Webinar Presenters

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Objectives

• Explain the FACT requirements for reporting quality management activities to program and bank personnel

• Provide recommendations on how to effectively communicate process control details, quality assessment activities and results, and corrective actions to program and bank personnel
How QM Connects Everyone

QM Program

Marrow

Processing

Apheresis

Registry or Banked Products

Clinical
Purpose of Presenting QM Information

- Education
- Process Improvement
  - Corrective Actions
  - Evaluation
- Culture of quality
Educational Aspect of QM Reporting

- Increases awareness of quality principles and practices
- Examples of commonly misunderstood terms:
  - Validation: The confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a cellular therapy product meeting its predetermined specifications.
  - Verification: The confirmation of the accuracy of something or that specified requirements have been fulfilled.
  - Qualification: The establishment of confidence that reagents, supplies, and equipment function consistently within established limits.
When to Report

• Quarterly at a minimum
  – Can be more frequent, such as monthly or every two weeks
• Can be fit into program’s schedule as desired
  – Stand-alone quality management meetings
  – Staff meetings (program and facility meetings)
  – Cross-functional meetings (hospital meetings)
Who reports the information?

• Program Director/Facility Director or designee
  – Quality Management Supervisor
  – Team members

• Cross-functional reporting
  – Shared Quality Management Supervisor, if applicable
  – Directors of individual facilities or designated team members
Who should receive the information?

• Everyone!
  – Key personnel, including directors, supervisors, etc.
  – Staff-level employees

• Cross-functional sharing is important
  – For example, adverse events are important to collection and processing, too
Communication Channels

• Face-to-face meetings
  – Ideal for discussion and questions

• Written reports
  – Useful for noncontiguous institutions, programs with large numbers of staff-level employees, or programs with 24-hour operations

• Online
  – Real-time access can be useful for creating a culture of continuous improvement
How to Report Information

• Verbally
  – Explain why various audits, outcome analyses, etc. were conducted
  – Describe the process
  – Discuss the results and needed corrective actions

• Graphically
  – Pictures enhance understanding
  – Charts, tables, etc. allow for sharing of a large amount of data in efficient manner (see Assessment Results handout)

• Written
  – Provide a record of QM results
  – Assist with passing the information along to all program or bank personnel
Information to Report

• Process control details
  – New, revised, and archived SOPs
  – Development process
  – Training requirements (staff meetings, one-on-one training, etc.)
  – Implementation strategies
Information to Report

- Quality assessment activities
  - Outcome analysis
  - Audits
  - Positive microbial cultures
  - Qualification
  - Validation
  - Deviations (discussed in future webinar)
Information to Report

• Corrective actions
  – Suggestions for addressing problems identified during assessment activities
    • Group discussion and brainstorming is recommended for “thinking outside of the box”
  – Corrective action plan
  – Evaluation of past corrective actions
Information to Report

- Near-miss reporting system (recommended)
  - Prevent errors or accidents
  - Investigate and evaluate situation to avoid similar problems
  - Proactive measure
Feedback Loop

• Discuss how to address issues identified by quality management activities
• Identify who should be part of corrective actions
• Evaluate corrective actions and share conclusions with the group
  – Bring closure to issues
Quality Reporting is Continuous

- Factors that contribute to revisiting a quality process:
  - Change in process
  - Change in staff involved
  - Change in regulations
  - Change in reporting systems
Documentation of QM Reporting

• Usually cited due to lack of documentation
• Meeting minutes
  – Include list of attendees
• Written reports
  – Include who distributed and received the reports
  – Signatures
EXAMPLES OF QM REPORTING
Example 1: Quality of Care Committee

- Existing committee discusses wide range of care-related issues on a monthly basis
- FACT is a standing agenda item
  - Opportunity to provide updates regarding FACT Standards, audits, adverse events, etc.
- Good method of communicating to entire clinical team
  - Puts QM activities in context of patient care
- See handout for list of members and committee responsibilities
Example 2: Quality Management and Assurance Team

- Meets quarterly
- Membership consists of multi-disciplinary team
  - Transfusion medicine
  - Processing facility
  - Clinical program
  - Data managers
- Good way to promote cross-functional communication
- Focuses on quality management activities
- See handout for responsibilities
Examples of Reporting via Information Technology

• **Intranet**
  – Access to spreadsheets, reports, etc.

• **Email**
  – Distribute meeting minutes to personnel who do not attend in-person meetings

• **Dashboard databases**
  – Provides snapshot of quality management indicators
Example of Reporting an Audit Activity

Identify

Brainstorming potential audits with personnel found that the timing of pregnancy assessments is difficult.

Describe

Explain why the audit was planned and that you will be evaluating whether or not pregnancy assessments are completed within 7 days prior to mobilization.

Execute

Audit: Timing of Pregnancy Assessment

Assess

Notify personnel that the audit found a 95% success rate, and that failures were usually due to donors who lived far from the program.

Follow up

Discuss with personnel potential corrective actions to ensure pregnancy assessment within 7 days for donors at a distance and then re-audit.

If data must be requested from other personnel, state exactly what information you need.
Thank you for joining us today.

- This was the first session of the QM Series Module 3: Quality Management Reporting.
- Join us for the upcoming sessions in this module:
  - Self-assessments and Mock Audits Virtual Roundtable: June 10, 2011
  - Reporting QM Changes and Deviations Webinar: TBD (June or July)
- Join us for the upcoming inspection and accreditation workshops:
  - Cellular Therapy: May 18, 2011 in Rotterdam, the Netherlands
  - Cellular Therapy Collection: May 31, 2011 in Scottsdale, AZ
  - Cord Blood: June 26, 2011 in San Francisco, CA
Continuing Education Credit

• Registrants signing up for credit will receive instructions via email
  – If you did not sign up but wish to receive credit, contact FACT at fact@unmc.edu
QUESTION AND ANSWER SESSION
References

• **FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration, Fourth Edition, 2008**