



مستشفى الملك فيصل التخصصي ومركز الأبحاث
King Faisal Specialist Hospital & Research Centre
مؤسسة عامة Gen. Org.

Workshop VII: Creating a Quality System that Works

Practical implementation – Essential elements resource tool

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Essential elements






- Serve as a guide for establishing a **complete quality program** for a stem cell transplantation program.

- AHCTA

- document for use as a resource for **new or developing programs**
- does not contain the full requirements of standards **but**
- provide clear **examples** of compliance to support basic quality system elements

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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	
2016-05-05 Quality Terminology English/Portuguese translation	05-05-2016	
2016-01-21 Quality Terminology English/Spanish translation -basic terminology to assist in raising awareness and understanding about quality in transplantation	05-02-2016	
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	

Purpose of Essential Elements

- Created as a tool to help developing HCT programs to attain accreditation
- Does not replace accreditation or set a lower standard
- Defines the minimal essential elements of quality required for a new program
 - explains the intent
 - describes process elements
 - and provides examples
- Provide a foundation on which to build a quality system
- Establish a program that meets requirements in standards and attains accreditation

Content of Essential Elements

- Based on elements found in existing standards (AABB, FACT, JACIE, EFI,...)
- Major focus: establishment of a **quality program** that should apply to the entire transplant program (clinical, collection, and processing facility).
- Structure of the document Essential Elements:
 - Explanation: helps to understand the intent of the element
 - Process Elements: gives guidance what is needed
 - Examples: show how the element applies

Main Topics

1. Education and promotion
2. Program organization
3. Facility and staffing requirements
4. Quality Management
5. Policies and Procedures
6. Donor Issues
7. Process Control
8. Coding and Labeling
9. Product release/distribution
10. Product storage
11. Product transportation, shipping, receipt
12. Product disposal
13. Data management, registry reporting, outcomes assessment
14. Records

More in detail.....

Education and promotion

- Healthcare professionals
- Public campaigns

Program organization

- Identify regulatory requirements
- Program structure
- Program Leadership

Facility requirements and staffing

- Clinical program
 - Clinical treatment facilities
 - Clinical requirements for physicians, mid-level practitioners, nurses, consultants
- Collection
 - Collection facility requirements
 - Requirements for collection staff
- Processing/Laboratory
 - Processing facility requirements
 - Requirements for processing staff

More in detail.....

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

Policies and Procedures

- Creation, Approval, Implementation
- Required procedures

Donor Issues

- Donor recruitment
- Donor selection and evaluation
 - Suitability and eligibility
 - HLA matching for allogeneic donors
- Consents and confidentiality
- Donor safety and follow-up

More in detail.....

Process Controls

- Process and procedure validation
- Materials Management
- Product collection and processing
 - Physician orders
 - Prevention of contamination and cross-contamination
 - Product sampling and testing
 - Records, including lot records
- Equipment use and maintenance
- Therapy Administration
 - Preparative regimens
 - Patient consent

- Physician orders
- Product administration
- Patient safety

Coding and Labeling

- Naming systems & product identification
- Labeling operations
- Label Content

Product release/distribution

- Release criteria
- Exceptional release, urgent medical care
- Accompanying documents

More in detail.....

Product storage

- Temperature and duration
- Safety and security
- Monitoring and alarms
- Inventory control

Product transportation, shipping, and receipt

- Within program facilities
- Between facilities

Product disposal

Data Management, registry reporting, outcomes assessment

Records

- General requirements for all records
- Electronic records

Examples of Essential Elements

1. Education and promotion

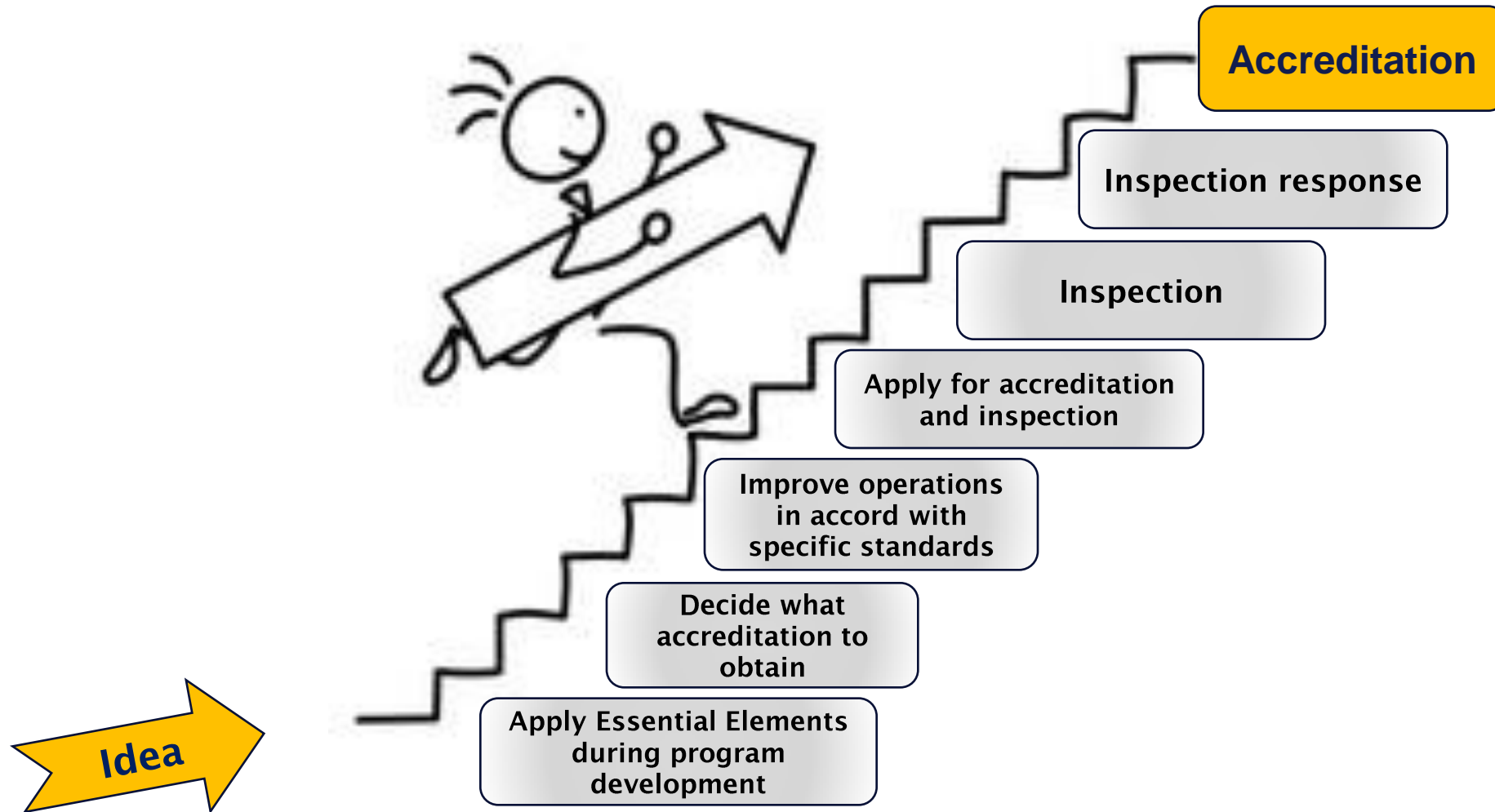
1.1. Healthcare professionals

Explanation	Process Elements	Examples
In order to promote optimal use of cells and tissues (cellular therapy), which are a true national resource, healthcare professions must first be educated as to need.	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.	<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
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	Establish campaigns to promote voluntary non- remunerated cell and tissue donation as an act of altruism.	<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

From the idea to accreditation









ahcta

**alliance for harmonisation of
cellular therapy accreditation**

<http://www.ahcta.org/index.html>

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