

## Low Yield Platelets: Safety and Efficacy for Patient Care

### Description of Low Yield Platelets

Per current FDA regulations, calculation of the platelet yield (volume of platelet bag x platelet count concentration) must be performed on every apheresis platelet. To be labeled and distributed as a “standard-dose” apheresis platelet, the bag must contain  $\geq 3.0 \times 10^{11}$  platelets.<sup>1</sup>

Low yield (aka variable content) platelets are apheresis platelets that contain less than  $3.0 \times 10^{11}$  platelets; about 10-15% fewer platelets than a standard apheresis unit. Low yield platelets undergo the same collection, processing, and safety measures as all other platelet components and thus may be either pathogen-reduced (PR) or large volume delayed sampling (LVDS) platelets. After labeling with the actual platelet yield, this platelet product may be distributed for patient use in the same manner as a standard apheresis platelet.

### Preserving a Precious Resource: Versiti’s Approach to Low Yield Platelets

A platelet donation collected via apheresis is optimized to allow for the collection to be separated or divided into 2 or 3 units, with the aim for each unit to contain 3.0 –

$5.9 \times 10^{11}$  platelets. The additional manufacturing steps required for PR and LVDS platelets<sup>2</sup> may result in one or more divided components having a platelet yield of less than  $3.0 \times 10^{11}$ . Rather than discard these transfusable products, those containing between  $2.6$  to  $2.9 \times 10^{11}$  platelets will be labeled and distributed as low yield platelets. Versiti will not distribute platelet products containing  $\leq 2.5 \times 10^{11}$  platelets.

### Labeling Requirements & ICCBBA Product Codes

Low yield apheresis platelet product codes are different from the standard divided apheresis platelet codes and must be built into the hospital/lab IT system to accept the product into the facility’s blood inventory. The product description label for these platelets will include “Contains  $< 3 \log_{11}$  Platelets”.<sup>3</sup> The actual platelet yield will also be noted on the label.

### Clinical Efficacy of Low Yield Platelets

The minimum requirement by the FDA<sup>1</sup> for a standard-dose apheresis platelet is  $3.0 \times 10^{11}$  platelets, which is higher than the requirement in many other countries. Internationally, the minimum platelet content for

standard apheresis units ranges from  $2.0 - 2.5 \times 10^{11}$  platelets per bag. No detrimental effect or increase in platelet usage has been reported in these other countries when transfusing platelets containing a lower platelet yield.<sup>4,5</sup>

Clinical trials have demonstrated that low-dose *prophylactic* platelet transfusions in patients with hematologic disorders is safe. The PLADO study<sup>6</sup> was a randomized controlled trial comparing prophylactic platelet transfusion at low-dose ( $1.1 \times 10^{11}/\text{m}^2$ ), medium-dose ( $2.2 \times 10^{11}/\text{m}^2$ ), and high-dose ( $4.4 \times 10^{11}/\text{m}^2$ ), based on recipient body size, to hospitalized hematology/oncology patients. For an 80 kg male patient, this dosing strategy translated to a bag containing about  $2.2 \times 10^{11}$  platelets for low-dose,  $4.4 \times 10^{11}$  platelets for medium-dose, and  $8.8 \times 10^{11}$  platelets for high-dose. This study found no effect of platelet dose on the primary endpoint, which was the proportion of patients experiencing minor bleeding (e.g. epistaxis, purpura or melena). While a low-dose platelet transfusion was as effective as a medium- or high-dose platelet transfusion, in the low-dose arm,

a shorter interval between transfusions was identified to maintain the platelet count at  $>10,000/\mu\text{L}$ .

A systematic review and meta-analysis of 7 randomized controlled trials<sup>7</sup>, including the PLADO study, compared whether different doses of prophylactic platelet transfusions (based on patient body size) affect efficacy and safety in preventing bleeding in over 1800 patients with hematological disorders receiving chemotherapy and/or stem cell transplantation. The authors found that when compared to a standard or high-dose strategy, low-dose platelet transfusion was not associated with increased bleeding risk (i.e. no difference in number of participants who had significant clinical bleeding, number of days with bleeding, or time to first bleeding episode). Low-dose platelet transfusions did lead to shorter transfusion intervals and increase in the number of platelet transfusion episodes. On a side note, there was no clinical benefit of the high-dose platelet transfusion strategy over the standard-dose.

Generalizing the results of the above studies to all patients or other indications should be undertaken with caution. No studies to date have evaluated the effectiveness of different platelet dose strategies for therapeutic transfusions in actively bleeding patients (e.g. surgical or trauma patients). For these patients a higher platelet threshold ( $>50,000/\text{mL}$ ) is desired for hemostasis. A standard-dose platelet may better meet the patient's clinical need.<sup>6</sup> Several patient factors such as weight, blood volume, clinical condition, bleeding, or impending invasive or surgical procedure should be considered when selecting platelets for transfusion.

## Conclusion: Implications for Practice

To optimize utilization of an already constrained resource, consider the following:

- Low-dose prophylactic platelet transfusions have demonstrated safety and efficacy for prevention of bleeding in thrombocytopenic hematology/oncology patients due to marrow hypoplasia.
- For these hospitalized patients, use of a low yield platelet ( $2.6 - 2.9 \times 10^{11}$  platelets/bag) should be considered.
- For patients requiring a higher platelet count increment after transfusion or longer interval between transfusions, use of a standard dose platelet, when available, may be a better strategy.<sup>7</sup>
- Monitoring and assessment of the effect of any platelet transfusion is essential for quality patient care.

### References:

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If you have any questions please contact the TxMD staff at [TxMDSupport@versiti.org](mailto:TxMDSupport@versiti.org) or your Versiti Hospital Relations Specialist.

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