

BACKGROUND

Platelets made with additive solutions (PAS) have been available in the United States since 2011, but have not become widely used. With the anticipated release of the FDA guidance: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, the use of pathogen reduced platelets (PR) which can be produced from PAS-C products should become more common. In the data validating PAS-C and PR, the immediate post counts for these products are lower than platelets in all plasma. Our study looks at whether the implementation of PAS and PR platelets has increased the number of units of platelets transfused.

Solution	PAS-C Intersol® mmole/L	PAS-F Isoplate® mmole/L
Sodium Citrate	11	
Sodium Acetate	28	28
Sodium Chloride	77	90
Sodium Phosphate	28	
Sodium Gluconate		23
Potassium Chloride		5
Magnesium Chloride		1.2

PAS platelets are made with 2/3 of the plasma replaced by an electrolyte solution which includes sodium acetate for anaerobic metabolism. In the United States PAS-C platelets first became available in 2010 and PAS-F in 2013. Beginning in 2016, platelets made with PAS-C can also be pathogen reduced using the Intercept process of Amotosalen and Ultraviolet A light exposure. The process cross links DNA making it unable to be replicated. The process works with bacteria, parasites, viruses, and white blood cells so it can be used in lieu of irradiation. In Europe, PR platelets have been available since 2003.

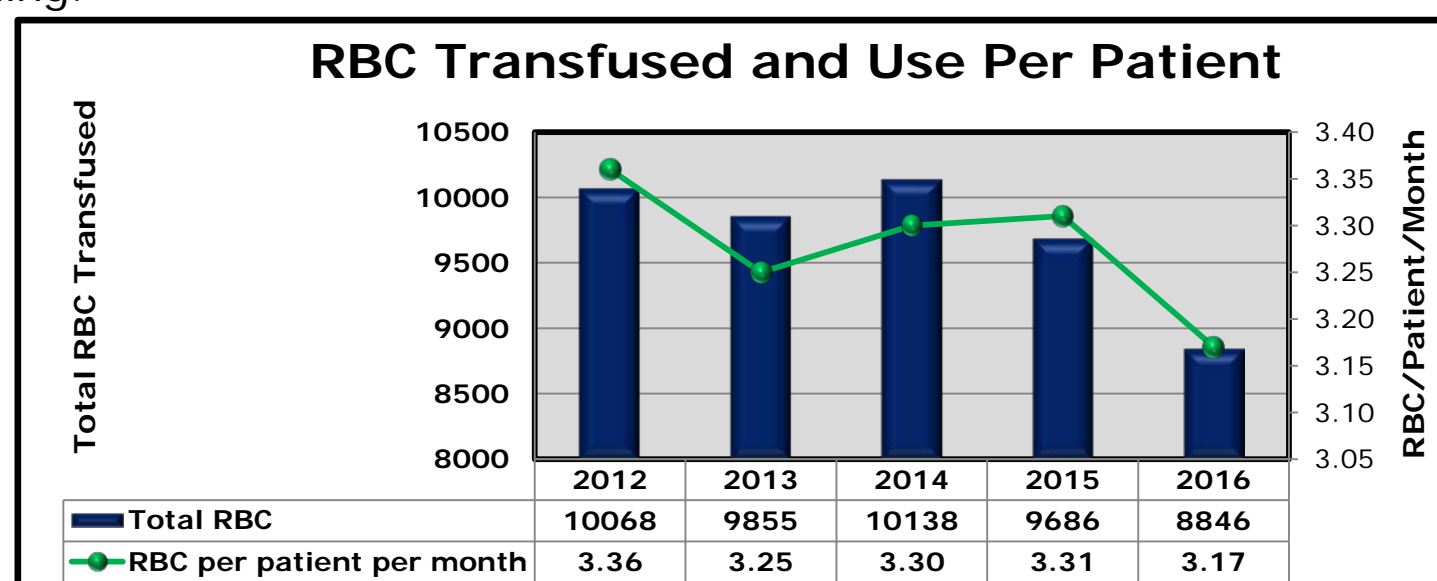
STUDY DESIGN

The data was obtained from the standing quality reports produced for the blood utilization committee at our facility and included data from the donor center and transfusion service. The donor center provided all of the PAS products used and until 2016 they also provided approximately 2000 units/year of all plasma products. All recipients had an oncology diagnosis.

The data includes the numbers of units and recipients receiving blood on a monthly basis. The data was standardized to units/month/recipient for analysis. Statistics were performed using the two sample T-test.

RED BLOOD CELL UTILIZATION

During the 5 years studied, the number of patients treated annually at the institution increased. The hematology services are the driver for both red cell and platelet transfusion. The base parameters for red cell transfusion on these services remains a hemoglobin of 8 g/dL when patients have no or limited marrow production. With the differences in post count for platelets, it was not unreasonable to assume that there would be an increase in the incidence of bleeding.



The number of red cells received was the surrogate marker. Over the period reviewed, the decrease in monthly red cell use per patient was statistically significant at $p < 0.05$. The lack of increase is consistent with other studies.^{3,4}

PLATELET UTILIZATION

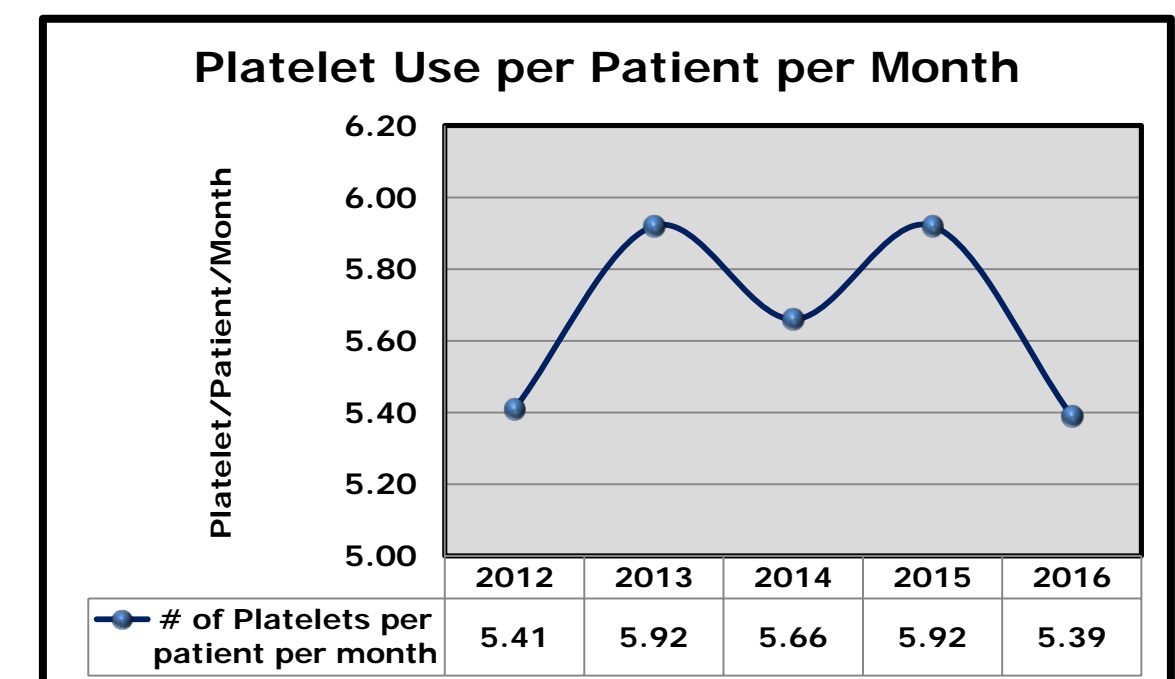
Between 2012 and 2016, PAS products increased from 13% to 40% of platelets transfused. This table does not differentiate the type of PAS given or pathogen reduction of a PAS-C product which was begun in August of 2016. The predominant PAS product is PAS C with greatest PAS F use in 2014.

	PAS Products	Plasma Products	All Products
2012	955	6134	7089
2013	1646	6251	7897
2014	2942	5217	8159
2015	2427	6369	8796
2016	3068	4480	7548

YEAR	Platelet Type	1 hr post – pre	N	p
2012	PAS-C	13.62	202	
	Plasma	19.92	452	<0.001*
2014	PAS-F	19.9	1545	
	Plasma	19.7	1099	0.087
2016	PAS-F	19.4	317	
	PAS-F	15.7	997	
	PR	14	323	0.746

*statistically significant

The number of platelets per recipient per month averaged 5.66 over the 5 years. There was annual variability, but no overall trend. The slope of the line was $y = -0.004x + 5.672$. The differences were not able to be explained by the use of different ratios of PAS and all plasma platelets. Statistical analysis showed this to be not statistically significant with $p = 0.81$.



CONCLUSION

The implementation of PAS and PR platelets has not increased the number of platelet transfusions given at our institution. In additional analysis, the red cell use has not decreased. We are making the interpretation that patients have not had increased bleeding episodes. Although the post platelet count from PAS and PR platelets may be lower, we do not have evidence from our platelet transfusion data that this is leading to clinical outcomes necessitating additional products to be given.

References:

- Tobian AAR, Fuller, AK, Ugluk K, et al. The impact of platelet additive solution apheresis platelets on allergic transfusion reactions and corrected count increment. *Transfusion* 2014, 54: 1523-1529.
- Kerkhoffs, JH, VanPutten WL, Novotny VM et. al. Clinical effectiveness of leucoreduced pooled donor platelet concentrates stored in plasma or additive solution with and without pathogen reduction. *British Journal of Haematology* 2010, 150: 209-217.
- Butler C, Doree C, Estcourt LI et. al. Pathogen Reduced Platelets for the Prevention of Bleeding. *Cochrane Database Systematic Review* 2013; 28.
- Osselaer JC, Doyen C, Defoin L et al. Universal adoption of pathogen inactivation of platelet components: impact on platelet and red blood cell component use. *Transfusion* 2009, 49: 1412-1422.