



Statement to the Food and Drug Administration's Blood Products Advisory Committee (BPAC)

November 22, 2019

Cold Stored Platelets for Transfusion

Presented by Michael Parejko
President, Americas Blood Centers

Americas Blood Centers' (ABC) is North America's largest network of FDA-licensed, independent, non-profit community-based blood centers. Our members collect, process, and distribute over half of the blood supply in the United States. We thank the FDA and BPAC for the opportunity to present our member's views on cold stored platelets.

The use of cold stored platelets presents challenges as well as opportunities. The most significant challenge appears to be related to the required 3-day expiration. The most significant opportunity lies in extending the expiration date to make widespread use of cold stored platelets more feasible. In order to gain more information on this important topic, ABC conducted a survey of our membership to gauge the level of interest in cold stored platelets. A total of 40 of the 46 ABC members participated in the survey, representing nearly 6.9 million collections. Currently, no member centers are manufacturing cold stored platelets, citing the 3-day expiration as the greatest challenge. Forty-three percent (43%) of participating centers are actively *planning* to manufacture and distribute cold stored platelets.

Forty-one percent (41%) indicate they either have, or are in the process of, seeking a variance for the use of cold stored platelets. The majority, sixty five percent (65%), intend to seek an expiration of 14 days. Current plans for 76.5% of respondents include providing cold stored platelets to trauma hospitals. Additionally, 70.6% of respondents indicate that cold stored platelets would serve geographically distant and rural hospitals and another 53% are interested in providing them to hospitals for use in Labor and Delivery. We therefore urge the committee and the FDA to seek data that would support use of cold stored platelets in these and other settings and not limit it only to trauma situations.

A concern expressed by our members is the time it may take to get a variance approved by the FDA to allow the use of 14-day cold stored platelets in other scenarios beyond trauma. Many members will not begin the discussions of using cold stored platelets with their hospital and clinician customers until more data is available on the feasibility of using this approach. We urge the committee and FDA to think broadly in their consideration of cold stored platelets and to seek data that would support expeditious decision making by the agency once the data is available.