems theory while incorporating knowledge from numerous fields including nursing, to describe the health and wellness of a system as a function of its parts (Neuman & Fawcett, 2002). An important aspect of the Neuman System Model is the dynamic nature in which information moves through and within the system. Neuman described the model as a unique, open systems-based perspective through which the model serves as a unifying focus and is appropriate for approaching a wide range of nursing concerns (Neuman & Fawcett, 2002). Accreditation occurs when a system successfully demonstrates quality patient outcomes through a process of collaboration and continuous quality improvement, thus demonstrating "wellness".

Key to Neuman Systems Model are four essential concepts: person, environment, health, and nursing. Application of Neuman's model as a foundation of the project requires identification of the concepts as they apply to the project. Neuman & Fawcett (2011) define the person as a client or client system that is impacted by five variables-physiological, psychological, sociocultural, developmental, and spiritual. The person possesses protective lines of defense and resistance. Nursing is concerned with how the person interacts with the environment. For the purposes of this project, the *person* is defined as the patient population being served by the stem cell transplant center. The *environment* is defined by Neuman & Fawcett (2011) as the many factors (internal, external, created) that surround and impact the client system. The client system (accreditation) is influenced by environmental stressors. For the purpose of the project, the environment includes factors that influence adherence to or deviation from the Foundation of Apheresis of Cellular Therapy (FACT) standards: the greater

organization, the stem cell transplant center, and the practitioners caring for the patient. *Health* is described by Neuman & Fawcett (2011) as a continuum, with maximum system stability as wellness. For the purpose of the project, health represents accreditation (or a continuously accredited transplant center). The final concept of the model, *nursing*, is the role of the clinical nurse leader in achieving optimal health through maintenance of system stability. The CNL serves as the interdisciplinary team leader in the project to maintain and support accreditation and continuous quality improvement. Application of the Neuman Systems Model as a theoretical foundation of this project allows nursing to serve as an intervention to improve the overall health and wellness of an identified system by describing potential environmental stressors as well as providing a unified focus essential to attain and maintain program success.

Review of the Literature

Topics searched included the impact of the CNL, accreditation, performance measures, and patient and facility outcomes. Databases used were the Montana State University Library CatSearch and Cumulative Index of Nursing and Allied Health Database (CINAHL). Key search terms used were *clinical nurse leader, CNL, outcomes, accreditation, quality, leadership, performance, performance measures, Neuman Systems Model, stem cell transplant,* and *balanced scorecard.* Inclusion criteria for identified studies included: articles published between 2016 and 2021, peer-reviewed references, English language, publications within the last five years unless seminal research, and focused on CNL coordinators. Bibliographies from identified studies were also hand searched. A total of 29 articles were identified as meeting the inclusion criteria and are included here in the review of literature.

Critical Appraisal and Synthesis of the Research

CNL Role and Competencies

Within the healthcare system, a need was identified to address quality improvement; the AACN answered this call with the creation of the CNL role. The *Competencies and Curricular Expectations for Clinical Nurse Leader Education and Practice* (AACN, 2013) describe the CNL as a leader able to act in all settings where health care is delivered and particularly well suited for complex healthcare delivery. The CNL possesses the competencies, knowledge, and skills to act as a leader through proficient to expert knowledge of health care financing, quality improvement, safety initiatives, statistics, and people management. The following section includes studies related to the role of the CNL and quality improvement essential for accreditation.

Accreditation and Quality Improvement

Evidence supports the conclusion that accreditation improves quality of care by requiring facilities to partake in continuous quality improvement, work cohesively, and meet standards of care (Azagury & Morton, 2016; Bogh et al., 2016; Cornish, 2008; Desveaux et al., 2017; LeMaistre et al., 2019; Snowden et al., 2017). Accreditation has contributed to significant program improvements by requiring facilities to not only meet standards but continually improve their outcomes with each re-accreditation (Cornish, 2008; LeMaistre et al, 2019). Through accreditation, facilities provide increasingly efficient, safe, and patient-centered care (Araujo et al., 2020). Accreditation is described by Desveaus et al. (2017) as a quality assurance process; quality assurance and quality improvement are key competencies in the CNL role. To provide quality care and meet accreditation standards, the interdisciplinary team must demonstrate

collaboration, efficiency, and engagement. The CNL supports an inclusive culture that inspires teams and promotes quality through the actions of interdisciplinary team members. Specific outcomes of CNL involvement in the care environment that impact team performance include improved coordination of care, fewer errors of omission, prevention of errors, increased time spent with patients, and decreased variation in quality (Bender, 2016; Bender et al., 2019a; Estrella et al., 2018; Phillips et al., 2012; Stanley et al., 2008).

The CNL Role and Accreditation Support

The CNL practices across the continuum of care and possesses the competencies necessary to support accreditation through enhancement of patient care quality while considering the strains placed on a healthcare system. Expert knowledge of quality improvement actions developed during CNL educational preparation supports better organizational practices. For accreditation success, the CNL nurtures the skills and knowledge of healthcare team members and promotes an effective interprofessional team.

Locus of Control for Safe Quality Care.

In the years since the CNL role was first defined, a number of researchers have provided significant evidence outlining the positive impact the CNL has on quality improvement within oncology (Estrella et al. 2018; McGowan, 2016), Veterans Affairs (VA) (Miltner et al., 2020; Ott et al., 2009), and clinical microsystems (Bender, 2016; Bender et al., 2019a; 2009; Phillips et al., 2012; Stanley et al., 2008). Actions by the CNL that positively impact quality improvement include clinical and team leadership (Bender et al., 2019a; Miltner et al., 2020; Ott et al., 2009; Phillips et al., 2012), development and implementation of evidence-based interventions (Estrella et al., 2018; McGowan, 2016; Miltner et al., 2020), care coordination (Bender et al, 2019a; Estrella et al., 2018; Phillips et al., 2012),

and process improvement (Estrella et al., 2018; Stanley et al., 2008). The CNL identifies significant problems and drives change that results in the provision of safe quality care (Noles et al., 2019).

A best practice example applied to quality/safe oncological nursing and the Neuman Systems Model is found in work presented by Salvador (2005; 2006). Salvador (2005) performed a retrospective descriptive study to explore the factors that impact oral mucositis development in autologous stem cell transplant patients. The incidence, associated factors, and resolution of oral mucositis in this patient population was examined. Salvador utilized Neuman Systems Model to then discuss primary and secondary levels of prevention for oral mucositis. Following the previously discussed study, Salvador (2006) utilized Neuman Systems Model to develop an oral care guide to prevent oral mucositis in the same patient population. Salvador successfully designed patient care through examination of factors, or stressors, that impact the development of oral mucositis in stem cell transplant patients. Salvador then addressed prevention of negative patient outcomes through application of the model and elimination or management of stressors. The work completed by Salvador (2005; 2006) supports the utilization of Neuman's Systems Model as an overarching tool to guide, achieve, and maintain accreditation in a stem cell transplant program

Educational Preparation. Educational preparation of a CNL includes competencies initially outlined by the AACN *White Paper* (2007) and updated in 2013 with the *Competencies and Curricular Expectations for Clinical Nurse Leader Education and Practice*. The CNL curriculum defined by the AACN (2013) requires masters students to obtain and demonstrate knowledge through didactic and clinical learning experiences that focus on the development of

nine essential competencies. The competencies address key areas of impact crucial for achievement and maintenance of accreditation; they include implementation of evidence-based practice, advocacy, quality management, and effective communication and collaboration. Educational preparation prepares the CNL to act as a generalist across various settings (Bender et al., 2017; Phillips et al., 2012; Sotomayor & Rankin, 2017) and promote use of best practices (Bender et al., 2019b). As such, the CNL is uniquely positioned to affect positive change in institutional quality and accreditation success. A novice CNL is prepared to understand care delivery gaps while an expert CNL improves care environments and care quality outcomes (Kaack et al., 2016). Depending on the experience of the CNL being utilized in a role, the organization can develop the support structures necessary to develop CNL practice and build upon the educational preparation, with the expectation that the CNL will be prepared to practice to the full extent of their role within one year of practice (Kaack et al., 2016).

Point of Care Clinical Leadership. Balanced application of the CNL competencies allows the CNL to support staff engagement and strengthen relationships (Bender et al., 2019b; Heinen, et al., 2019; Sotomayor & Rankin, 2017; Stanley et al., 2008; Wong, et al., 2013) while directly engaging in quality improvement. CNL practice embodies four key concepts identified by Bender et al. (2016), communication, interprofessional relationship building, team building, and supporting staff engagement, all necessary in achieving quality outcomes. Whether working with the interdisciplinary colleague or providing direct patient care, the CNL integrates and communicates to ensure high quality outcomes (Phillips et al., 2012; Wong et al., 2013) and effective relationships (Bender, 2016).

In addition to CNL competencies, some settings like the stem cell transplant center require the CNL to hold specialty certification(s) to ensure best practices related to complex patterns, processes, and the role of all interdisciplinary colleagues. The vulnerable transplant patient is best served when highly competent team members work together to provide protection from harm, and ensure quality and safe care.

Measuring Success

A successful CNL benefits a microsystem by connecting necessary actions that ensure quality (and safety) with an organization's mission and purpose (Roussel et al., 2018). For the purposes of this project, balanced scorecards were identified as a method that provided data driven approaches to help monitor client-based improvement measures and guide accreditation success. The balanced scorecard allows for quantitative and qualitative evaluation of progress towards full accreditation.

Balanced Scorecard. The balanced scorecard allows for quality outcomes such as adherence to accreditation requirements to be translated into metrics and measured periodically (Jepsen, 2015; Baker, 2015). Performance measurement systems address care processes and effectively improve performance of health care organizations (Demartini & Trucco, 2017). Implementation of the CNL role within the healthcare system requires careful consideration to maximize the impact and allow for adequate evaluation of the role (Bender et al., 2016a; Miltner et al., 2020l; Ott et al., 2009). The balanced scorecard will be utilized in this project as an example of a tool adapted to measure quality improvement in the context of CNL driven accreditation priorities. The scorecard will also reflect the CNL's impact on deficiencies identified through the accreditation process. In the language of Neuman's model, the scorecard

protects the patient core during stem cell transplant care through identification of potential trends or deficiencies (stressors) that when mitigated (prevented) ensure quality patient care and accreditation.

Summary

The CNL is particularly well-suited to improve and sustain facility performance and support accreditation through their educational preparation, focus on quality, and leadership capabilities. The literature supports the conclusion that CNL implementation positively impacts quality of care across various microsystems. The balanced scorecard has the potential to allow organizations to measure how the CNL supports achievement and maintenance of accreditation. Accreditation of a transplant center ultimately confirms a facility's ability to provide safe, high-quality care even as patients undergo treatment that assaults the immune system (stressors) during stem cell transplant treatment.

Research Gaps

While the CNL is well-positioned and well-prepared to address facility performance there is limited research supporting CNL impact on accreditation status. Further, the role remains vague and poorly defined (Bender et al., 2019b). These gaps in knowledge act as obstacles to full integration of the CNL into healthcare organizations (Bender et al., 2016b; Bender et al., 2019a; Miltner et al., 2020; Williams et al., 2016). To address this gap in knowledge, a crosswalk of CNL competencies that pertain to FACT accreditation standards will be performed. The balanced scorecard will be investigated to serve as performance indicators of CNL impact on accreditation success.

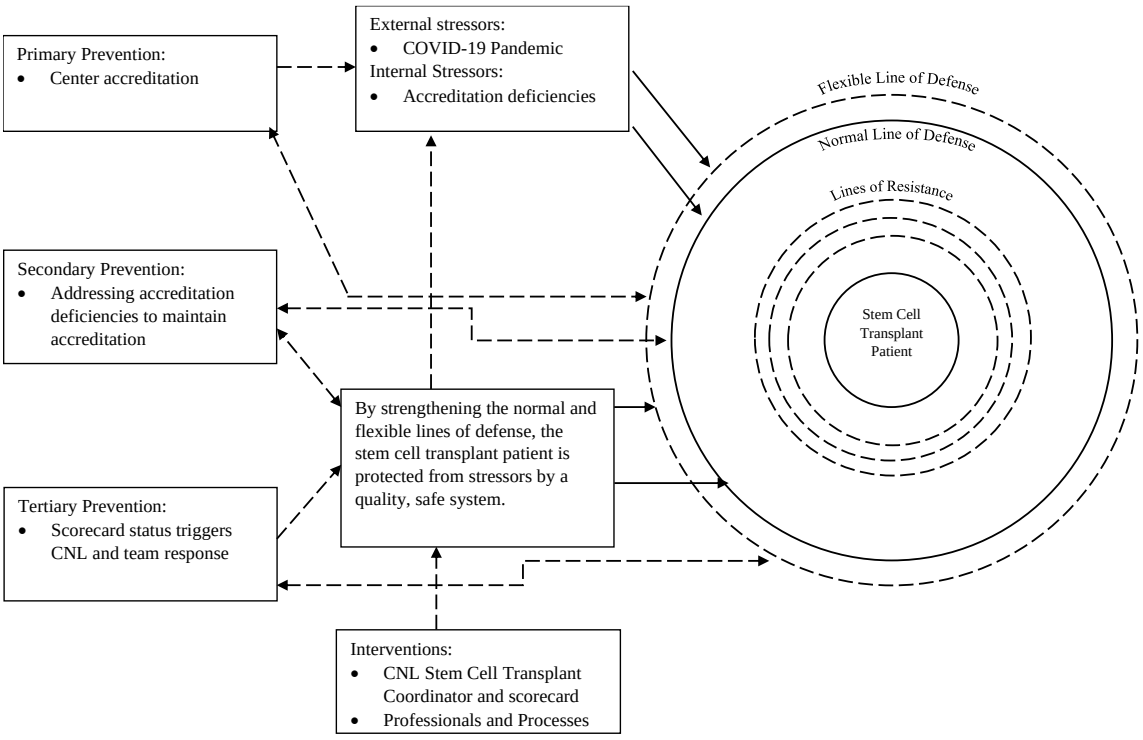
METHODS

Introduction

Purpose and Design

The purpose of this project was to examine the role of Clinical Nurse Leader (CNL) competencies that align with the stem cell transplant center's goal to maintain accreditation and their commitment to continuous quality improvement. The Facility X Stem Cell Transplant Center microsystem assessment established the need for and the potential design of the project by uncovering areas of system strengths and vulnerabilities. The Neuman Systems Model (see Figure 1) guided insight into this project by identifying the stem cell transplant patient as the client system (core) or *person.* Protective lines of defense and resistance of the client system include the professionals and processes identified in the microsystem assessment that ensure the provision of safe, quality care through adherence to accreditation standards. The *environment* (external and internal stressors) impacts the lines of defense and resistance that protect the stem cell transplant patient. External stressors of an immunocompromised patient might present with the onset of a pandemic; internal stressors might occur when accreditation deficiencies are noted. *Health* of the system exists when quality care is provided to ensure positive patient outcomes; thus, accreditation represents primary prevention and wellness of the system. Secondary prevention involves the impact of accreditation deficiencies, and tertiary prevention includes the use of a scorecard to trigger an urgent response by the CNL stem cell transplant coordinator and stem cell transplant multidisciplinary team. To support accreditation and manage the environmental stressors that threaten the client, the *nurse*, or CNL stem cell transplant coordinator, leads the team to support the professionals, processes, and accreditation standards.

This model supported the need for a tool (a balanced scorecard) to guide quality improvement based on patterns identified in the microsystem assessment as priority accreditation citations.



Adapted from The Neuman Systems Model Diagram © 1970 by Betty Neuman

Figure 1. The Neuman System Model Applied to The Stem Cell Transplant Center

Target Setting

The project will be implemented in the clinical and collection sites of a stem cell transplant center, referred to as Facility X, that offers autologous hematopoietic stem cell transplant (HSCT). The stem cell transplant center is part of a Magnet-designated and Foundation for Accreditation of Cellular Therapy (FACT) accredited health care system situated in a metropolitan core of a geographically large area in a predominantly rural setting. The organization has a catchment area that encompasses four western states.

Instruments.

Balanced Scorecard. To help guide accreditation success and visually demonstrate CNL competencies in alignment with accreditation standards, a draft scorecard was adapted from The Virginia Hospital and Healthcare Association Hospital Quality and Patient Safety Scorecard (2020) and Jepsen (2015). The adapted scorecard identifies specifics, applicable CNL competencies as described by the AACN (2013) (see Appendix B) and FACT accreditation standards (2018) (see Appendix A). Citations and variances were noted during the November 2019 site visit and communicated to the facility in a March 2020 report. Development of measures reflecting stem cell transplant adherence to accreditation priorities are listed alongside the identified citation/variance and CNL competency (see Table 1). The CNL collaborates with team members to review the stem cell center's progress towards rectifying the citation in the final column and these priorities will be reflected visually using red, yellow, green color-coding. In addition, data monitored continuously will signal the need for attention to specific criteria.

Accreditation Priority for the CNL	Citation/Variance (see Appendix A)	Clinical Nurse Leader (CNL) Foundation (AACN, 2013, pp. 4-5) and Competency (See Appendix B)	Measures	Status (met: green; in progress: yellow; not met: red)
Management of policies, procedures, Standard Operating Procedures, and guidelines	B4.5.1	Design and implementation of evidence-based practice E2.6; E3.1, 3-5; E4.1 and 7; E5.1.a-f; E8.8	Annual critical document identification with team	
	C4.5.3.8		Annual document review with team	
	C4.10.4.1		Development of reporting policy and procedure	
Staff education and competencies to support accreditation requirements		Team leadership, management, and collaboration E2.7; E4.3-4; E6.1; E7.1, 3-7; E8.8	% HSCT staff annual competency completed	
Outcome analysis	B4.5.3.6	Accountability for evaluation and improvement of point-of-care outcomes E4.9; E8.6; E9.14	Ongoing monitoring of # of central line infections	
Auditing required data	B4.8.3	Accountability for evaluation and collection of care outcomes E3.3; E8.3; E9.11	Annual RCA of audit findings	
Documentation and data collection	B9.1	Information management E1.1; E3.11; E5.5	Quarterly report of % data reported to CIBMTR	
	C8.9		Quarterly report of % daily assessments completed	
Collection of feedback from sites, donors, and legal representatives	B4.16.1	Participation in identification and collection of care outcomes E2.2; E3.7	Quarterly report of feedback	
	B4.16.2			
	C4.16.1			
Staff education of and compliance with labelling of cellular therapy product	C7.2.6	Clinical leadership for patient-care practices and delivery E5.4; E8.4	% compliance with labelling requirements, periodic audit during stem cell harvesting procedures	
	C7.4.3			
	C7.4.5			
Inventory control	C8.2.2	Stewardship and leveraging of human, environmental, and material resources E1.4; E5.6	Quarterly report of inventory review	

Table 1. Draft Scorecard Priority Criteria and CNL Competencies to Ensure Continuous Quality Improvement

The scorecard supports the dynamic nature of patient outcomes, allowing for ongoing evaluation and immediate intervention when patient wellbeing is threatened. When items in the scorecard indicate “not met” (red), the CNL stem cell transplant coordinator and multidisciplinary team are triggered to act urgently to resolve threats to patient wellbeing. For instance, a single instance of central line blood stream infection will trigger attention to accreditation criteria B.4.5.3.6, change the status to red (not met) and require the CNL stem cell transplant coordinator to complete an outcome analysis using a root cause analysis (RCA). While

completing the outcome analysis the status moves to yellow (in-progress). The CNL stem cell transplant coordinator will then convene a team meeting to share the outcome analysis findings, implement changes, and the status will return to green (met). The status column for scorecard measures that involve annual review will be set to unfilled (colorless) status at the beginning of the calendar year (or upon a set timeframe determined by the team) to indicate the need for reassessment. The item's status will become green once the item has been assessed unless changes occur, or deficiencies are identified. Quarterly reports will be reset to yellow status on January 1, April 1, July 1, and October 1 (or another date as determined by the team). In the event that the previous report was unresolved (yellow or red) at the end of the quarter, the current status will roll over with the addition of text that states "TBR (to be resolved" to trigger re-assessment. The status will turn to green (met) when the report is shared with team members. If the quarterly report finds that an accreditation standard was not met or patient wellbeing was compromised, the status will change to red and trigger the CNL stem cell transplant coordinator to complete an RCA and disseminate the findings with the team so interventions can be developed.

Proposed Implementation and Evaluation.

The CNL actively participates in continuous assessment, implementation, and evaluation of accreditation requirements as described in the adapted draft scorecard (see Table 1). The stem cell transplant center care team convenes every other month to review accreditation progress. The adapted draft scorecard proposed here will serve as a starting point for assessment of accreditation status. Continuous evaluation and revisions of the tool will reflect reassessment of problems and potential solutions.

Summary

CNL Roles

The scholarly project discussed here places the CNL in a role that utilizes the full breadth of their knowledge and competencies as outlined by the AACN (2013) to support organizational accreditation. The CNL is uniquely positioned to affect positive change in organizational quality and accreditation success in a stem cell transplant center. In particular, the CNL stem cell transplant center coordinator fulfills the functions of clinical leadership, participation in and accountability for improvement of care outcomes, and team leadership.

As coordinator of the stem cell transplant program, the CNL acts as an expert clinician in the transplant process while participating in, and leading, continuous quality improvement. The CNL will access the relevant data to monitor and evaluate program effectiveness through tracking and analysis of patient care outcomes. The completion of chart audits and root cause analyses to articulate outcomes and trends supports identification of system needs. The CNL assists in the fulfillment of accreditation standards for outcome analysis while supporting the provision of quality patient care through improvement science and resolution of practice gaps. Review of policies and procedures supports evidence-based care and minimization of errors. As team leader, the CNL supports multidisciplinary staff education, collaboration, and communication.

Next Steps

The center is awaiting a final determination from FACT regarding successful re-accreditation. Regardless of the accreditation outcome, the next steps in the stem cell transplant center's efforts to provide quality patient care require the implementation of the draft scorecard

alongside the newly hired oncology certified CNL stem cell transplant coordinator. The proposed scorecard monitors client-based improvement measures and guides accreditation success. The CNL, equipped with their education and skill set, will utilize the scorecard to address accreditation deficiencies, modify the scorecard to mitigate newly identified areas of concern, and prepare for the next accreditation renewal cycle. After six months the CNL stem cell transplant coordinator and team will evaluate progress of the scorecard to determine tool efficacy and plans for the future.

REFERENCES CITED

American Association of Colleges of Nursing (AACN). (2007). *White paper on the education and role of the Clinical Nurse Leader.* Washington, DC; Author. https://www.aacnnursing.org/Portals/42/News/White-Papers/CNL-Competencies-October-2013.pdf

American Association of Colleges of Nursing (AACN). (2013). *Competencies and curricular expectations for Clinical Nurse Leader education and practice.* Washington, DC; Author. https://www.aacnnursing.org/Portals/42/News/White-Papers/CNL-Competencies-October-2013.pdf

Agency for Healthcare Research and Quality (AHRQ). (n.d.). *Balanced scorecard.* Digital Healthcare Research. https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/balanced-scorecard

Araujo, C.A.S., Siqueira, M.M., & Malik, A.M. (2020). Hospital accreditation impact on healthcare quality dimensions: A systematic review. *International Journal for Quality in Health Care*, *32*(8), 531-544. https://doi.org/10.1093/intqhc/mzaa090

Azagury, D. & Morton, J.M. (2016). Bariatric surgery outcomes in US accredited vs non-accredited centers: A systematic review. *Journal of the American College of Surgeons, 223*(3), 469-477. https://doi.org/10.1016/j.jamcollsurg.2016.06.014

Baker, J.D. (2015). Language of improvement: Metrics, key performance indicators, benchmarks, analytics, scorecards, and dashboards. *Association of periOperative Registered Nurses Journal*, *102*(3), 223-227. https://doi.org/10.1016/j.aorn.2015.07.015

Bender, M. (2016). Clinical Nurse Leader integration into practice: Developing theory to guide best practice. *Journal of Professional Nursing*, *32*(1), 32-40. https://dx/doi/org/10.1016/j.profnurs/2015.06.007

Bender, M., Murphy, E., Cruz, M., Ombao, H. (2019a). System- and unit-level care quality outcome improvements after integrating Clinical Nurse Leaders into frontline care delivery. *Journal of Nursing Administration*, *49*(6), 315-322. https://doi.org/10.1097/NNA.0000000000000759

Bender, M., Spiva, L., Su, W., & Hites, L. (2017). Organizing nursing practice into care models that catalyse quality: A Clinical Nurse Leader case study. *Journal of Nursing Management, 26*, 653-662. https://doi.org/10.1111/jonm.12596

Bender, M., Spiva, L., Patrick, S., Meffert, S., Moton, L., Clarke, S., Mathis, K., Leclerc, L., Knotts, K., & Mount, A. (2019b). Clinical Nurse Leader knowledge production to quality improvement in a seamless trajectory. *Journal of Nursing Care Quality*, *34*(4), 301-306. https://doi.org/10.1097.NCQ.0000000000000386

Bender, M., Williams M., Su, W., & Hites, L. (2016a). Clinical Nurse Leader integrated care delivery to improve care quality: Factors influencing perceived success. *Journal of Nursing Scholarship, 48*(4), 414-422. https://doi.org/10.1111/jnu.12217

Bender, M., Williams, M., Su, W., & Hites, L. (2016b). Refining and validating a conceptual model of Clinical Nurse Leader integrated care delivery. *Journal of Advanced Nursing, 73*(2), 448-464. https://doi.org/2010.1111/jan.13113

Bogh, S.B., Falstie-Jensen, A.M., Hollnagel, E., Holst, R., Braithwaite, J., Johnsen, S.P. (2016). Improvement in quality of hospital care during accreditation: A nationwide stepped-wedge study. *International Journal for Quality in Health Care, 28*(6), 715-720. https://doi.org/10.1093/intqhc/mzw099

Center for International Blood and Marrow Transplant Research. (December 12, 2018). *Transplant activity report covering 2013-2017.* https://bloodstemcell.hrsa.gov/data/donation-and-transplantation-statistics/transplant-activity-report

Cornish, J.M. (2008). JACIE accreditation in paediatric haemopoietic SCT. *Bone Marrow Transplantation, 42*, S82-S86. https://doi.org/10.1038/bmt.2008.290

Desveaux, L., Mitchell, J.I., Shaw, J., Ivers, N.M., Understanding the impact of accreditation on quality in healthcare: A grounded theory approach. *International Journal for Quality in Health Care*, *29*(7), 941-947. https://doi.org/10.1093/intqhc/mzx136

Estrella, J. M., Sullivan, H., Febryani, I., Vaughn, J., Villamin, C., & Bowman, G. (2018). Clinical Nurse Leader: Evolution of the role in oncology care. *Clinical Journal of Oncology Nursing*, *22*(4), 457–459. https://doi.org/10.1188/18.CJON.457-459

Facility X. (n.d.) Cancer Center mission.

Facility X. (2012). Hematopoietic progenitor cell infusion following high dose chemotherapy policy.

Facility X. (2016a). Autologous HSCT high-dose chemotherapy policy.

Facility X. (2016b). Hematopoietic stem cell transplantation program description policy.

Facility X. (2016c). Recovery and long-term follow up care within the HSCT program policy.

Foundation for the Accreditation of Cellular Therapy (FACT). (2020a). *About FACT.* http://www.factwebsite.org/AboutFACT/

Foundation for the Accreditation of Cellular Therapy (FACT). (2020b). *Why you should become a FACT accredited organization.* http://www.factwebsite.org/Accreditation/

Foundation for the Accreditation of Cellular Therapy (FACT). (2020b). *Establishing global standards in cellular therapies.* http://www.factwebsite.org/Standards/

Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee-ISCT and EBMT (JACIE). (2018). *FACT-JACIE international standards for hematopoietic cellular therapy product collection, procession, and administration* (7th Ed). http://www.factwebsite.org/ctstandards/.

Godfrey, M.M., Nelson, E.C., Wasson, J.H., Mohr, J.J., & Batalden, P.B. (2003). Microsystems in health care: Part 3. planning patient-centered services. *Joint Commission Journal on Quality and Safety, 29*(1), 159-170. https://clinicalmicrosystem.org/uploads/documents/JQIPart3.pdf

Heinen, M., van Oostveen, C., Peters, J., Vermeulen, H., & Huis, A. (2019). An integrative review of leadership competencies and attributes in advanced nursing practice. *Journal of Advanced Nursing, 75,* 2378-2392. https://doi.org/10.1111/jan.14092

Jepsen, S. (2015). Using a scorecard to demonstrate clinical nurse specialists' contributions. *AACN Advanced Critical Care, 26*(1), 43-49. https://doi.org/ 10.1097/NCI.0000000000000066

Kaack, L., Bender, M., Finch, M., Borns, L., Grasham, K., Avolio, A., Clausen, S., Terese, N.A., Johnstone, D., & Williams, M. (2018). A Clinical Nurse Leader (CNL) practice development model to support integration of the CNL role into microsystem care delivery. *Journal of Professional Nursing, 34*(1), 65-71. https://doi.org/10.1016/j.profnurs.2017.06.007

LeMaistre, C.F., Wacker, K.K, Akard, L.P., Al-Homsi, A.S., Gastineau, D.A., Godder, K., Lill, M., Selby, G.B., Steinberg, A., Anderson, J.M., Leahigh, A.K., Warkentin, P.I. (2019). Integration of publicly reported center outcomes into standards and accreditation: The FACT model. *Biology of Blood and Marrow Transplantation, 25,* 2243-2250. https://doi.org/10.1016/j.bbmt.2019.06.035

McGowan, K. (2016). Physical exercise and cancer-related fatigue in hospitalized patients: Role of the Clinical Nurse Leader in implementation of interventions. *Clinical Journal of Oncology Nursing, 20*(1), E20-E27. https://doi.org/ 10.1188/16.CJON.E20-E27

Merriam-Webster. (n.d.). *Apheresis.* https://www.merriam-webster.com/dictionary/apheresis

Miltner, R., Haddock, K.S., Patrician, P., Williams, M. (2020). Implementation of the Clinical Nurse Leader role in the Veterans Health Administration. *Nursing Administration Quarterly, 44*(3), 257-267. https://doi.org/10.1097/NAQ.0000000000000428

National Cancer Institute. (September 25, 2020). *Cancer Statistics.* https://www.cancer.gov/about-cancer/understanding/statistics#:~:text=%20Statistics%20at%20a%20Glance%3A%20The%20Burden%20of,colorectal%20cancers%20account%20for%20an%20estimated...%20More%20

Neuman, B., & Fawcett, J. (Eds.). (2011). *The Neuman systems model* (5th ed.). Prentice Hall.

Noles, K., Barber, R., James, D., & Wingo, N. (2019). Driving innovation in health care: Clinical Nurse Leader role. *Journal of Nursing Care Quality, 34*(4), 307-311. https://doi.org/10.1097/NCQ.0000000000000394

Office of Disease Prevention and Health Promotion. (n.d.-a). Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis—C-11. *Healthy People 2030.* U.S Department of Health and Human Services. https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-cancer-survivors-who-are-living-5-years-or-longer-after-diagnosis-c-11

Office of Disease Prevention and Health Promotion. (n.d.-b). Increase quality of life for cancer survivors—C-R01. *Healthy People 2030*. U.S Department of Health and Human Services. https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-quality-life-cancer-survivors-c-r01

Office of Disease Prevention and Health Promotion. (2018*).* Healthy People 2030 framework. *Healthy People 2030*. U.S Department of Health and Human Services. https://health.gov/healthypeople/about/healthy-people-2030-framework

Ott, K.M., Haddock, K.S., Fox, S.E., Shinn, J.K., Walters, S.E., & Hardin, J.W. (2009). The Clinical Nurse Leader: Impact on practice outcomes in the Veterans Health Administration. *Nursing Economics, 27*(6), 363-370. https://msu-primo.hosted.exlibrisgroup.com/permalink/f/rbfqn8/TN_cdi_proquest_miscellaneous_734221815

Phillips, S., Swiger, P.A., Flores, R., Clutter, P, & Reineck, C. (2012). Clinical Nurse Leader: Emerging role to optimize unit level performance. *U.S. Army Medical Department Journal, 10,* 77-83. https://msu-primo.hosted.exlibrisgroup.com/permalink/f/rbfqn8/TN_cdi_proquest_miscellaneous_1080643009

Roussel, L.A., Thomas, P.L., & Harris, J.L. (2018). Achieving excellence in CNL practice. In J.L. Harris, L.A. Roussel & P.L. Thomas (Eds.), *Initiating and sustaining the Clinical Nurse Leader role: A practice guide* (3rd ed., pp. 357-378). Jones & Bartlett Learning.

Salvador, P.T. (2005). Factors influencing the incidence and severity of oral mucositis in patients undergoing autologous stem cell transplantation. *Canadian Oncology Nursing Journal, 15*(1), 29-31. https://doi.org/10.5737/1181912x1512931

Salvador, P.T. (2006). Development of an oral care guide for patients undergoing autologous stem cell transplantation. *Canadian Oncology Nursing Journal, 16*(1), 18-21. https://doi.org/10.5737/1181912x1611820

Snowden, J.A., McGrath, E., Duarte, R.F., Saccardi, R., Orchard, K., Worel, N., Kuball, J., Chabannon, C., & Mohty, M. (2017). JACIE accreditation for blood and marrow transplantation: Past, present and future direction of an international model for healthcare quality improvement. *Bone Marrow Transplantation, 52*, 1367-1371. https://doi.org/10.1038/bmt.2017.54

Sotomayor, G. & Rankin, V. (2017). Clinical Nurse Leaders: Fulfilling the promise of the role. *MEDSURG Nursing, 26*(1), 21-24, 32. https://msu-primo.hosted.exlibrisgroup.com/permalink/f/rbfqn8/TN_cdi_proquest_miscellaneous_2125294582

Stanley, J.M., Gannon, J., Gabuat, J., Hartranft, S., Adams, N., Mayes, C., Shouse, G.M., Edwards, B.A., & Burch, D. (2008). The Clinical Nurse Leader: A catalyst for improving quality and patient safety. *Journal of Nursing Management, 16,* 614-622. https://doi.org/10.1111/j.1365-2834.2008.00899.x

Virginia Hospital & Healthcare Association. (2020). *Hospital quality and patient safety scorecard.* https://www.vhha.com/quality-patient-safety/scorecard/

Williams, M., Avolio, A.E., Ott, K., & Miltner, R.S. (2016). Promoting a strategic approach to Clinical Nurse Leader practice integration. *Nursing Administration Quarterly, 40*(1), 24-32. https://doi.org/10.1097/NA.0000000000000143

Wong, C.A., Cummings, G.G., & Ducharme, L. (2013). The relationship between nursing leadership and patient outcomes: A systematic review update. *Journal of Nursing Management, 21*, 709-724. https://doi.org/10.1111/jonm.12116

APPENDICES

APPENDIX A

FACT STANDARDS IDENTIFIED AS CITATIONS AND VARIANCES

Citations received by the Clinical Site:

- B4.5.1 There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:
    - B4.5.1.1 Policies, protocols, Standard operating Procedures, and guidelines
    - B4.5.1.2 Worksheets
    - B4.5.1.3 Forms
    - B4.5.1.4 Labels
- B4.7.3 Review of outcome analysis and or/product efficacy shall include at a minimum:
    - B4.7.3.2 For immune effector cells, an endpoint of clinical function as approved by the Clinical Program Director.
    - B4.7.3.6 Central venous catheter infection
- B4.8.3 Audits shall include at a minimum:
    - B4.6.3.4 Annual audit of safety endpoints and immune effector cellular therapy toxicity management
- B4.16 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback
    - B4.16.1 Feedback shall be obtained from associated Collection and Processing Facilities
    - B4.16.2 Feedback shall be obtained from donors and recipients or legally authorized representatives
- B9.1 The Clinical Program shall collect all the data necessary to complete the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT
    - B9.1.1 Clinical programs shall submit the data specified in B9.1 to a national or international database if required by applicable laws and regulations.
    - B9.1.2 Clinical Programs should submit the data specified in B9.1 for allogeneic and autologous transplants to a national or international database
    - B9.1.3 Clinical Programs should collect the data specified in B9.1 for all patients for at least one (1) year following administration of the cellular therapy product

Variances received by the Clinical Site:

- B4.7.6 The Clinical Program should set benchmarks for non-relapsed mortality at one hundred (100) days after cellular therapy product administration and describe the rationale and process for review in the Quality Management Plan

Citations received by the Collection Site:

- C2.4 There shall be a written assessment of critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, or cross-contamination during collection
    - C2.4.2 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded
- C4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.
    - C4.5.3 The document control system shall include:
        - C4.5.3.8 A system for the retraction of obsolete documents to prevent unintended use
- C4.6 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements
- C4.10 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:
    - 4.10.4 Reporting
        - 4.10.4.1 When it is determined that a cellular therapy product has resulted in an adverse reaction, the event and results of the investigation shall be reported to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws and regulations
- C4.14 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.
    - C4.14.2 Significant changes to critical procedures shall be validated and verified as appropriate
- C4.15 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.
- C4.16 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback
    - C4.16.1 Feedback shall be obtained from associated Clinical Programs and Processing Facilities
- C4.17 The Apheresis Collection Facility Director or designee shall review the Quality management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.

    - C4.17.3 The Apheresis Collection Facility Director or designee shall now have oversight of his/her own work if this person also performs other tasks in the Apheresis Collection Facility
- C4.18 The Apheresis Collection Facility Director or designee shall annually review the effectiveness of the Quality Management Program
- C7.2 LABELING OPERATIONS
    - C7.2.6 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents
- C7.4 LABEL CONTENT
    - C7.4.3 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II
    - C7.4.5 A cellular therapy product collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documentation table in Appendix Vi at the time it leaves the control of the Apheresis Collection Facility
- C8.2 There shall be a process for inventory control that encompasses equipment, supplies, reagents, and labels
    - 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
- C8.9 There shall be written documentation of a daily assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedures

(Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee-ISCT and EBMT [FACT-JACIE], 2018)

APPENDIX B

CLINICAL NURSE LEADER (CNL) COMPETENCIES IDENTIFIED IN SCORECARD

The Master's Essentials and Clinical Nurse Leader Competencies:

- Essential 1: Background for Practice from Sciences and Humanities
    - 1.1: Interpret patterns and trends in quantitative and qualitative data to evaluate outcomes of care within a microsystem and compare to other recognized benchmarks or outcomes, e.g. national, regional, state, or institutional data.
    - 1.4: Integrate knowledge about social, political, economic, environmental, and historical issues into the analysis of and potential solution to professional and healthcare issues.
- Essential 2: Organizational and Systems Leadership
    - 2.2: Assume a leadership role of an interprofessional healthcare team with a focus on the delivery of patient-centered care and the evaluation of quality and cost-effectiveness across the healthcare continuum.
    - 2.6: Evaluate the efficacy and utility of evidence-based care delivery approaches and their outcomes at the microsystem level.
    - 2.7: Collaborate with healthcare professionals, including physicians, advanced practice nurses, nurse managers and others, to plan, implement and evaluate an improvement opportunity.
- Essential 3: Quality Improvement and Safety
    - 3.1: Use performance measures to assess and improve the delivery of evidence-based practices and promote outcomes that demonstrate delivery of higher-value care.
    - 3.3: Use evidence to design and direct system improvements that address trends in safety and quality.
    - 3.4: Implement quality improvement strategies based on current evidence, analytics, and risk anticipation.
    - 3.5: Promote and culture of continuous quality improvement within a system.
    - 3.7: Demonstrate professional and effective communication skills, including verbal, non-verbal, written, and virtual abilities.
    - 3.11: Use a variety of datasets…appropriate for the patient population, setting, and organization to assess individual and population risks and care outcomes.
- Essential 4: Translating and Integrating Scholarship into Practice
    - 4.1: Facilitate practice change based on best available evidence that results in quality, safety, and fiscally responsible outcomes.
    - 4.3: Implement strategies for encouraging a culture of inquiry within the healthcare delivery team.
    - 4.4: Facilitate the process of retrieval, appraisal, and synthesis of evidence in collaboration with healthcare team members, including patients, to improve care outcomes.
    - 4.7: Lead change initiatives to decrease or eliminate discrepancies between actual practices and identified standards of care.
- Essential 5: Informatics and Healthcare Technologies

- 5.1: Use information technology, analytics, and evaluation methods to:
    a. collect or access appropriate and accurate data to generate evidence for nursing practice;
    b. provide input in the design of databases that generate meaningful evidence for practice;
    c. collaborate to analyze data from practice and system performance;
    d. design evidence-based interventions in collaboration with the health professional team;
    e. examine patterns of behavior and outcomes; and
    f. identify gaps in evidence for practice
- 5.4: Use technologies and information systems to facilitate the collection, analysis, and dissemination of data including clinical, financial and operational outcomes.
- 5.5: Use information and communication technologies to document patient care, advance patient education, and enhance accessibility of care.
- 5.6: Participate in ongoing evaluation, implementation, and integration of healthcare technologies, including the electronic health record (EHR).

- Essential 6: Health Policy and Advocacy
    - 6.1: Describe the interaction between regulatory agency requirements, (such as The Joint Commission (TJC), Centers for Medicare and Medicaid (CMS), or Healthcare Facilities Accreditation Program (HFAP)), quality, fiscal, and value-based indicators.
- Essential 7: Interprofessional Collaboration for Improving Patient and Population Health Outcomes
    - 7.1: Create an understanding and appreciation among healthcare team members of similarities and differences in role characteristics and contributions of nursing and other team members.
    - 7.3: Facilitate collaborative, interprofessional approaches and strategies in the design, coordination, and evaluation of patient-centered care.
    - 7.4: Facilitate the lateral integration of healthcare services across the continuum of care with the overall objective of influencing, achieving and sustaining high quality care.
    - 7.5: Demonstrate a leadership role in enhancing group dynamics and managing group conflicts.
    - 7.6: Facilitate team decision making through the use of decision tools and convergent and divergent group process skills, such as SWOT, Pareto, and brainstorming.
    - 7.7: Assume a leadership role, in collaboration with other interprofessional team members, to facilitate transitions across care settings to support patients and families and reduce avoidable recidivism to improve care outcomes.
- Essential 8: Clinical Prevention and Population Health for Improving Health
    - 8.3: Monitor the outcomes of comprehensive plans of care that address the health promotion and disease prevention needs of patient populations.

    - 8.4: Apply public health concepts to advance equitable and efficient preventive services and policies that promote population health.
    - 8.6: Use epidemiological, social, ecological, and environmental data from local, state, regional, and national sources to draw inferences regarding the health risks and status of populations, to promote and preserve health and healthy lifestyles.
    - 8.8: Provide leadership to the healthcare team to promote health, facilitate self-care management, optimize patient engagement and prevent future decline including progression to higher levels of care and readmissions.
- Essential 9: Master's-Level Nursing Practice
    - 9.11: Design appropriate interventional using surveillance data and infection control principles to limit healthcare acquired infections (HAI) at all points of care).
    - 9.14: Evaluate the care of at-risk populations across the lifespan by identifying and implementing programs that address specialized needs.

(American Association of Colleges of Nursing [AACN], 2013, p. 9-21)