**Extended platelet storage makes a welcome difference**

By Louise Townsend

It is no different for blood centers and transfusion services where laboratorians ensure the safety, purity, and potency of the blood supply daily.

According to the American Association of Blood Banks (AABB), more than 29 million units of blood components are transfused annually in the United States. Within one unit of blood, healthcare providers manufacture red blood cells, plasma, and platelets. The red blood cells can be used for trauma or surgical patients; plasma is administered to patients with clotting problems; and platelets are often used in cancer and transplant patients.

Thanks to advanced and reliable technology, blood centers now have more options when it comes to storage of platelets. This can potentially save the blood-banking industry a considerable amount of money and alleviate inventory shortages to better meet the constant demand for more blood donations.

### Freshness matters

Behind the scenes, blood banks must work diligently and carefully to keep blood components free of contamination and safe for use. Red blood cells can be refrigerated, thereby dramatically decreasing chances for microbial growth and contamination. Alternatively, platelets must be kept at room temperature (20°C to 24°C) in order to protect their fragile composition. Common skin contaminants and isolated bacteria harboring just below the skin’s surface can grow rapidly in this protein-rich and warm environment, and result in a real and unexpected transfusion risk. Cleansing the skin’s surface prior to venipuncture reduces but does not totally eliminate the risk.

Bacterial contamination of platelets carries the highest risk for transfusion-transmitted infections in the United States. Contamination carries the second highest rate of transfusion-related death, with mortality rates for platelet-related sepsis ranging from 1:20,000 to 1:85,000 donor exposures. The problem is magnified because platelets cannot be refrigerated; the warmer temperatures facilitate the growth of bacteria.

In 1986, the U.S. Food and Drug Administration (FDA) mandated platelet storage be limited to five days. If the platelets are not used within five days, they are considered expired product and must be destroyed. In April 2004, the AABB (American Association of Blood Banking) mandated that a method be performed to limit and detect the presence of bacteria prior to transfusion. As a result, platelets tested by blood-culture methods are not available for the first 24 to 48 hours after donation. This provides time for any bacteria that may be present to proliferate and be detected in culture. Current five-day storage limitations reduce optimal use down to three days, resulting in a large amount of wasted (expired) platelets.

Now, the blood-banking industry has another option. The FDA recently approved a longer (seven-day) storage period for apheresis platelets that are routinely tested for bacterial contamination. Seven-day storage is contingent upon 100% bacterial screening and participation in the nationwide PASSPORT — or post-approval surveillance study of platelet outcomes release-tested study, which was implemented in 2006. PASSPORT requires 50,000 data points to evaluate seven-day storage for all apheresis-platelet products that are release tested using a completely automated, continuous microbial-decision system. The study is expected to take up to three years.

As a participant in the PASSPORT study, FDA-regulated blood establishments are required to utilize a release test for each collection. The release test takes place after a 24-hour lag phase and a 24-hour log-growth phase of a potential bacterial contaminant. The FDA cleared two automated apheresis-collection companies to store platelets for seven days. The platelets must be collected with a specific system required by the FDA, and release tested for contamination using an objective, perfundary detection system.

### The difference two days makes

A number of benefits derive from seven-day platelet storage. Two extra days can reduce outdated and wasted product, thereby improving inventory management. Longer platelet storage provides more flexibility for blood centers and transfusion services. The two-day extension also helps recoup and defray the cost of bacterial-testing implementation.

With current storage limits of five-days, resources require careful planning. For example, products collected and tested early in the week outdate on the weekends when usage is less. Longer storage periods could help hospitals avoid platelet shortages and reduce the need for expensive weekend collection. A survey by the AABB revealed 8.4% of hospitals reported the delay of elective surgery at least one day in 2004 as a result of a blood shortage. An increased platelet supply may also reduce the hospital stay for some patients. In addition to saving lives, blood banks could reap savings by avoiding outdated products and regaining the two days lost to bacterial testing on the front end.

Patient safety is a key factor in blood-platelet collection. More than 70% of the annual 2.2 million platelet transfusions in the United States are done through apheresis and incorporate contaminant testing.

### Early adopters of seven-day platelet storage via PASSPORT study

Florida Blood Services in St. Petersburg/Tampa, FL is one participant in the PASSPORT study. The organization received...
approval in March to implement seven-day apheresis-platelet storage. The transition from five-day to seven-day storage took 12 weeks and under this study, bacterial detection is considered a “release test.”

The FDA is looking for more data points for inclusion in the PASSPORT study. Blood centers like the one in Tampa must include data related to seven-day storage in its annual report to the FDA. Additional information includes a summary of collections and results from the microbial-discovery-system tests and microbiological follow-up on any positives.

The implementation of seven-day storage and complete bacterial testing requires a substantial investment. Each test for bacterial contamination requires two bottles, which increases incubator space and cost per test. The technical director for Florida Blood Services, Tim Malone, MT(ASCP) SBB, believes the payoff will compensate for the initial investment.

“If we can reduce outdated platelets by 30% each month, the new seven-day storage platform will pay for itself,” says Malone. “We are working with a cost model that indicates we will exceed this benchmark, and the benefits will outweigh the challenges.”

“Our blood center has been a strong advocate for seven-day platelet storage because the current five-day system creates quite a bit of waste. On an average week, 5% of our stored platelets reach expiration and must be destroyed. By extending the shelf life of this valuable resource, we will provide better service to nearby hospitals through cost-effective inventory management,” continues Malone.

The first 24 to 48 hours of product availability after donation is lost due to bacterial-contamination release testing. “The additional two days of shelf-life with seven-day storage gives us those days back so the blood product can be available over a longer period of time,” says Malone.

There are several details to consider when transitioning from five-day to seven-day storage. FDA requirements mandate using a second (anaerobic) bottle for bacterial-contamination testing. Information systems and labels need to be revised to allow for new product coding and expiration-date table changes. This method involves process change and validation of the current system.

“Overall, the process of switching from five-day to seven-day storage has been relatively painless” says Malone. The new process offers more options to a tedious and detail-oriented industry. For Florida Blood Services, the benefits have been worth the effort; surely, the hospitals as well as the patients and families served in the Tampa Bay area will agree.

Louise Townsend is a Florida-based writer who formerly specialized in legislative issues for a major Washington, DC, pharmaceutical association. The system to which she refers in the text is bioMerieux’s automated BacT/ALERT, based on the detection of carbon dioxide released by microorganism activity.

References

