2016 AABB ANNUAL MEETING ORAL PRESENTATION REVIEW:

Predicted costs of implementing PGD Testing and Pathogen Reduction in a Hospital Transfusion Service

Sorkin EJ, Jacobson JL. Estimated Financial Impact of Complying with the FDA Draft Guidance Entitled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion". TRANSFUSION 2016; 56: 213-4A (Supplement S4).

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At the 2016 AABB Annual Meeting Sorkin and Jacobson evaluated the relative costs of performing daily testing of apheresis platelets starting on storage day 4 using a rapid test for bacterial detection cleared as a "safety measure" or purchasing apheresis platelets that have undergone pathogen reduction (PR). Their study is particularly relevant and timely since the March 2016 FDA Draft Guidance addressing the mitigation of risk of bacterial contamination of platelets recommends using either a rapid test starting on day 4 or PR.[1] The draft guidance also outlines a pathway for extending the storage of apheresis platelets to 7 days. This extension requires the use of a technology cleared or approved by the FDA as a "safety measure". The Verax Platelet PGD Test is the only such technology and, as such, its use is the only means of extending apheresis platelet storage beyond 5 days. PR had not been approved as a safety measure and cannot be used to extend platelet storage.

Readers are referred to the white papers "Implementing 7 Day Platelet Dating with the Platelet PGD® Test", "FDA Draft Guidance: Recommendations for Addressing Bacterial Contamination Risk in Platelets and Pathway for Immediate Extension of Platelet Dating to 7 Days", and "Safety and Efficacy of Seven Day Platelets" all of which are available at http://veraxbiomedical.com/cmo-perspective.asp

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The authors evaluated the cost of both 5-day and 7-day apheresis platelet inventories. A cost of $25 and $35 per PGD test and an upcharge of $100 and $125 per PR apheresis platelet were used for the analysis. The cost per SDP was fixed at $523 per unit. A 2-month audit of all apheresis platelet transfusions at their institution was performed from 2/23/16 to 4/22/16 to ascertain the platelet shelf-life at the time of issuance. Audit data were extrapolated to determine the annualized numbers of PGD tests that would be required. The cost of the 5-day standard SDP inventory in 2015 (including outdates) was compared to the estimated cost using the PGD test starting on day 4 for both a 5-day and a 7-day inventory and for a PR inventory.

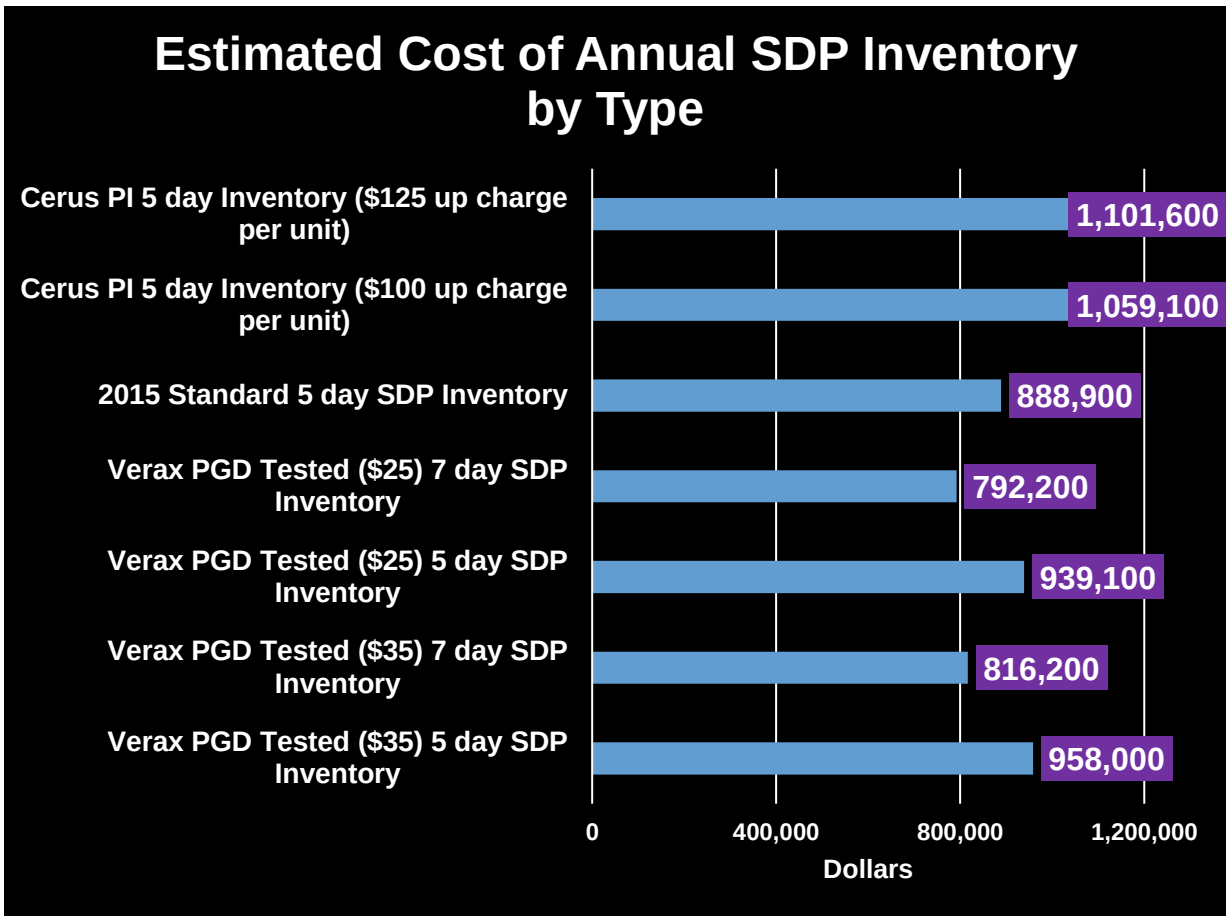
210 SDPs were issued during the audit period. The annualized number of SDP transfusions was 1,260 which closely matched the actual 2015 SDP transfusion volume of 1208. The authors found that 50% of SDPs were issued on day 5, 32.9% on day 4, 14.8% on day 3, and 2.4% on day 2. Storage age did not differ by ABO Rh type. The SDP outdate rate was 28% (1.25 units per day) meaning that about 1,700 platelets were purchased annually. Testing all units purchased would result in just 9 PGD false positive tests annually.

Results are displayed in the table below. Their current annual platelet budget is $888,900. A PR upcharge of $125 per unit would increase the inventory cost by 24% ($212,700). PGD testing keeping a 5-day inventory at a cost of $25 per test would increase costs by 5.6% ($50,200). PGD testing with a change to a 7-day inventory at $25 per test would decrease costs by 11% ($96,700), assuming a 15% outdate rate and no additional labor costs. In this regard, Hornbaker and colleagues reported a survey of 50 US institutions performing the PGD test (including many with a testing volume greater than that reported by Sorkin and Jacobson). They found that all the facilities were able to implement and perform PGD testing with existing staff.[2]

Importantly, the authors presumed they would be performing daily PGD testing on every platelet while it was in inventory. This is not a requirement. A platelet needs to be PGD tested within 24 hours of transfusion but need not be tested every day. Vauthrin and colleagues reported performing an average of <1.17 tests per platelet with a five-day storage period on every platelet transfused in their transfusion service (about 3,000 SDPs transfused annually) regardless of storage age.[3]

The authors assumption that switching to a 7-day storage period would only reduce outdating from 28% to 15% is likely very conservative. A U.S. study published in 2010 observed a 7-day outdate rate of 1.55% among bacterially tested apheresis PLTs.[4] The reported outdate rate at the University of North Carolina Medical Center dropped from a 5-day stored platelet outdate rate of 2.9% to 1.3% with a 7-day stored platelet outdate.[5] The authors would likely find that a 7 day shelf-life would result in a greater reduction in outdating than they used in their calculations.

In conclusion, the authors calculated they could achieve substantial cost savings from extending platelet storage time to 7 days using the Verax Platelet PGD test.



1. http://www.fda.gov/downloads/Guidances/Blood/UCM425952.pdf Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion. Draft Guidance for Industry. Washington (DC): US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research.

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