



Lowering the US Platelet Content Requirement (PCR) - Good for Both Donors and Patients

- **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. They are collected either as a part of whole blood donation or through platelet apheresis, the use of a special machine that filters platelets to allow a donor to keep red and white cells and plasma.
- **History**- When apheresis technology was initially adopted in 1972, the Food and Drug Administration set the minimum PCR of 3×10^{11} /unit that remains the current standard. This was not derived from clinical effectiveness studies but instead came from the average total number in a pool of six whole blood donations, which was the standard way platelets were provided before apheresis was available. Indeed, these whole blood-derived platelets still account for five percent of transfusions and are not subject to apheresis PCR standards; contemporary platelet pool doses generally contain $2.0\text{-}3.0 \times 10^{11}$ platelets.
- **US and Other Developed Countries** – The United States (US) has a minimum PCR higher than Canada and the majority of European Union (EU) nations (which range from 2.0 to 2.5×10^{11} platelets).¹
- **Impact on platelet supply**- One apheresis platelet donation, if large enough, can be split into multiple units. By increasing the number of donations eligible to split, reduction of the PCR will allow blood collection facilities to increase the number of platelet units produced.² An analysis of two large blood center databases of 5,805 apheresis platelet units suggested this change in PCR had the potential for a 21 to 23 percent increase in platelet units, without changes to collection procedures.²
- **Consideration of a lower count** – A lower PCR generally does not correlate with more platelet transfusions. Clinical trials in the US, including the Platelet Dose Study (PLADO), and elsewhere 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).³ Harmonization of the US with EU minimum PCR will increase the number of platelet units available. Additionally, it will expand the availability of Pathogen Reduction Technology (PRT), the most effective process for mitigation of the risk from platelet bacterial contamination, the most frequent infectious complication from platelet transfusion, by inactivating harmful organisms in platelets. Lowering the minimum PCR is necessary to allow substantially larger portions of platelet products to be treated with currently licensed PRT.
- **Impact on donors** – Additionally, a lower PCR would allow for a reduction in the number of platelets collected from some donors without reducing the platelet units available. Donors may experience shorter times for collection. Longer collection times increase the risk of donor adverse events (AE),² and decrease donor satisfaction. Donors who suffer AE are less likely to return to donate so the strategy of shorter collection times could reduce the risk of intermittent shortages by increasing donor satisfaction and donor retention.²

- **Impact on patients-** The contemporary size of a platelet pool is four to six units (2.0 to 3.0×10^{11} platelets); with no appreciated impact on clinical efficacy. Platelets collected from whole blood donations have been safely used for transfusion both before and after apheresis platelets became available. Similarly, there were no differences in the rate of transfusion reactions. Most studies have concluded the equivalency in apheresis platelets and pooled platelets.^{4,5}
- **US Hospital Practice-** Based on findings from clinical studies and experience from other countries, some US hospitals have begun to transfuse apheresis platelets with a content of less than 3.0×10^{11} platelets either routinely or during times of shortage to increase availability. At Stanford Blood Center, in order to increase the production of PRT platelets and better meet the demand for these products, PRT platelets containing less than 3×10^{11} platelets have been produced since January 2018. Approximately 30 percent of PRT platelets provided have a platelet content of less than 3.0×10^{11} platelets (minimum required content is 2.0×10^{11} platelets), and these units are labeled with the actual platelet counts. From January 2018 to December 2019, about seven percent of apheresis platelets transfused in pediatric and adult patients at Stanford Hospitals were PRT platelets with an average content of 2.8×10^{11} platelets.
- **Recommendation-** While the research supports the safety and efficacy of a range of platelet dosages, reducing the minimum PCR to 2.5×10^{11} is a conservative approach which will remove some barriers for the adoption of PRT and increase platelet availability to address anticipated increased demand without compromising patient safety.

References

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