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Unveiling Platelet Quality Challenges: A Comprehensive Analysis of Flocculation in Apheresis-Derived Products since April 2023

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Since April 2023, platelet concentrates from apheresis have increasingly exhibited flake-like flocculation. The occurrence and intensity of these flakes varied across different sections of the production line. We investigated a possible relation between the end-product quality, measured as number of platelets, and characteristics that relate to the blood donation as well as the development of flakes formation across different production stages.

Conspicuous products were observed over a period of approximately eight months. The affected products were divided into three groups based on the level of flake formation (low=1, medium=2, high=3). We measured thrombocyte cell concentration (Tc) in the affected products at following time points during the production: (a) in the evening upon delivery to the production site, (b) immediately before pathogen inactivation on the following day and (c) after pathogen inactivation in the final product.

In order to find a relevant difference in the process in relation to specification limits, we compared Tc of the end-products with flocculation with the end-products from the regular quality control using scatter plots. Blood donors whose products led to flocculation in 2023 were compared with donors from an earlier observation period in 2019-2020 in which similar flocculation problems were detected. A simulation was applied to test the expected random pairing with donors who have already generated products with flakes in the earlier observation period. We also aimed to identify the donor and blood collection characteristics related to flocculation. Following characteristics were analyzed: blood donor age, number of donations during the observation period, blood collection duration, blood collection type and volume, blood pressure, weight, height, hematocrit, hemoglobin, platelet percentage, leukocyte percentage, pulse.

The scatterplots show a clear reduction in end-product quality that increases with the degree of flocculation, but most products were still within the specification limits. Importantly, our simulation indicates a strong relationship between the donor and flake formation in the products.

Due to the observed reduction in quality, all products with flocculation grade 2 and 3 are subjected to additional quality control. The established reference to the blood donor and the type of collection indicates the direction in which further tests are to be investigated.