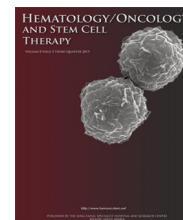


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Practical implementation – Essential elements resource tool

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KEYWORDS

Stem cell transplantation;
Quality management system;
Accreditation

Abstract

Hematopoietic stem cell transplantation (HSCT) is an established treatment for patients with severe congenital or acquired hemato-/oncological disorders. Despite major improvements, HSCT remains associated with substantial morbidity and mortality. Implementation of a quality management system has become standard practice not only for industries when their products or services are associated with significant risks to human safety but also in the healthcare sector. The use of a quality management system contributes to better products and services and improved patient's outcome after medical interventions. Members of the Alliance for Harmonization of Cellular Therapy Accreditation prepared the document *Essential Elements*, which is intended to serve as a guide for establishing a quality program for new or developing HSCT programs. It is intended for use as a resource and does not contain the full requirements of all standards but seeks to provide clear examples of compliance to support basic quality system elements. The content is based on common elements found in already existing standards with a major focus on the establishment of a quality program that applies to the entire transplant program. *Essential Elements* is structured as an explanation helping to understand the intent of the element giving guidance what is needed, and examples showing how the element applies. Centers seeking accreditation are subjected to a detailed document review, on-site inspection and follow-up procedure. In conclusion, new and developing stem cell transplantation programs should focus on quality and safety and step on the path towards full accreditation. The HSCT community must continue its efforts to offer education and training to support developing programs to attain accreditation.

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Introduction

Hematopoietic stem cell transplantation (HSCT) is an established treatment for patients with severe congenital or acquired hemato-/oncological disorders. Approximately 41,000 HSCTs in about 36,500 patients (43% allogeneic, 57% autologous) were reported to the European Society for Blood and Marrow Transplantation (EBMT) in 2014 by 656 centers in 47 countries. A continued growth in transplant activity especially in Eastern European countries and an increase in the use of haploidentical family donors and growth for unrelated donor HSCT contribute to this activity [1]. But despite major improvements, HSCT remains associated with substantial morbidity and mortality [2–5]. The use of a quality management system contributes to better products and services and improved patient outcome after medical interventions and not least of all, raises consumers' trust [6–8]. As a consequence, quality management has become an essential component of today's management strategies, not only for industries but also in the healthcare sector, leading to increased safety and reduced costs [6,9–11]. First introduced about two decades ago in hospital pharmacies and laboratories [12], quality management has altered previously established mechanisms, induced structural changes and promoted high quality organizational processes [6].

HSCT in particular requires the close cooperation of different healthcare professionals and presents an example to assess the value of a quality management system in a medical setting. This system defines infrastructures, responsibilities, training of personnel, equipment, release of products or services, and acceptable criteria for admission and discharge, and requires implementation of standard operating procedures and continuous improvement strategies as key elements [6,9–11]. However, new or developing centers experience problems in establishing a quality management system especially if they are located in low- to middle-income economies. In this context, the Alliance for

Harmonization of Cellular Therapy Accreditation prepared a document entitled *Essential Elements*, which is intended for use as a resource tool for these target programs. It does not contain the full requirements of all applicable standards but seeks to provide clear examples of compliance and additional detail to support the elements making up a basic quality system.

Essential elements cells and tissues for administration

This document can be found on the Alliance for Harmonization of Cellular Therapy Accreditation homepage (<http://www.ahcta.org/>) and covers 14 main topics including education and promotion, program organization, facility requirements, quality management, policies and procedures, donor issues, process controls, coding and labeling, product-related issues such as release and distribution, storage, transportation, shipping, and receipt, disposal, data management and records. The main topics are further divided into several subtopics.

The structure of the document is based on three principles. The column "explanation" helps the reader to understand the intent of the element, the description of "process elements" gives guidance what is needed, and the provided examples show how the element applies. The content is based on common elements found in already existing standards with a major focus on the establishment of a quality program that should apply to the entire transplant program including clinical, collection, and processing facility. The ultimate goal is to establish a program that meets requirements in standards and attains accreditation.

Education and promotion

To promote optimal use of cells and tissues, healthcare professions must first be appropriately educated and trained. The public must be made aware of the value of cell and

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