

Several items in the Draft Guidance for Industry, Collection of Platelets by Automated Methods, will adversely impact the availability of platelets in our blood centers and the hospitals we serve. The following issues are of concern to us:

1. Donation frequency – the requirement of no more than 24 total components in a 12 month period, rather than the current industry standard of no more than 24 collections in a 12 month period could severely limit our plateletpheresis availability, and require the increased use of random platelet pools. This becomes an issue for the hospitals that we serve. They count on pheresis platelet products, since they are superior to random platelet pools and the burden of bacterial screening is on the hospital when random platelets are given.

For increased available plateletpheresis inventories, the donor center's plateletpheresis program targets donors that can donate a double rather than single product. If these requirements are instituted, we expect to see a 10% decrease in pheresis products from our current donor pool.

2. Medical coverage – to require a physician to be present on the premises or able to arrive within 15 minutes during the collection of plateletpheresis would require that we collect our plateletpheresis during normal working hours only. This will decrease our supply of plateletpheresis products. To say that calling 911 is not a sufficient substitute implies that the plateletpheresis donor is at higher risk and requires a higher standard of care than a trauma victim. Our collections staff are all trained in CPR and AED. Plateletpheresis donors complete a screening process which includes a mini physical, just prior to donating. Pre-screened donors may be at a lower risk than the general public for an adverse event. We feel that most physicians in our community, as well as the public, have confidence in the emergency care provided by para-medics and ER physicians.

The donor center has collected apheresis platelets since 1989 and it is our opinion that the presence of a physician would not have added to the care received by our platelet donors during those 16 years.

3. The recommended use of “scan statistics” for evaluation of QC data will be a problem for small and mid-sized Blood Centers. The assessment window is too long to be statistically useful in centers with plateletpheresis collections less than 4000.
4. Deferring donors for 5 days who are taking aspirin will also reduce our available donor pool. Many donors who are on an aspirin regimen are allowed by their physicians to discontinue the aspirin for 3 days prior to donation. Stopping for 5 days may not be an acceptable alternative for them. The AABB recommends a 3 day deferral because there is no documented evidence that 5 days produces a safer or more effective product.

Thank you for considering our comments. Please reconsider the points mentioned above.