

Essential Elements: A Guide For Establishing a Complete Quality Program. Cells & Tissues for Administration

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Purpose

- List essential elements of quality required for a BMT program
 - Explain intent
 - Describe Quality Element
 - Provide Examples
- Preparatory to attaining accreditation
- Best to apply essential elements from time of initiation to full accreditation

Background

- Assigned by WBMT to AHCTA as a draft Aide-Memoire in 2010 with instruction to complete as a freely available resource
- Developed and reviewed by AHCTA subcommittee
- Reviewed by AHCTA Donor Committee
- Finalized and posted to AHCTA website May 2013
- Links established from WBMT participating organizations
- Dynamic document subject to periodic review and updating

Main Headers

- Education and promotion
- Program organization
- Facility and staffing requirements
- Quality Management
- Policies and Procedures
- Donor Issues
- Process Control
- Coding and Labeling
- Product release/distribution
- Product storage
- Product transportation
- Product disposal
- Data management, registry reporting, outcomes assessment
- Records

Quality Management

- Organization and responsible individuals
- Quality Plan
- Personnel
 - Training
 - Competency
 - Continuing education
- Define critical processes, policies, and procedures
- Document control
- Agreements
- Audits and assessments
- Errors, accidents, biological product deviations, adverse events
- Process improvement plan
- Interruption of operations and disaster plans

Format Example

1. Education and promotion

1.1. Healthcare professionals

Explanation	Process Elements	Examples
<p>In order to promote optimal use of cells and tissues (cellular therapy), which are a true national resource, healthcare professionals must first be educated as to need.</p>	<p>Develop policies and procedures for education and training of healthcare professionals in optimal use of cells and tissues for administration and how to encourage donors.</p>	<ul style="list-style-type: none"> • Plan educational activities for healthcare professionals and clinicians in use of cells and tissues for cellular therapy • Liaise with clinical programs treating patients that might benefit from cellular therapy • Collect data to monitor progress in use of the national resource of cell and tissue donation • Collect data to monitor success of educational programs in increasing donations

1.2. Public campaigns

Explanation	Process Elements	Examples
<p>The public must be made aware of the value of cell and tissue donation to overall public health and the importance that such donations be voluntary without expectation for remuneration</p>	<p>Establish campaigns to promote voluntary non- remunerated cell and tissue donation as an act of altruism.</p>	<ul style="list-style-type: none"> • Ensure policies and procedures indicate voluntary and non-remunerated donation • Hold public educational seminars (e.g. schools, colleges, universities, other professional bodies) • Use social media such as Facebook, YouTube, or Twitter, to create population awareness

Example #2

1. Data Management, registry reporting, outcomes assessment

Explanation	Process Elements	Examples
<p>Data Management, Registry reporting, Outcomes assessment</p> <p>Management of data related to cellular therapy is an important element of good clinical care and investigation. Outcome analysis is a requirement of the Quality System for the clinical program, and to measure outcomes data from each patient must be collected. Programs contributing to transplant registries (e.g. CIBMTR, EBMT, APBMT) are familiar with data reporting elements required by these registries. Such forms are excellent starting points for programs to determine what data elements should be collected and assessed. Data management should be part of every program from the beginning, since it is easier to capture information in real time rather than retrospectively.</p>	<p>A process should be in place for collection of data sufficient for evaluation of cellular therapy administration outcome. Data collection should include minimal elements required by registries such as CIBMTR or EBMT.</p>	<p>A process for data management is established and minimally includes:</p> <ul style="list-style-type: none"> • Collection of data from each use of cellular therapy products to include that minimally required by established transplant registries (e.g. CIBMTR) • Regular assessment of cellular therapy administration outcomes including overall survival and non-relapse mortality at day 100 and 1 year, and time to engraftment of neutrophils and platelets



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Documents

Title	Updated	Link
Mission statement		
Towards a Global Standard for Donation, Procurement, Testing, and Distribution of HSC and Related Cellular Therapies Position Paper (revised 27 May 2008)	27-05-2008	
Essential Elements - Cells & Tissues for Administration This document is intended for use as a resource for new or developing programs. It does not contain the full requirements of standards but seeks to provide clear examples of compliance and additional detail to support basic quality system elements.	14-05-2013	