



November/December 2022

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.

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### HOT TOPICS

# Transfusions During Patient Transport – What are the Admitting Hospitals' Responsibilities? *Laurie J. Sutor, MD, MBA*

Transfusion during transport of a critically ill patient is becoming increasingly common, especially during air ambulance transfers. More and more transport services are stocking either whole blood or red cells and/or plasma on the carrier during runs. Nearly all ambulances probably would stock such blood if the community blood supply accommodated it. Unfortunately, in our region, it is very difficult to provide enough group O blood to stock all the ambulances that request it and still serve hospital transfusion needs.

The scientific literature supports the use of blood products during transport in many situations (see references). More and more peer reviewed articles from the civilian practice in the U.S. are adding to the evidence that already existed from the battlefield: quick resuscitation with blood saves lives. Therefore, this practice is unlikely to go away.

How does this process work, logistically? Blood and/or plasma are provided to the transport company for use in their emergency trips to pick up patients with severe injury and hemorrhage. The red blood cells are group O, Rh positive and the whole blood is low titer for anti-A and anti-B antibodies. The plasma is most often group A and given without regard to blood type. The ambulance personnel are trained to watch for adverse effects and report them if appropriate. They document the transfusion and pass this on to the local hospital where the patient is ultimately admitted. The ambulance company also keeps a copy of the transfusion records so that they can notify the patients in case of a unit recall or lookback (under our local contract conditions).

The admitting hospital may have the following responsibilities:

- 1) Documentation in the medical record of any blood product that was transfused pre-hospital, including any in the process of being transfused when the patient reaches their doors (and making it clear that it came with them from outside).
- 2) Discard of any blood that didn't get completely transfused en route.
- 3) Complete a work up of any adverse event related to transfusion discovered once the patient reaches the hospital and is in their custody.

We highly recommend that facilities develop a close communication between their emergency room and the hospital blood bank for information about transfusions in transit. While it may be easy to simply add a page from the ambulance team to the medical record documenting transfusion en route to the hospital, the blood bank is usually the storage site for all records of transfusion and should also be informed of this information.

Note: AABB issued a set of Standards for Out-Of-Hospital Transfusion Administration Services, but it is not intended to cover transfusion in emergency pre-hospital transport situations.





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### HOT TOPICS Continued

References:

Association of prehospital blood product transfusion during medical evacuation of combat casualties in Afghanistan with acute and 30-day survival. SA Shackelford, DJ del Junco et al. JAMA 2017, 318(16):1581-91.

Prehospital plasma during air medical transport in trauma patients at risk for hemorrhagic shock. JL Sperry, FX Guyette et al. NEJM 2018, 379(4):315-26.

Prehospital whole blood reduces early mortality in patients with hemorrhagic shock. Braverman MA, Smith A, Pokorny D et al. Transfusion 2021, 61:S15-S21.

# Supply Chain Issues Threatening to Impact Blood Collections: What's All the Fuss About? *Nicole De Simone, MD, MPH*

Supply chain issues have been creating unprecedented and unique challenges in healthcare. Several of the major manufacturers of blood collection supplies have had ongoing issues that have led to subpar inventory levels of various supplies. One critical item has been the blood pack units (BPUs), which are used in collection and processing of whole blood into components. Fresenius Kabi informed blood centers in late October that they were anticipating even more shortages of the Bioflex, their BPU, due to their Puerto Rico manufacturing plant being affected by both COVID-19 and Tropical Storm Fiona. As part of their efforts to restore supply, they worked with the FDA to temporary license a manufacturing facility in the Czech Republic. This facility, located in Horatev, Czech Republic, has been manufacturing BPUs approved for use in the European Union, and thus these BPUs have been commonly referred to as the "Horatev bag."

The FDA approval for use of the Horatev bag, however, was predicated on the EU's approval, which included red cell storage of only 35 days. Comparatively, the Bioflex was approved for 42-day red cell storage. In looking at the product features and specifications of the Bioflex compared to the Horatev bag, there are few, subtle differences that ultimately would not impact products. As such, the 35-day red cell unit was given the same product code as the 42-day red cell unit. The implications of the same product having two different expiration dates was concerning, and blood centers immediately started voicing concern to the FDA and asked them to extend the Horatev red cell product to 42 days.

Carter Bloodcare (CBC), as well as many other blood centers, has been working expeditiously to validate the Horatev bag and to also communicate with hospital transfusion services of any potential upcoming changes. CBC has also been working with America's Blood Centers and Association for the Advancement of Blood & Biotherapies to urge the FDA to prioritize the approval of 42-day red cell storage. On November 10<sup>th</sup>, Fresenius Kabi announced that the Horatev bag had been approved for red cell storage for up to 42 days in the U.S.

Unfortunately, there have also been shortages of the Terumo BCT Trima double red cell apheresis collection kits with inline leukoreduction (LR) filter. We immediately began looking for other options, as a lot of our group O and A red blood cells (RBCs) are collected using these kits. The Trima kits without an inline filter were readily available so we looked to obtain additional filters that could be used during processing to perform leukoreduction, but these filters were also on shortage. Due to lack of other viable solutions, we notified hospital transfusion services of the possibility of non-LR RBCs being distributed so that they would have time to accordingly adjust workflows. Fortunately, LR filters were located, and we have been validating their use with the Trima collection kits.

We are hopeful that these bag shortages are coming to an end but know that this may not be the last supply chain issue. We are closely monitoring inventory levels and working hard to ensure no disruption to the blood supply.





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HOT TOPICS Continued

# New Platelet Pooling Set for Whole Blood-Derived Platelets Approved by FDA *Frances Compton, MD*

As of August 26, 2022, Terumo BCT received FDA 510(k) clearance for their new whole blood-derived platelet pooling set. This newly developed pooling set is called the IMUGARD<sup>®</sup> WB PLT Pooling Set and can pool up to six whole blood-derived platelet concentrates. This is exciting news for the blood industry because this is the first whole blood platelet pooling set which is approved for seven-day pooled platelet storage. Up until now, pre-storage pooled platelets had a maximum shelf life of five days.

Carter BloodCare has been distributing seven-day *apheresis* platelets since we implemented large volume delayed sampling of apheresis platelets according to the 2020 FDA platelet bacterial risk control Guidance for Industry. However, there has not been a pooling kit approved to store *pooled* platelets for more than five days (until now).

Due to the national supply chain shortages, The IMUGARD<sup>®</sup> pooling kit is not yet available for use. Carter BloodCare will continue to distribute Acrodose<sup>™</sup> pooled platelets in the meantime and plans to explore implementation of the IMUGARD<sup>®</sup> kit once it is available. We hope that a seven-day pooled platelet product can help alleviate the blood shortage which has occurred since the COVID-19 pandemic.

If your hospital is interested in receiving whole blood-derived pooled platelets, please reach out to our Hospital Relations department at <u>hospitalrelations@carterbloodcare.org</u> to inquire about availability.

#### References:

CBER Letter to Terumo BCT dated August 26, 2022 BK210658 Letter (fda.gov)

FDA Guidance for Industry: "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" Updated December 2020.

Single donor platelets versus whole blood derived platelets: are they the same? - Ness - Annals of Blood (amegroups.com) December 2020

### PHYSICIAN RESOURCES

#### **Review Updates**

Blood Bulletin: Cryoprecipitate (Cryo) and Alternatives

### MEDICAL MINDS

### What topics would you like to see in a future issue of Blood Matters?

Click here to submit your choice.





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#### **CROSSWORD PUZZLE**



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#### Click here to download the answer key.

#### Across

- 1. Hematopoietic cell transplant
- Virus for which blood donor testing was stopped in June 2021 9.
- 12. Colloid administered to granulocyte apheresis donors (abbr)
- 13. Type of business document largely replaced by scanned pdfs
- 14. Music genre for Grover Washington Jr.
- 16. She played both twins in the 1998 movie The Parent Trap (init)
- Blood enzyme elevated in hemolysis (abbr)
   Test for engraftment potential of progenitor cell harvests (abbr)
- 19. Animal related to the stoat or ferret
- Value that must be recorded for plasma donors during screening
   PK-\_\_: automated version of donor syphilis test
- 24. Latin for "that is", used to restate the previous phrase (abbr)
- 25. RH36: low incidence antigen once called Berrens
- 27. The mythical beast that the "C" in CAR-T comes from
- 30. The department that helps you hire new staff (abbr)
- 31. What blood products do when they reach the end of their shelf life
- 32. Designation largely now replaced by "MLS" in the lab (abbr)
- 33. Ru-Paul's \_\_\_\_ Race (TV show)
- 35. Baseball's Young award for best pitcher
- 36. Microsoft program for giving presentations (abbr)
  38. \_\_\_\_\_ freeze RBC elution technique
- 39. Colorado resort town near Telluride
- 41. Where on the body the donor pulse is usually checked
  43. NCAA conference of Texas A&M (abbr)
  44. Sport for the Texas Rangers and the Astros (abbr)

- 45. Highest possible \_\_\_\_\_on the SAT is 1600
  47. Storage life for frozen RBCs at -65C is 10 \_\_\_\_\_.
  49. Non-ABO hemolytic disease of the newborn is rarely a risk with pregnancy the
- 51. Progenika ID Core \_: molecular RBC testing platform 52. \_\_\_\_ de Armas, star of "Knives Out"
- 55. Outdated process to use barcode to let donors defer themselves (abbr)
- 56. Vim and vigor
- 59. DNA has a double shape
- 61. An organism that develops a membrane sac during gestation
- 63. Common body imaging scan (abbr)
- 65. Brain gland that makes melatonin
- 67. Protein to which COVID vaccine is directed
- 68. One type of donor arm scrub: povidone-
- 70. Computer operating system that pre-dated Windows (abbr)
- 71. Hospital triage area (abbr) 72. 40-all in tennis scoring
- 73. Jaundiced

#### Down

- Procedure for drawing blood
- 2 Danger color
  - 3. Medical term for an opening
  - The ability to produce a desired effect 4. 5
  - On Santa's list: or nice? Clotting factor deficient in Christmas disease 6
  - Breakfast beverage with vitamin C (abbr) 7
  - 8. Not cooked
  - 9. Reagent to treat RBCs to remove IgG and complement, that destroys Kell and Duffy antigens 10. Quantitative slide test for fetomaternal hemorrhage (2 words)

  - 11. Type of transfusion reaction with hives 15. The negatively charged surface of the RBC gives a repulsive potentia
  - between cells
  - 18. Lab professionals need credits to maintain certification (abbr)
  - 20. Equipment to thaw FFP (2 words)
  - 21. Encouraging word to a team of mules
  - 22. Our profession (abbr)
  - 26. Agency that inspects some blood centers sending plasma overseas (abbr)
  - 28. Based on experience not theory
  - 29. Storage condition for tradition platelet products (abbr)
  - 34. Reported lower extremity complication of iron deficiency (abbr)
  - 36. Affectionate name for fully promoted university faculty member
  - 37. It usually pays time and a half (abbr) 40. \_\_\_\_\_ europaeus = anti-H lectin

  - 41. Another name for the loo (abbr) 42. Liquid from clotted blood
  - 46. BMI = wt (kg) divided by
  - (m) squared 48. Crystalloid approved to be infused with blood

  - 50. Device on apheresis machines to detect air embolus or hemolysis Inch Nails (band)
  - 54. Hewing tool
  - 56. Hawaiian dish made from taro root
  - 57. Review of flagged charts at Transfusion Review Committee review process is a
  - 58. Most common RBC elution method in tube testing
  - 60. Common electronic medical record system in hospitals
  - 62. Prefix meaning "same"
  - 64. One of ten digits
  - 66. Organization providing 35% of the nation's blood supply (abbr)
     69. Old name for the weak D test

  - 70. State Joe Biden represented in the Senate (abbr)