Outcome Analysis

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Webinar Presenters

• Donna Salzman, MD
  University of Alabama
  Birmingham in Birmingham, AL USA

• Therese (Tracy) Dodd, BA, MBA, RN, CPHQ
  Medical College of Wisconsin in Milwaukee, WI USA

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OUTCOME ANALYSIS

Donna Salzman, MD and Therese (Tracy) Dodd, BA, MBA, RN, CPHQ
Presentation Outline

• Describe FACT requirements
• Explain the importance of communicating outcomes
• Outline the outcome analysis process
FACT REQUIREMENTS FOR OUTCOME ANALYSIS
FACT Definition of Outcome Analysis

“The process by which the results of a therapeutic procedure are formally assessed”

Results of Therapy
• Measure success of therapy using outcome metrics

Formal Assessment
• Thoughtful planning, data collection, evaluation, investigation, and follow-up
FACT Requirements for Outcome Analysis

✓ Inclusion of, or summarization and reference to, policies and procedures for outcome analysis in the QM Plan
  – Documentation
  – Review
  – Track
  – Evaluate
FACT Requirements for Outcome Analysis

✓ Implied requirements also includes reporting, investigation, and follow-up
  - Need to share data with others in the program
  - Need to investigate unexpected outcomes found during review and tracking
  - Need to follow requirements for errors, accidents, suspected adverse events, and biological product deviations as they are found
FACT Requirements for Outcome Analysis

✓ For HPC products, documentation and review of time to engraftment following administration

✓ For other products (i.e., therapeutic cells, HPCs for non-homologous use):
  – Determine criteria for product efficacy and/or the clinical outcome
  – Requires consultation with Clinical Program
  – Review at regular time intervals
FACT Requirements for Outcome Analysis

✓ Cord blood banks must make good faith effort to collect within specified timeframes:
  – Viability and cell yield results on thawed units
  – Adverse events associated with administration of units
  – Time to neutrophil and platelet engraftment
  – Survival rates
  – Chimerism and GVHD (allogeneic only)
  – Information regarding dual cord transplants and, if possible, which unit engrafted
Evidence of Compliance for Inspections

- QM Plan: for inclusion
- SOPs: for adequate process
- Reports: for review and analysis of data
- Meeting minutes: for information sharing
- Forms: for compliance to the SOP
- Corrective action plans and follow-up: for addressing unexpected outcomes
- Engraftment data: for data collection and tracking
IMPORTANCE OF COMMUNICATING OUTCOMES
Why Communication During Outcome Analysis is Important

• Outcome data originates with the Clinical Program
  – Collection Facilities, Processing Facilities, and Cord Blood Banks reliant on Clinical Programs to obtain data

• Poor outcomes can result during any step of the manufacturing and/or administration of products
  – All entities need to investigate the cause and participate in corrective actions
Inherent Difficulty of Communicating Outcomes and Analysis Results

Finding efficient method of obtaining and sharing outcome data (Clinical Programs)

Relying on someone else to obtain and share the data (sometimes includes multiple Clinical Programs)
Opportunities for Teamwork

• Data review and analysis
  – Independent analysis at each facility or bank is not required
• Reporting
• Investigation
• Regular Quality Management meetings:
  – Planning
  – Evaluation
  – Brainstorming potential causes of unexpected outcomes
  – Identification of needed corrective actions
Example Communication Structure

- Registry or Banked Products
  - Pediatric Clinical Program
    - Clinical Program
    - Marrow Collect
  - Apheresis Services
    - Blood Center
    - QI Program
  - Adult Clinical Program
    - Marrow Collect
    - Clinical Program

Cell Processing
Planning Outcome Analysis

• Start with direction provided in QM Plan and SOP
• Create forms to use as a guide
• Remember the difference between outcome variables and outcome metrics:
  – Variables: characteristics that may impact outcome, such as age, disease stage, product characteristics, etc.
  – Metrics: measures of outcome, such as time to engraftment, length of hospital stay, survival, etc.
• Define expected outcomes
  – Clinical Program is most qualified
Planning Outcome Analysis

- Definition of Expected Outcome
- Data Collection
- Data Sharing
- Data Review and Analysis
- Investigation of Unexpected Outcomes
- Corrective Actions When Indicated
- Follow-Up
Definition of Expected Outcome
Data Collection/Sharing
Data Review and Analysis
Investigate Unexpected Outcomes
Corrective Action Plans
Follow-Up
Outcome Analysis Plan - EXAMPLE

Potential Adverse Reaction Reporting

Expected Outcome: 100% Accurate and Complete Report to CPL 48 Hours of Infusion
Outcome Data Collection

- Mobilization with Perixafor
  - Ex. 1 How many pts collected a sufficient number of PRSC’s after a single mobilization?
    Increased from 80 to 85%
  - Ex. 2 How many high risk patients collected?
    Increased from 10 to 30%

- Identify what questions you want to answer
- Identify which data points need to be examined (consider variables when deciding metrics)
Outcome Data Collection: Perixafor

Low risk for mobilization failure

G-CSF Only:
On day __, if absolute CD 34 count is

Chemotherapy plus G-CSF:
On day + ?? AND WBC is ≥ __?__, if absolute CD 34 count is ???

High risk for mobilization failure
Non Myeloma patients:
Age> 59
Prior XRT to marrow sites (vertebral column, pelvis)
___ cycles of prior chemotherapy
Prior treatment with _______
Bone marrow involvement at BMT workup
All prior mobilization failures

Multiple Myeloma Patients:
___ months of treatment with _______
≥ 2 episodes of prior XRT

• Participation by multi-disciplinary team
• Consideration of variables:
  Disease Age WBC/CD34 counts
  Mobilization strategy Prior Therapy
• Determination of data points to be collected:
  Successful collection Number of collections required
• Determination of process for data collection
Sharing Outcome Data

- Communications
- Internal Program Reporting
- Clients/Payors
- Regulatory
Reviewing and Analyzing Outcome Data

• Collection is not enough – must analyze the data
• Ongoing analysis
• Should include analysis for the various products and transplant procedures performed
• Should include average (or median) and observed ranges
Investigating Outcome Data - EXAMPLE

Potential Adverse Reaction Reporting

Expected Outcome: 100% Accurate/Complete Report to CPL with 48 Hours of Infusion

Basic Root Causes:

- Practices are not the same as written procedures
- No or poor procedures
- Defective raw material (form design)
- Poor communication
- Training or education lacking
- Poor recognition of hazard
Implementing Corrective Actions

• Appropriate identification of problem (root cause analysis)

• Corrective Action Plans/PDSA Cycles
  – Corrective actions
    • Change in SOP
    • Education or retraining
Follow-Up

- Changes to policies or procedures
- Validation
- Re-evaluation (PDSA)
- Audit
Thank you for joining us today.

- This was the second session of the QM Series Module 2: Quality Assessment Activities.

- Join us for the upcoming sessions in this module:
  - Audit Webinar: April 20, 2010 at 2 pm ET
  - Virtual Roundtable, Example Assessment Programs: June 11, 2010

- Join us for the upcoming inspection and accreditation workshops:
  - Cellular Therapy: May 23, 2010 in Philadelphia, PA
  - Cellular Therapy Collection Facility: May 25, 2010 in New Orleans, LA
  - Cord Blood: June 6, 2010 in San Francisco, CA
Evaluations and Continuing Education Credit

- All inspectors can obtain CME/CNE certificates free of charge via the online Inspector Area.
- Program and bank personnel requesting CME/CNE credit can purchase credit for $20 via the FACT webinar web page.
- Evaluations will be distributed to participants not wishing to receive CME/CNE credit.
QUESTION AND ANSWER SESSION