LIFESOUTH
Community Blood Centers

May 17, 2023

To: Directors of Clinical Laboratories
Directors of Transfusion Services
From: Chris Lough, MD, Vice President of Medical Services
Subject: **Transfusion of Low Count Platelets**

LifeSouth currently offers variable count, or low count, platelets to increase the available platelet supply. Current clinical recommendations are that platelet products with counts between 2.5 to 2.9 x 10^{11} be treated as equivalent to products with at least 3.0 x 10^{11} platelets, the current FDA minimum for a traditional apheresis platelet. Additional information and publications around this recommendation may be found in ***ABC Blood Bulletin Vol. 20, No. 4*** (see Figure 1). Not only are products with lower counts between 2.0 to 2.5 x 10^{11} routinely utilized as the standard of care in Canada and the European Union, but the Platelet Dose Study (PLADO) trial has proven the effectiveness of such products. Additional studies have had similar results in multiple patient types, and in general, an increase in the number of platelet products transfused is not seen until much lower doses are utilized.

Utilization of variable count platelet products is one way that our partners can actively help mitigate the impact of any potential shortages on their patients and our communities without placing quality of care at risk. LifeSouth asks that you strongly consider implementing the use of variable count products in your facility. Variable count platelet products are routinely available, and all units will have the platelet count recorded on the face label of the bag. See Table 1 for a list of ISBT component codes currently assigned to variable count platelet products.

If you have any questions, or would like any additional information/resources, please feel free to contact me directly at cmlough@lifesouth.org or 352-224-1644.

Table 1, Low Count Platelet Product Codes

Code	ISBT 128 Description
E5075	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts|Bacterial monitoring
E9970	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=24h
EA011	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=36h
E5370	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring
E9971	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=24h
EA012	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=36h
E5371	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring
E9972	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=24h
EA013	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=36h
E5372	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring
E9973	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=24h
EA014	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=36h
E5073	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|<3E11 plts|Bacterial monitoring
E9978	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=24h
EA019	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=36h
E5532	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring

E9979	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=24h
EA020	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=36h
E5533	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring
E9980	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=24h
EA021	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=36h
E5534	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring
E9981	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=24h
EA022	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=36h
EA052	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|<3E11 plts|Bacterial monitoring
E9986	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=24h
EA027	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=36h
EA053	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring
E9987	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=24h
EA028	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=36h
EA054	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring
E9988	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=24h
EA029	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=36h
EA055	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring
E9989	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=24h
EA030	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=36h
EA060	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|<3E11 plts|Bacterial monitoring
E9994	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=24h
EA035	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|<3E11 plts|Bacterial monitoring >=36h
EA061	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring
E9995	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=24h
EA036	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts|Bacterial monitoring >=36h
EA062	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring
E9996	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=24h
EA037	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|<3E11 plts|Bacterial monitoring >=36h
EA063	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring
E9997	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=24h
EA038	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|<3E11 plts|Bacterial monitoring >=36h
E8335	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts|Psoralen-treated
E8971	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|<3E11 plts|Psoralen-treated
E8972	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|<3E11 plts|Psoralen-treated
E8973	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts|Psoralen-treated

Figure 1, ABC Blood Bulletin Vol. 20, No. 4

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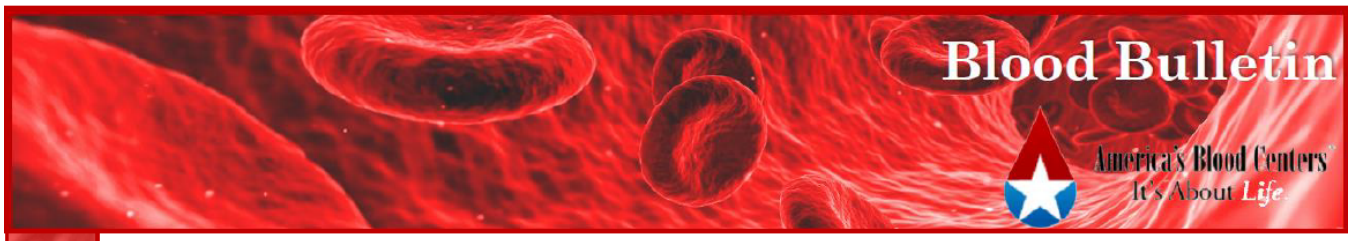

The Case for Transfusion of Low Yield Platelets

By Nancy Van Buren, MD, Medical Director at Innovative Blood Resources, a division of New York Blood Center, Richard Gammon, MD, Medical Director at OneBlood, Kip Kuttner, DO, Medical Director at Miller-Keystone Blood Center, & Susan Rossmann, MD, PhD, Chief Medical Officer at Gulf Coast Regional Blood Center; The authors disclose no conflicts

Key Points

- Platelet shortages are anticipated due to strategies necessary for implementation of the FDA's September 2019 final guidance for mitigation of platelet component bacterial contamination due to fewer single donor apheresis platelets meeting the FDA minimum content of 3.0 x 10^{11}/unit.
- Low (variable) yield single donor platelets have fewer than 3.0 x 10^{11} should be labelled with the actual platelet count per FDA requirements.
- Use of low yield platelets is an important strategy for optimizing the use of available platelet resources.
- It is time to consider integrating low yield platelets into the platelet inventory in the United States, which is already the standard of practice in other countries.

Background: Platelets are cells in your blood that form clots to help stop bleeding. They are used to stop or avoid massive bleeding for cancer patients, patients undergoing major surgery, and trauma victims. Currently, most blood suppliers collect them through platelet apheresis, the use of a special machine that filters platelets to allow a donor to keep red and white cells and plasma. They may also be collected as a part of whole blood donation. When apheresis technology was initially adopted in 1972, the Food and Drug Administration (FDA) set the minimum platelet content requirement (PCR) of 3 x 10^{11}/unit; however, there is no restriction on transfusing units with lower platelet yields. The 2007 FDA guidance states that apheresis platelet components for transfusion containing less than 3 x 10^{11} platelets should be labelled with the actual platelet count.[1] In comparison, whole blood-derived platelet concentrates (often referred to as random-donor platelets) should contain at least 5.5 x 10^{10} platelets,[2] which continue to account for less than five percent of transfusions in the United States (U.S.).[3] In fact, the U.S. has a minimum PCR higher than Canada and the majority of European Union (EU) nations (which range from 2.0 to 2.5 x 10^{11} platelets).[4]

Anticipated shortages due to FDA guidance: Strategies for implementation of the FDA's September 2019 final guidance for mitigation of platelet component bacterial contamination[5] all adversely impact platelet component dose and split rate of apheresis platelet collections, which are typically maximized to collect two to three platelet doses. It is estimated that 20-25 percent of single donor platelets (SDPs) may be produced with lower yields due to the burden of additional sampling required for bacterial cultures.[6] Pathogen reduction (PR) technology is an alternative choice for complying with FDA's September 2019 final guidance. This process can also decrease the yield of apheresis platelet units below what was stated in the 2007 FDA Guidance[1,6] leading to low (also called variable) yield platelets. This will further impact platelet availability, which is already challenged by factors such as limited shelf-life (5-7 days), a rising demand as the population ages, increasing prevalence of hematological malignancy, and the impact of the COVID-19 pandemic (as well as future events) on platelet inventory and blood donation. Donor age is beginning to affect the platelet supply. From 2001 and 2017, the peak age of platelet donors increased from 41-45 years to 56-60 years, respectively.[7] In one medium size blood center, 65 percent of platelet donors are 50 years of age or older.[8] Younger donors are often less able or unwilling to make the 2-3-hour commitment required of platelet donation, and older donors are more likely to develop medical conditions or be receiving medications that prohibit them from giving blood or platelets.[7]

Transfusion of low yield platelets as a strategy for optimizing the use of available resources: Low yield platelets (apheresis platelets with PCR less than 3 x 10^{11}/unit) generally do not correlate with more platelet transfusions. Clinical trials in the U.S., including the Platelet Dose Study (PLADO), have demonstrated acceptable clinical effectiveness of a lower PCR for the prevention of bleeding in thrombocytopenic hematology-oncology patients (patients who do not produce enough platelets because of their cancer or its treatment).[9] In the PLADO study, patients receiving the lower (50 percent) dose did not manifest more bleeding, which should alleviate concerns about the efficacy of the platelet dose in low yield platelets, i.e. between 2.5 and 2.9 x 10^{11}. Specifically, more frequent transfusions observed in the PLADO low dose arm would be an unlikely result from a product with only 10-15 percent fewer platelets. Finally, harmonization of the U.S. with EU minimum PCR will increase the number of platelet units available.[10]

Recommendations: It is time to consider integrating low yield platelets into the standard platelet inventory. These have already been accepted in other countries as standard of care and is an important measure to optimize the use of available platelet resources which will be impacted by implementation of FDA's September 2019 final guidance for mitigation of platelet component bacterial contamination. Research should be sponsored to identify optimal platelet transfusion thresholds and dosing strategies for non-hospitalized patients for prophylactic use, in the presence of congenital or acquired platelet dysfunction, and for bleeding patients in surgical and trauma settings.[11]

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