Carter BloodCare
SPECIALTY SERVICES

Blood Matters

Aug/Sept 2019

News for Blood Bank Medical Directors, Physicians and the Lab

Blood Matters is a quarterly news *outlet with important medical information for you, our customers and colleagues, from Carter BloodCare. We hope you will share it with others interested in the work we do together.*

IN THIS ISSUE

HOT TOPICS

Cold-Stored Platelets

Laurie J. Sutor, MD, MBA

Our practice for decades has been to store platelet components at 20 to 24ºC ("room temperature"). This convention likely arose from the finding that platelets stored at refrigerator temperatures have significantly shorter lifespans in circulation after transfusion.

However, there are clearly disadvantages of room temperature storage of platelet components: 1) Increased risk of bacterial growth, 2) regulatory requirement for either bacterial testing or pathogen reduction of the platelet component, 3) the need for agitation of the product during storage, 4) a short component shelf life (5 to 7 days), and 5) delayed activation of platelet function after transfusion. In addition, more regulation regarding bacterial testing is on the horizon, with a pending FDA guidance document on this topic. Further, there have been recent reports of bacterial contamination of platelet products despite bacterial testing and/or pathogen reduction that led to patient illness or death.

Cold storage could overcome all of these short comings. Currently the FDA allows for cold storage of platelets at 1 to 6ºC without agitation for up to 3 days for trauma patients (21 CFR 640.24 and 640.25). The Mayo Clinic has implemented use of such 3 day platelets for trauma patients in recent years. The military, after significant research and data collection, submitted a variance request to the FDA. This variance was just approved by the FDA in August with the statement "To store apheresis platelets at 1-6 C for up to 14 days without agitation. The cold stored platelet products will be used to treat actively bleeding patient when conventional platelet products are not available, or their use is not practical." Now that this variance has been approved, other facilities will be able to apply for a similar variance.

Because of the short circulation time after transfusion for cold-stored platelets, they are really only appropriate for actively bleeding patients. Hospitals will have to maintain an inventory of room temperature platelets for cancer and transplant patients.

The big advantage of cold-stored platelets to the community is to improve the flexibility of the platelet inventory. Some smaller or remote hospitals need a platelet to be in stock at all times in case of a trauma or other bleeding patient, but rarely use it. Currently this requires a large expenditure of resources to move platelets around to keep them from out dating. A platelet with a longer shelf life would be very useful for these facilities and help reduce platelet expirations.

Reference:

1. Sepsis attributed to bacterial contamination of platelets associated with a potential common source – multiple states, 2018. SA Jones, JM Jones, V Leung et al. MMWR 2019, 68(23):519-523. (Contamination despite bacterial testing or pathogen reduction)
2. Cold platelets for trauma-associated bleeding: regulatory approval, accreditation approval, and practice implementation – just the "tip of the iceberg". JR Stubbs, SA Tran, RL Emery et al. Transfusion 2017; 57:2836-2844. (Mayo Clinic implementation)
3. Cold stored platelets in treatment of bleeding. TO Apelseth, AP Cap, PC Spinella et al. ISBT Science Series 2017; 12:488-495. (review)
4. Studies of platelet concentrates stored at 22 C and 4 C. GA Becker, M Tuccelli, T Kunicki et al. Transfusion 1973; 13:61-68. (classic article).

MEDICAL MINDS

What topic do you want included in the next issue of Blood Matters?

A) Pre-hospital Transfusions
B) Review of Anti-G
C) Iron Deficiency and Blood Donors
D) Other

Click **here** to submit your choice. If you answered ***D (Other)***, remember to include your topic.

HOT TOPICS Continued

Proposed Changes to AABB Standards, 32nd Edition

Laurie J. Sutor, MD, MBA

A new version of the AABB Standards for Blood Banks and Transfusion Services is scheduled to go into effect on April 1, 2020. The draft version has been circulated for member comments this summer. The following article summarizes what I think are the most important changes for hospital blood banks. The wording is my own for simplification sake. I am not including every change in this summary.

1. The medical director is now specifically required to have continuing education in activities related to blood banking.
2. The disaster plan shall now address business continuity plans.
3. The blood bank/transfusion service (BB/TS) shall have a policy to address product inventory shortages.
4. Facilities must have measures in place to minimize the risks of data breaches (cyber security issues).
5. Zika virus testing was added in the pertinent donor testing sections.
6. Rh negative RBCs should be issued to females of child bearing potential if an Rh testing discrepancy is found, until resolution of the testing problem.
7. If a single sample is to be used for retyping the patient in determining ABO type prior to transfusion, the validated electronic identification system should be FDA approved (or something similar outside the USA).
8. The blood bank computer system used for electronic cross match must be FDA 510(k) cleared.
9. The BB/TS must have a policy for the use of washed cellular products
10. The BB/TS must have a policy for the use of specially selected platelet products including cold stored platelets.
11. There must be final visual inspection of a unit prior to issue.
12. For outpatient transfusions, recipients must be given emergency contact info for reaction reporting.
13. An emphasis was added to utilization review for group O blood and AB plasma.
14. Some safety standards for liquid nitrogen were added, including oxygen alarms.

Of note, there are two new standards relating to donor iron mitigation which will affect the blood donor center and potentially the blood supply.

The final version of AABB Standards has not been published yet, so it is possible that some of these proposed standards will be changed or dropped following a review of comments by the Standards Committee. Stay tuned!

Download updates.

- **Blood Bulletin: Using Group A Plasma to Support Emergently Bleeding Patients**
- **AABB: Recommendations on the Use of Group O Red Blood Cells**

HOT TOPICS Continued

Low-Yield Platelets Bring a Cost Benefit to Your Transfusion Service and Can Help Meet Platelet Demand

William Crews, MD

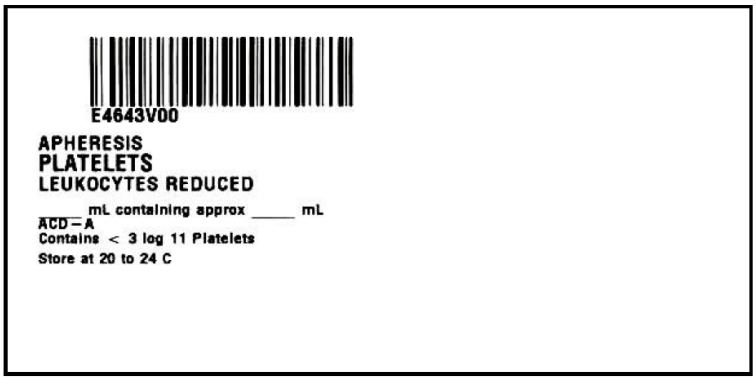
There are many FDA required quality control measurements that must be met to ensure the safety, purity, and potency of blood components before they can be labeled and made ready for patient use. One of the required measurements for every apheresis platelet is calculation of the platelet yield (volume x platelet count). For apheresis platelets the FDA considers an acceptable platelet yield to be ≥ 3.0 x 10(11) platelets, but does allow components containing less than 3.0 x 10(11) platelets to be labeled for transfusion if the actual platelet count is on the product.

When the platelet yield is < 3.0 x 10(11) the apheresis platelet is considered a low-yield product. At Carter Bloodcare, when the yield does not meet the minimum threshold, but is ≥2.8 X 10(11), we consider the potency of the product acceptable for transfusion since it is likely the platelet count is sufficient for patient care. When the yield is < 2.8 X 10(11) these products are not labeled for transfusion and the product is discarded or used for research. Use of low-yield platelets should routinely be considered for pediatric patients who will receive an aliquot transfusion, a thrombocytopenic patient who is being transfused prophylactically, and during periods when platelet transfusion demand is higher than minimum inventory levels. We recommend discussing the use of low-yield platelets with your transfusion committee to explore other patient populations that may benefit from this product. Examples of a memo for the blood bank medical director and a possible facility policy follow this article.

The following ISBT codes are available for use with low-yield platelets: E4643, E4644, E4645, E5656, E4639, E4640, E4641, E4642.

One last and important point: low-yield platelets are provided at a discount to incentivize their use and avoid wasting a good, acceptable product.

Example



Blank Leukocyte Reduced Plateletpheresis, Variable Content (E4643V00) Label

Carter BloodCare

Date: July 2019

To: Transfusion Service Medical Director

From: Carter BloodCare Medical Directors

Subject: Use of low-yield platelet units in time of shortage

We would like your help in utilizing low-yield platelet unit in times when apheresis platelets are in short supply and you have a patient that needs transfusion urgently. We are always working to maintain an adequate platelet inventory, but occasionally, especially around holiday times, temporary shortages may occur.

We sometimes have apheresis platelet units that do not quite meet the regulatory standard of 3 X 10^{11} platelets per bag. Often these lower-yield bags just barely missed the cut-off and have a count of 2.9 or 2.8 X 10^{11}. If we haven't told you over the phone what the exact bag count is, please feel free to ask. We do give you a substantial price discount on these units, so the clinical impact should be minimal, it is a platelet that is available in a time of need, and it is a financial win too. We should not be offering you any platelets with counts below 2.8 X 10^{11}.

If this practice is acceptable to you and your hospital, to help your blood bank staff take advantage of these units with minimal hurdles in the future, we suggest putting in place a standing order (or something similar) that gives them the ability to accept these units without calling for approval each and every time this situation might arise.

If you have any questions or concerns you would like to discuss, please feel free to contact Dr. Laurie Sutor at 817-412-5601 or Lsutor@carterbloodcare.org

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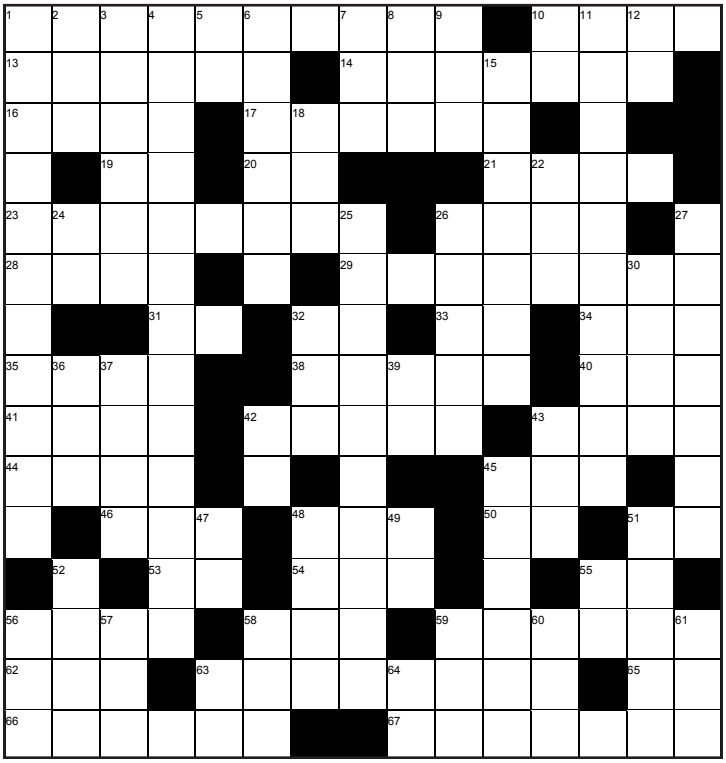
Example of Standing Policy

The blood bank technologists shall be empowered to accept into inventory apheresis platelets with a bag count between 2.8 X 10^{11} and 3 X 10^{11} when patients are in need of transfusion and no other platelets are available for transfusion. These platelets shall only be used if other platelets are not available, but may be issued to patients who urgently need transfusion.

Signed by Blood Bank Medical Director (or Transfusion Committee)

Blood Matters

CROSSWORD PUZZLE - *Created by Dr. Laurie Sutor*



- Click **here** to download the answer key.

Across

1. Type of crossmatch done on the computer
10. Blood group to which cellano belongs
13. Only crystalloid that can be mixed with red cells
14. Its capital is Quito
16. ____ d'etat
17. Lui _____ eluate
19. State of Little Rock (abbr)
20. Spinal tap (abbr)
21. Prevention for D immunization (abbr)
23. Outer layer of a blastocyst
26. You might get this at a bank
28. Coral accumulation
29. Big donor center in Florida
31. Home to Cedars-Sinai Medical Center (abbr)
32. Cryptantigen that can cause polyagglutination
33. The Badger state (abbr)
34. Not post
35. Component that contains fibronectin, for short
38. Part of LISS
40. Second imperial dynasty of China
41. Deception
42. Name of lab standards organization CLSI until 2005 (abbr)
43. Bacterial hair-like appendages
44. La ____ Bonita: 1987 Madonna song
45. Web address (abbr)
46. Apheresis procedure done on the Cellex (abbr)
48. Charged molecule
50. "Show me" state (abbr)
51. Hamlet's "To _____ or not to…"
53. Factor number for prothrombin
54. Home health organization (abbr)
55. Chemical element in old-time donor hemoglobin screening method (abbr)
56. The lab must have a disaster ____
58. Antigen agglutinated by Dolichos biflorus lectin
59. Fully developed
62. Afghani monetary unit
63. Red cell stacking phenomenon in high protein environment
65. EIA test result considered "positive" (abbr)
66. Rare complication of citrate excess in PBSC donors
67. Platelet storage device

Down

1. _____ coli
2. Language spoken in Vientiane
3. Test to remove antibody from red cells and identify it
4. Fluoroquinolone antibiotic
5. State where Dollywood is located (abbr)
6. Sympathetic _____ dystrophy, rare phlebotomy complication
7. Word found in wedding announcements meaning "born as"
8. Early treatment for hematoma
9. Slang for "this is why!"
10. Actor born Issur Danielovitch in 1916 (init)
11. Cell in abundance in allergy reactions
12. Filtered to remove WBC (abbr)
15. Type of bacteria or exercise
18. Non-treponemal syphilis test (abbr)
22. Computer in "2001: A Space Odyssey"
24. The other Rh gene other than D
25. Common type of blood bank reagent these days
26. Blood group associated with the secretor system
27. Substrate added in extended storage media to RBCs
30. By mouth
32. Nervous habit or twitch
36. Check off by the physician of a patient's major organ groups for disease (abbr)
37. Dr. Ed Snyder's academic institution
39. Usual (abbr)
42. Expected answer to most blood donor questions
43. Not amateur
45. Two dots over a vowel in some languages
47. 3.14159
48. High risk activity for HIV and hepatitis (abbr)
49. Electrolyte in 13 Across (abbr)
51. Pack animal
52. Color of anti-A reagent
55. Boulder institute of higher learning (abbr)
56. What factor VIII does when FFP is thawed in the cold (abbr)
57. Chemistry test once used as a blood donor test for hepatitis (abbr)
58. Nondairy type of milk
59. Chinese "chairman"
60. Antifibrinolytic drug (abbr)
61. Make a mistake
63. Nursing degree (abbr)
64. Hospital triage site (abbr)