2016 AABB ANNUAL MEETING POSTER REVIEW:

PGD Testing All Platelets in a University Transfusion Service While Minimizing the Number of Tests Performed

Vauthrin M, Greene M, Weinstein R. Verax Platelet PGD Test Workflow Strategy. TRANSFUSION 2016; 56:198-9A (Supplement S4)

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At the 2016 AABB Annual Meeting, Vauthrin and colleagues presented a strategy for performing a Platelet PGD test on each platelet within 24 hours of transfusion at a university medical center with a level 1 trauma program. They tested platelets of all storage ages, including those on storage days 2 and 3. The authors' medical center transfuses approximately 3,000 apheresis platelets annually. Their study was not sponsored by Verax Biomedical, and none of the authors has a conflict of interest with Verax Biomedical.

The authors sought to balance the need for immediate access to PGD-tested platelets (including emergency release) with the budgetary necessity to minimize the retesting of platelets prior to issue. They developed and implemented a testing strategy at their hospital to ensure that there were always platelets available that had been PGD tested within 24 hours of transfusion. Each blood bank shift assessed the number of tested units available, all pending orders for platelet transfusion (including the operating room and outpatient clinics), and the number of platelets needed to maintain their required inventory. Platelets with the shortest outdate, regardless of ABO group, were selected for PGD testing. As necessary, batches of up to six platelets were tested and made available in approximately 45 minutes. Testing on each shift allowed for a range of PGD-test expiration times. Routine policy was for the blood bank to issue the units with the shortest outdates.

To evaluate if this strategy was effective in limiting repeat PGD testing of apheresis platelets while maintaining a sufficient inventory of tested platelets, the authors reviewed data from two years to determine the number of times a platelet was tested before it was issued. Results are presented in the table below. More than 80% of apheresis platelet products were tested only once in each year analyzed. Fewer than 2% of platelet products were PGD tested three times. On average, each platelet component was tested <1.17 times.

Although the authors noted that 5.39% of their apheresis platelets were outdated/wasted annually, if their institution were to implement the now available seven-day platelet outdate policy in accord with FDA draft guidance[1], this rate would drop dramatically. A U.S. study published in 2010 observed a 7-day outdate rate of 1.55% among bacterially tested apheresis PLTs.[2] 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.[3] 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

The authors concluded that PGD testing in batches based on inventory and transfusion needs is an effective strategy to limit repeat testing while maintaining a sufficient inventory of platelets for immediate release. Testing all platelets in inventory every day is not necessary. In their practice, testing throughout all shifts allowed for a staggered outdate and the availability of tested platelets whenever needed. It also ensured that each member of the blood bank staff was capable of performing the PGD test. The authors determined that in their institution they were able to implement a policy that ensured an in-date Verax PGD test had been performed on every platelet within 24 hours of transfusion while minimizing the number of tests performed (an average of 1.17 PGD tests per dose).

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. (Accessed 08 January 2017)**

2. **Dumont LJ, Kleinman S, Murphy JR, et al. Screening of single-donor apheresis platelets for bacterial contamination: the PASSPORT study results. Transfusion 2010;50:589-99.**

3. **Hay SN, Immel CC, McClannan LS, Brecher ME. The introduction of 7-day platelets: a university hospital experience. J Clin Apher 2007;22(5):283-6.**

Apheresis Platelets Tested	2014	2015
1 time	2686 (84.6%)	2440 (81.7%)
2 times	452 (14.2%)	501 (16.7%)
3 times	36 (1.2%)	44 (1.6%)
Total	3174	2985
Average tests per unit	1.15	1.18

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Verax Platelet PGD® Test Workflow Strategy

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Background

Our university medical center blood bank implemented the Verax Platelet PGD® Test, which detects both gram positive and gram negative bacteria in platelet components prior to release for transfusion. As an academic center that transfuses 3000 apheresis platelets annually, and a Level 1 trauma center that must maintain an inventory of PGD®-tested platelets for emergency release, we sought to balance the need for immediate access to PGD®-tested platelets with the budgetary prerogative of minimizing the retesting of platelets prior to release.

Study Design/Methods

We developed the following testing strategy to ensure that there are always PGD® tested platelets available.

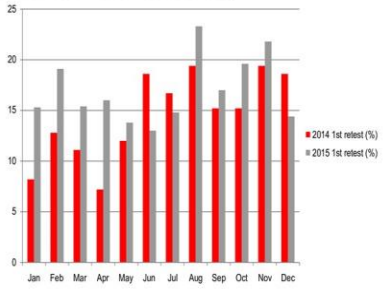
- The PGD® package insert stipulates that a platelet product must be tested no more than 24 hours prior to transfusion.
- Each blood bank shift assesses the number of
  - tested units available,
  - all pending orders for platelet transfusion, including the operating room and outpatient clinics, and
  - platelets needed to maintain the required inventory.
- Platelets with the shortest outdate, regardless of ABO group, are selected for testing.
- When necessary, additional platelet units are tested in batches of up to six thus enabling a technologist to test six units in approximately 45 minutes.
- When the test is complete the platelet product is labeled with the date and time the test expires.
- Testing on each shift allows for batches of platelets with different PGD® test expiration times.
- When issuing platelets the blood bank chooses the units with the shortest outdates.

To determine if this testing strategy was effective in limiting the number of PGD® tests that were performed while maintaining an adequate inventory of tested platelets, we evaluated two years of testing data to determine the number of times a platelet was tested before it was transfused.

Results

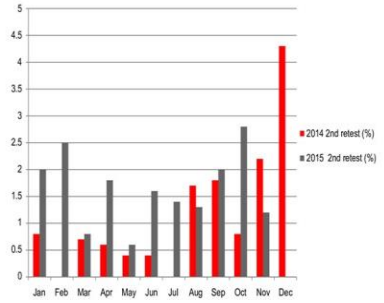
Percent of Platelets Tested Two Times

	2014 1st retest (%)	2015 1st retest (%)
Jan	8.2	15.3
Feb	12.8	19.1
Mar	11.1	15.4
Apr	7.2	16
May	12	13.8
Jun	18.6	13
Jul	16.7	14.8
Aug	19.4	23.3
Sep	15.2	17
Oct	15.2	19.6
Nov	19.4	21.8
Dec	18.6	14.4
Total	14.2	16.7



Percent of Platelets Tested Three Times

	2014 2nd retest (%)	2015 2nd retest (%)
Jan	0.8	2
Feb	0	2.5
Mar	0.7	0.8
Apr	0.6	1.8
May	0.4	0.6
Jun	0.4	1.6
Jul	0	1.4
Aug	1.7	1.3
Sep	1.8	2
Oct	0.8	2.8
Nov	2.2	1.2
Dec	4.3	0
Total	1.1	1.5



Summary of Data

- 80% of platelet products were tested only once
- Fewer than 2% of platelet products were tested three times.
- Platelet were tested an average of <1.2 times.
- 5.39% of platelets are outdated/wasted annually.

Doses Tested	2014	2015
Tested 1X	2686 (84.6%)	2440 (81.7%)
Tested 2X	452 (14.2%)	501 (16.7%)
Tested 3X	36 (1.2%)	44 (1.6%)
Total	3174	2985
Average tests per dose	1.15	1.18

CONCLUSIONS

Testing in batches based on inventory and transfusion needs is effective in limiting repeat testing while maintaining sufficient inventory for immediate release.

Testing all platelets in inventory every day is not necessary.

Testing throughout all work shifts allows for a staggered outdate of the PGD® test and the availability of tested platelets at all times. It also ensures that all staff in the Blood Bank is proficient and competent to perform the test.

We are able to perform a PGD® test on every platelet component issued for transfusion in our hospitals with a consistently low repeat test rate.