



Tracking and Trending Adverse Events and Quality Issues

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Tracking and Trending Overview

- Current Processes for
 - Recipient Adverse Events (AE)
 - Donor AEs
 - Product-Related Quality Issues
- Future Plans



Current Processes: Recipient AEs

- Transplant Centers (TC): asked to report all serious AEs, independent of attribution, assoc. temporally w/product infusion or resulting in transmission of infx'ous diseases
- **Events:** For the last reporting quarter (4/1/13-6/30/13), 8 recipient AE reports were received, reviewed by a medical monitor: all 8 were expected, 6/8 were serious, no infectious diseases
- **Database:** NMDP retired QIF database in 2011 and moved to the FDA-compliant MasterControl (MC) system
 - Establishment of baseline rates in the MC system continues
- **Process:** Each reviewed AE which is serious or assoc with infxn transmission results in a MC query to look for similar events



Current Processes: Donor AEs

- Donor centers are asked to report any Grade 3 or greater AE, any serious, or any unexpected AE
- **Events:** *Serious* donor AEs are rare
 - For PBSC, the rate of SAEs is 0.6% (Pulsipher 2009); of the 15 described in the paper, **all were expected events**
 - From 4/1/13-6/30/13
 - No serious and unexpected events
 - 2 events reported to HRSA, both serious and expected
- **Process**
 - The TMS team and medical monitor review each AE report
 - Serious and/or unexpected AEs result in a CIBMTR data pull as needed (these are rare)

Current Processes: Quality Issues

- Annually, reports are generated for ACs and CCs looking for important trends that may indicate performance issues
- Apheresis Centers (HPC-A, Nucleated cell products)
 - Central line placement rate, citrate toxicity, product issues
- Collection Centers (HPC-M)
 - Nucleated cell concentration, marrow volume per donor weight, collection duration, product issues

Future Directions

- Additional reports using MasterControl incident management system data and QI Macros software are in development to enhance tracking and trending functionality for AEs and quality incidents
 - Prioritization of incident types by product for tracking and trending is ongoing
 - Implementation of QI Macros is underway