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RESIDUAL RISK OF SEPTIC TRANSFUSION REACTIONS FROM BACTERIAL-TESTED APHERESIS PLATELETS

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Background: Bacterial testing of apheresis platelets using the BacT/ALERT[®] 3D (bioMérieux) automated culturing system was implemented in a large blood collecting organization. A sample was inoculated into an aerobic culture bottle at least 24 hours after collection. Culturing was continued until the end of product shelf-life or a positive reaction was indicated. Platelet products were released after a minimum of 12 hours. Products associated with a positive reaction were re-cultured; bacteria from those products and associated culture bottles were isolated for species identification.

Aims: To measure the rate of bacterial contamination in apheresis platelets and the residual risk of septic transfusion reactions from bacterial-tested apheresis platelets.

Methods: Systemwide bacterial testing data were collected and analyzed. Reports of septic transfusion reactions after the implementation of bacterial testing were reviewed and investigated.

Results: From March 2004 to December 2005, a total of 843,443 units of apheresis platelet were collected and tested for bacterial contamination. The overall positive rate was ~1:1,500. Of these, ~30% were confirmed as true positive (~1:5,000), and the rest were either confirmed false positive (~1:2,600) or not confirmed and considered indeterminate (~1:10,500). For the true positive group, the most prevalent bacteria isolated were *Staphylococcus* species (~60%) and *Streptococcus* species (~20%). Gram-negative bacteria accounted for ~12%. No gram-negative bacterium was identified in the false positive and indeterminate groups. From March 2004 to February 2006, only one true positive (coagulase negative *Staphylococcus*) unit was transfused at the time (2 days after collection) when positive culture was indicated; however, no reaction was reported in the recipient. During this period of time, 17 high-probability septic transfusion reactions, including two fatalities, from screened units with negative QC cultures were investigated from a total of 1,277,508 products released, representing a residual risk of sepsis at ~1:75,100 and fatality at ~1:638,800. In 8 of 17 cases the same organism was demonstrated in the component and recipient blood cultures. Six of these cases involved split-products from three platelet apheresis collections. In 13 cases, including two fatalities, *Staphylococcus* species were implicated; the remaining were *Enterobacter* (2), *Enterococcus* (1), and unknown (1). These septic cases were found to be significantly ($p=0.006$) associated with the use of double-needle apheresis collection sets which lack a sample diversion pouch on the inlet line.

Conclusions: Implementation of routine bacterial testing effectively intercepted majority of bacterially contaminated platelet units from transfusion. However, septic transfusion reactions in recipients of apheresis platelets were not completely eliminated, likely reflecting the low level of bacteria present at the time of initial sampling. Additional interventions, including the routine use of apheresis collection sets with inlet line sample diversion, should be implemented in order to minimize septic transfusion reactions.