Use of Platelet Apheresis Software to Perform Product Qualification

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BACKGROUND

Various factors influence the outcome of platelet apheresis products that must comply with both regulatory and manufacturer's specifications for release. These products must meet both platelet concentration and volume parameters to meet requirements for labeling and ultimately transfusion. With the advent of splitting products into multiple units the activities associated with this process are very onerous. Multiple calculations must be performed to ensure products meet acceptable product specifications. Oklahoma Blood Institute implemented Platelet Manager™ software developed by Sigma Blood Systems in August 2008.

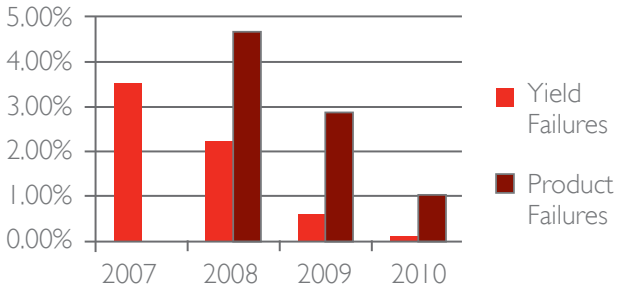
METHODS

A manual system for platelet apheresis product qualification was compared with a software program Sigma Blood Systems Platelet Manager™. This study compared product failure rates, manufacturing efficiency and resource requirements between the manual and software systems. Data was compared from the manual system for the period of July 2007 to August 2008 and the software system from August 2008 to March 2010.

RESULTS

Product quality control (QC) failure rates between the two systems were reviewed. This review showed that the QC failure rate decreased from 3.5% to an average of 0.1% while utilizing the software. Product failures decreased from 4.70% to 1.00% . The investigation activities associated with failed QC were also reduced.

Platelet Apherisis QC Failures



The number of FTEs and the tasks required to perform platelet manufacturing were reviewed. The comparison of this process revealed productivity increased by 40% utilizing the software. Prior to using Platelet Manager™ the time to process 25 units was 3 hours and 45 minutes. After the use of Platelet Manager™ and a staff reduction of 2 FTE's, the time to process 25 units was 1 hour and 30 minutes with a staff savings of $75,000.00 dollars annually.

CONCLUSION

The total number of platelet apheresis products prepared was compared between the manual system and Sigma Blood Systems Platelet Manager™. The manufacturing process required intensive calculations to determine products that should be made based on platelet concentration and product volume. This process required staff to first determine product criteria and then manipulate the base product into acceptable sub products. The Platelet Manager™ software provided electronic splitting information based on pre-established logic tiers that eliminated the need for manual calculations during the platelet apheresis product splitting activities. The software aided in the tracking of the process and workflow while providing a comprehensive audit trail of all activities. This comparison demonstrated that with the use of the software QC failures were reduced. Platelet yield failures were reduced from 3.50% to 0.10% and product failures were reduced from 4.70% to 1.00%. This demonstrated both an increased state of control of the platelet production processes and an increase in the number of products available for transfusion. Additionally, this comparison demonstrated that the use of Sigma Blood Platelet Manager™ increased productivity by 40% which reduced the number of FTE's required to perform these activities.

Oklahoma Blood Institute