CREATING A QUALITY SYSTEM THAT WORKS

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Session Outline

- Overview and principles of a quality management system
- Summary of standards and accreditation organizations in HCT
- Practical implementation: Using the essential elements resource tool
- Where do we start?
  - Success stories in accreditation
  - Open discussion of challenges and benefits

CREATING A QUALITY MANAGEMENT SYSTEM

What is a quality management system?

- On overall and integrated plan describing how a program or organization plans, creates, develops and delivers its services or products, including managing its quality assurance activities, quality control, quality monitoring or assessments and improvement activities
  - Must be documented (captured in writing or electronically)
  - Describes each area's role and scope of service
  - Details how business functions are carried out
    - Policies and procedures
    - Contracts and agreements
    - Organization and personnel
    - Equipment and patient care
    - Other functions

ELEMENTS OF A QUALITY SYSTEM

Intended to apply to entire HCT program

Applies to cell processing laboratory, cord blood banks and ancillary services (HLA typing)

Must be documented

Organization

- Describes how program is structured including reporting structure
- Details management and leadership functions
- Lists personnel who direct and oversee program
- May be separate or part of parent facility/institution
  - If separate, should be integrated and connected in defined manner
- Some staff may have multiple functions reflected in organogram

Resources or Personnel

- Personnel – documented requirements
- Job descriptions
- Education and training requirements
- Competency assessments and retraining
- Facility and staffing requirements
- Written policies for each

Policies, Procedures and Document Control

- Documented policies and procedures for all activities
  - Donor selection and management, laboratory functions, nursing care, obtaining informed consent, transplant recipient management
- SOP for SOPs (format, supplies, expected results, references, etc)
- Documented process for policy and procedure development, review, approval, and revision
- Document tracking (numbering or revision history)
- How records are established, recorded, maintained and stored, including access to and confidentiality of records
- Record retention time and destruction

Process Control

- Addresses critical aspects of operations
- Ensures processes are under control (change is planned for and implementation is controlled)
- Includes process and procedure validation
  - Examples: Donor collection – method for evaluation and acceptance of apheresis equipment change
- Process improvement plan
- Interruptions of operations and emergency or disaster preparedness

Equipment, Supplies and Materials

- Defines selection criteria for equipment
- Use and maintenance
- Sanitation and policies to prevent cross contamination and mix up
- Records requirements, including validation and traceability of critical equipment
- Identification of critical supplies and materials
- Vendor qualification of suppliers
- Records of material receipt and utilization
- Labeling operations (receipt, usage and control of labels)
- Naming systems and identification of products

Assessments and Audits

- May be internal or external
- Includes procedure for reporting results of audits to leadership
  - Monitoring of engraftment (engraftment failure)
  - Tracking of patient outcomes against predetermined criteria
- Monitoring positive microbial results
- Tracking of medical errors

Product Storage, Release and Deviations

- Defined criteria and procedures to store products
  - Monitoring of temperature and storage conditions
  - Back up procedures for emergency power loss, etc.
- Defined criteria for release of products
- Exceptions to the procedure
- Accompanying documents and records
- Policies for product transport and shipping
- Patient monitoring during/after infusion
- Adverse events and serious adverse events
  - May apply to any part of transplant process
- How deviations are handled including errors and accidents

Facilities and Safety

- Policies and procedures to minimize risk to health and safety of: employees, donors, patients, volunteers
- Suitable facilities (design, space, hazards of biological and chemical items) including storage, intervention to mitigate exposure and discard of hazardous materials
  - Staff training on hazards, exposure and action
  - Documented training records of specific topics addressed
- Controls and monitoring of conditions
  - Controlled and limited access to restricted areas
  - Intended to prevent cross contamination
  - Notify key staff of impending situation in time to react and correct the situation (when possible)

Agreements

- Applies to other services (outsourced testing, collection facility, equipment)
- Promotional materials
- Medical or physician orders for collection or administration
- Informed consent
- Qualification and monitoring of suppliers (external companies or providers)
- Policy for recalls and notification of changes

Summary

- Quality is a work in progress
- Continuous opportunities for improvement
- Programs that have successfully implemented their Quality System have dedicated resources to the task and have started with the most critical, safety (donor and patient) related items first
- A fully implemented Quality System is a critical component of any successful program

References and Resources

- Wealth of information on the internet
- Sample quality plans
  - www.ahcta.org
  - Several standards setting organizations (AABB, FACT, JACIE, EFI, ASHI, etc.)
- Educational programs
  - Offered regularly by standards setting organizations and professional organizations

Thank you!