

inSIGHTS

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LETTER FROM THE CHAIR

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Dr. Philip Syng Physick conducted the first human blood transfusion in 1795, and the first transfusion of human blood for treating hemorrhage was carried out in England by Dr. James Blundell in 1818. Since those early days, transfusion has become relatively routine and medicine has made significant strides in its safety and efficacy. The field of transfusion medicine will continue to evolve, as research explores better ways to reduce the risk of reactions and optimize product storage.

A blood transfusion can be a life-saving measure, and laboratory professionals are responsible for ensuring that the best and safest blood products are given to patients. As a family physician in rural/-frontier Idaho for decades, I've seen first-hand how transfusion medicine saves lives.

To deliver on this responsibility, our industry must remain up-to-date with the changing healthcare landscape and the needs of the populations we serve. In this edition of inSights, our authors examine changes to donation criteria and blood utilization. National Blood Donor Month will be celebrated in January, and donated blood is used every day to save countless lives.

Please reach out to us at learn@cola.org to share how your own laboratory is adapting to changes in transfusion medicine or how blood donation recruitment initiatives in your area are implementing new donation criteria.



Keith Davis, MD, FAAFP

Chair, COLA Board of Directors

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Changes in Criteria For Blood Donation

By: **Runyararo M. Munyikwa**, MSTM, MLS(ASCP)^{CM} SBB^{CM}

Runyararo M. Munyikwa joined COLA in 2022 as a surveyor before taking the role of a Technical Advisor in 2023. Ru has over 20 years of clinical laboratory experience especially in the field of blood bank. Prior to COLA, she worked as a Blood Bank Lead Technologist at Quest Diagnostics in Maryland. She also Worked at American Red Cross Immunohematology Reference Laboratory (IRL) Baltimore, Maryland. Ru's interest in the field of Transfusion Medicine began while working in the blood bank, reference laboratory and hospital-based donor room at Brigham and Women's Hospital in Boston, Massachusetts 2006-2008. She went on to earn the Specialist in Blood Bank in 2017 and Master of Science in Transfusion Medicine in 2021 at University of Texas Medical Branch (UTMB), Galveston Texas. Ru had an Abstract Poster Presentation at AABB 2021 annual meeting, and she also published a peer-reviewed article in the field of Transfusion Medicine in 2022.



FDA Changes Blood Donation Criteria: New Inclusive Screening Rule

The safety of blood and blood components for transfusion begins with a healthy donor. All donors must meet federal blood donation screening criteria to ensure they are free of diseases known to be transmissible by blood transfusion.

While keeping the blood supply safe is the ultimate responsibility of all blood collection facilities,

the US Food and Drug Administration (FDA) is the principal regulatory agency and plays an essential role in establishing policies for blood donation.

On May 5, 2023, the FDA issued a final guidance establishing a donor screening process based on individual donor assessment (IDA), not sexual or gender identity. The new guideline recommends all potential blood donors be asked the same set of screening questions which focus on behavior that raises the risk of transfusion-transmitted HIV. The new process removes the previous restrictions against donations from men who have sex with men (MSM), and should ultimately increase the number of people who are eligible to donate blood.

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The FDA included an already existing rule in this new guidance: permanent donor deferral for any person who has been tested and confirmed positive for HIV infection or who has been treated or taken medication for HIV infection. It also reiterates the required deferral period for people taking pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) against HIV. Available data has shown that the use of PrEP or PEP makes it difficult to detect the virus with current testing methods.

All blood and blood component collection facilities including those collecting source plasma may now implement these recommendations by revising their donor history questionnaires, policies, procedures and educational materials for assessing blood donors.

Blood collection staff should be trained and educated based on the new donation criteria.



Please refer to the FDA website for more details regarding these new recommendations in donor screening criteria.

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Cold Stored Platelets

By: Runyararo M. Munyikwa, MSTM, MLS(ASCP)^{CM} SBB^{CM}

Runyararo M. Munyikwa joined COLA in 2022 as a surveyor before taking the role of a Technical Advisor in 2023. Ru has over 20 years of clinical laboratory experience especially in the field of blood bank. Prior to COLA, she worked as a Blood Bank Lead Technologist at Quest Diagnostics in Maryland. She also Worked at American Red Cross Immunohematology Reference Laboratory (IRL) Baltimore, Maryland. Ru's interest in the field of Transfusion Medicine began while working in the blood bank, reference laboratory and hospital-based donor room at Brigham and Women's Hospital in Boston, Massachusetts 2006-2008. She went on to earn the Specialist in Blood Bank in 2017 and Master of Science in Transfusion Medicine in 2021 at University of Texas Medical Branch (UTMB), Galveston Texas. Ru had an Abstract Poster Presentation at AABB 2021 annual meeting, and she also published a peer-reviewed article in the field of Transfusion Medicine in 2022.



Transfusion of platelets is indicated in patients with thrombocytopenia, dysfunctional platelet disorders, or active platelet-related bleeding and patients at serious risk of bleeding. Most platelets are collected by apheresis, a widely used automated procedure which collects a therapeutic adult dose of platelets from a single donor. Platelets can also be made from whole blood: 4 to 6 donors are pooled for an equivalent adult apheresis dose.

Platelets are stored at room temperature between 20 to 24 degrees Celsius with gentle agitation. They have a short 5-day shelf life because changes to their structure and function after this period render them less effective for hemostasis.

In addition, storage at room temperature can encourage bacterial growth and create a risk of platelet transfusion-associated bacteremia or sepsis.

Cold-Stored Platelets

Cold-stored platelets (CSP) are not a new product. In 1975, the FDA regulatory standards were established for CSP with a storage shelf life of 72 hours at 1 to 6 degrees Celsius. However, in the next several years, research showed that room temperature platelets (RTP) stored at 20 to 24 degrees Celsius had a higher post-transfusion platelet recovery and longer survival. The use of CSP stopped and RTP became the standard practice.

Clinical research on CSP continued even after they were abandoned in the late 1970s and today clinical trials of CSP are providing new data showing that they are more effective hemostatically than RTP in stopping serious bleeding and are effective over a longer period, giving them a longer shelf life. In addition, data shows that cold storage significantly decreases bacterial growth. Agitation is optional for CSP, which simplifies their storage.

Today, the need for transfusion of platelets has increased for actively bleeding patients such as those receiving cardiac surgery. The effects of blood shortage during the recent COVID-19 pandemic have pushed the much-needed regulatory approval from the FDA for clinics and blood establishments to implement the manufacture of CSP.

On June 23, 2023, FDA issued a final guidance, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical." This document was issued in response to a public health need and addresses the immediate need for platelets for the treatment of active bleeding when conventional platelets are not available or their use is not practical. The guidance allows blood establishments to manufacture CSP without submitting a variance request to the FDA under 21 CFR 640.120. In this guidance, the FDA outlines comprehensive recommendations to be followed when implementing this alternative method to manufacture and use CSP.

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FDA Guidance Recommendations

The FDA defines conventional platelets to include all platelets (as defined in 21 CFR 640.20) intended for transfusion and stored at 20 to 24 degrees Celsius.

Cold-stored platelets are defined as those stored continuously at 1 to 6 degrees Celsius within a specified time after collection.

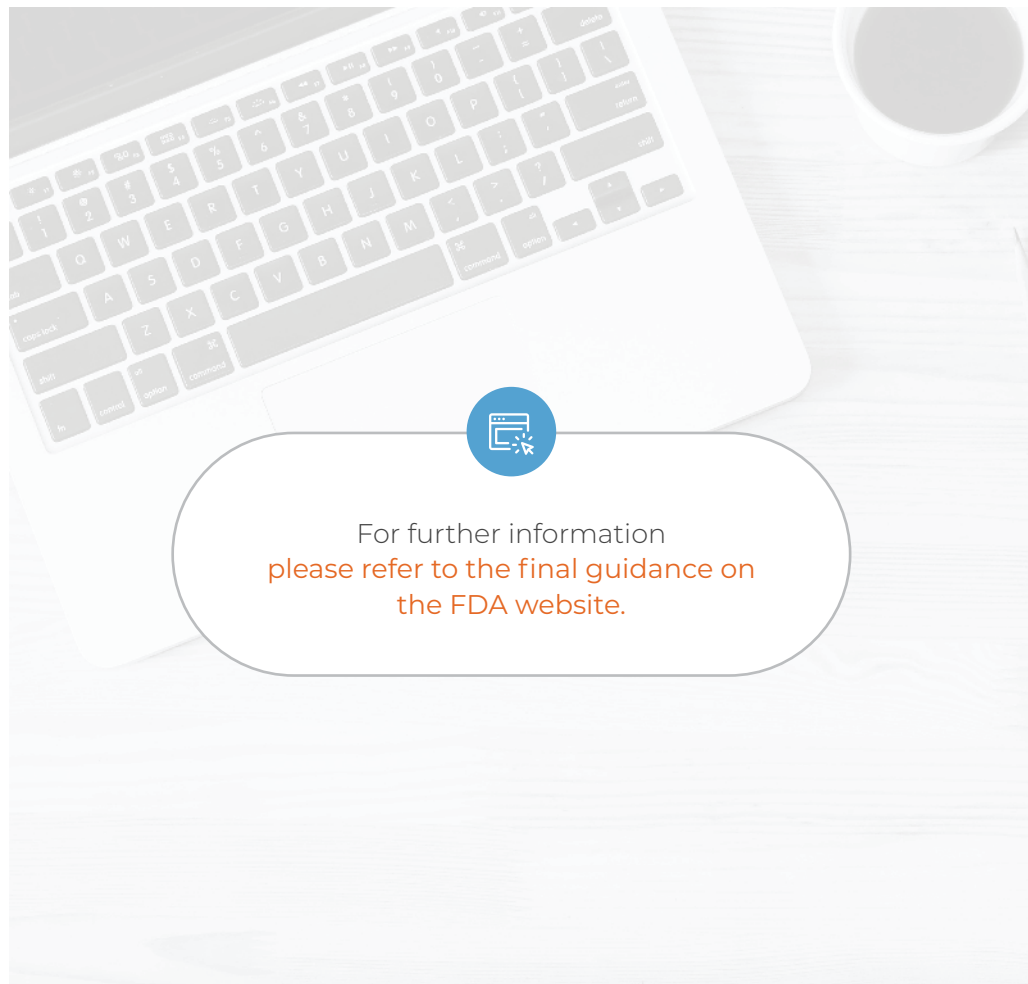
The FDA offers recommendations for blood establishments for the manufacture of CSP to perform process validations, quality control testing (21 CFR 640.25 (b)(2), 21 CFR 211.160(b), and 21 CFR (211.165(c), and container labeling of CSP according to 21 CFR 606.121. The guidance specifies the following to be added in the *Circular of information* (21 CFR 606.21) to provide adequate directions for the use of CSP:

- ▶ *CSP are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical.*
- ▶ *CSP must be stored continuously at 1-6°C to control the risk of bacterial contamination for up to 14 days.*
- ▶ *Transfusion services should establish procedures for examining CSP for visible aggregates before transfusion.*

The guidance states that the cold storage of platelets is an adequate method to assure the risk of bacteria is adequately controlled, but establishments may implement additional measures for bacterial control.

The guidance discusses the need for additional data on efficacy of CSP

to address whether their use is supported when conventional platelets are not available and not practical.



For further information
please refer to the final guidance on
the FDA website.

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The Investment in You:

Continuing Education

By: **Jennifer MacCormack**, MLS (ASCP)^{CM}

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science, and regulatory oversight. She received her Bachelor of Science in Physiology from McGill University.



Continuing education is especially important in the field of healthcare, where the technology we use and the regulatory landscape we work in are always changing. For laboratory personnel and managers, staying updated with the latest advancements is essential to the continued delivery of quality test results. Continuing education ensures that professionals are equipped with the newest skills and knowledge, enabling high-quality patient care. By embracing lifelong learning as a regular and integral part of the job, laboratory professionals enhance their expertise and contribute to the overall excellence of the healthcare system.



Many professional bodies require laboratory personnel to provide proof of ongoing education to renew their license or certification.

However, even if documenting continuing education activities is not a requirement for your continued employment, it is nonetheless a best practice to regularly seek out new information in your field of work, to be prepared for any changes ahead.

Stay Ahead of Changes in Technology

Change is constant in laboratory science. New tests and techniques are being developed and approved every year, with many of them trickling down to even smaller physician office laboratories. Molecular testing platforms, for example, are now one of the most commonly used methods for detecting common viral and bacterial infections such as influenza, RSV, COVID-19 and group A Strep.

While it may not be strictly necessary to understand the underlying science that makes the testing possible, deeper knowledge of the mechanisms means a better ability to recognize and handle problems and to troubleshoot questionable results.

In addition to the adoption of new platforms and systems, the laboratory field experiences regular shifts in the regulatory landscape. Accreditation organizations regularly review and revise their criteria to ensure that their member laboratories are operating at the highest level of quality and patient safety. Public health emergencies such as the COVID-19 pandemic can cause regulatory agencies to make changes in enforcement discretion relating to certain regulations, which may lead to temporary changes in laboratory workflows. The regulations themselves also change periodically; for example, the upcoming changes to the CLIA proficiency testing (PT) regulations ([inSights Q3 2022: PT Changes, pg5](#)) will require many laboratories to assess their current PT practices and adapt to meet the new requirements.

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Where to Find Laboratory Continuing Education

There are many sources online and in print for laboratory continuing education. Depending on an individual's preferred learning style, some resources may be a better fit than others. Written articles, either in peer-reviewed scientific journals or in industry magazines and publications such as *inSights*, are often easy to access for free or for a small subscription cost. Laboratory science webinars and podcasts are excellent options for visual or auditory learners; some live webinars even offer an interactive element where questions can be asked of the presenters.

Manufacturers' websites can be a resource for learning about specific types of technology and instrumentation, and professional laboratory organizations often offer a range of continuing education courses to their members as well. Finally, accreditation organizations are an excellent resource for keeping up with changes in the industry; for example, COLA Academy offers several courses that are approved for official continuing education credits.

A web search for laboratory continuing education will bring up dozens of different resources. Keep in mind, however, that some of the resources will require payment or membership. In addition, while all continuing education is valuable for what it adds to your knowledge of the laboratory, not all courses will count towards official continuing education credit.

If that is a requirement for recertification, confirm eligible types of continuing education with your certifying body.

Making Time for Continuing Education

Laboratory work is demanding, and with an ongoing personnel shortage many laboratory staff are already feeling stretched thin – how can we consistently make time for continuing education? Reading and education can always take place during personal hours away from work,

but there is an argument to be made for laboratory leadership to build time into the regular workload for employees to learn and grow.

Allocating time for employees to earn continuing education credits on the job can foster a culture of growth and adaptability within the laboratory team. By providing dedicated time for continuing education, management not only invests in the professional development of their staff but also ensures that the laboratory remains competitive and compliant as technology and regulations shift. This support from leadership boosts employee morale, enhancing job satisfaction and loyalty. Educated and skilled employees who feel supported by their managers directly contribute to the laboratory's efficiency, accuracy and overall quality of service.

Ultimately, enabling employees to pursue ongoing education not only benefits their individual growth but also strengthens the laboratory's capabilities, leading to improved patient care and sustained success in the industry.



Patient Blood Management:

Revolutionizing Transfusion Medicine

By: David Chhieng, MD, MBA, MSHI, MSEM, MLS, MD

Dr. David Chhieng is the Chief Medical Officer of COLA. Before he joined COLA, he was a Professor, the Director of Anatomic Pathology and Pathology Informatics, and Vice Chair of Clinical Operation, of the Department of Pathology at the University of Washington in Seattle WA. Prior to that, he was the Director of Cytopathology at Yale University and the Icahn School of Medicine at Mount Sinai. He is board certified in Anatomic and Clinical Pathology, Cytopathology, and Clinical Informatics. He has been a practicing surgical and cytopathologist for 20+ years and in a directorship position for 10+ years.



Blood transfusion, a routine medical procedure in modern healthcare, has undergone a significant transformation in term of its utilization over the past two decades. In 2021, the United States administered 10.7 million units of red blood cells (RBCs), marking a decrease from over 11.3 million units in 2015. This shift can be attributed to the effectiveness of patient blood management (PBM) initiatives pioneered by Australian hematologist Professor James Isbister in 2005. PBM, as defined by the World Health Organization, is a "patient-focused, evidence-based and systematic approach", with the aim of optimizing patient care while minimizing unnecessary blood product exposure. It redirects the focus from transfusion practices to patient outcomes, emphasizing the maintenance of hemoglobin levels, optimization of hemostasis and reduction of blood loss.



The Growth of PBM:

The growth of PBM programs over the past two decades can be attributed to two key factors. First, there has been a steady trend of blood transfusions surpassing blood donations, as documented by the National Blood Collection and Utilization Survey (NBCUS) since 1997. While blood transfusions increased until reaching a peak in 2008, blood donations remained stable or declined. Since 2008, both blood transfusions and collections have gradually decreased. Second, there is a growing recognition that more restrictive transfusion thresholds are generally safe for most patient populations.

Multiple randomized controlled trials have compared restrictive and liberal RBC transfusion thresholds and found no significant differences in 30-day mortality.

Additionally, evidence-based guidelines for the use of various blood components have become available,

guiding healthcare providers in making appropriate transfusion decisions.

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The Pivotal Role of PBM:

PBM represents a paradigm shift in transfusion medicine towards a patient-centric approach that not only minimizes blood product usage but also enhances patient outcomes. PBM not only promotes judicious transfusion practices but also prioritizes the conservation of a patient's own blood throughout their medical journey. PBM's origins can be traced back to accommodating patients with religious objections to transfusions, addressing concerns about disease transmission and being grounded in evidence supporting the safety of restrictive transfusion practices. This concept plays a pivotal role in the ever-evolving landscape of blood management, offering the promise of improved patient care while concurrently reducing the occurrence of unnecessary transfusions.

Implementing PBM:

Implementing a PBM program is a complex process involving various strategies aimed at optimizing transfusion practices and improve patient outcomes. Key components include effective management of anemia pre-operatively, minimization of blood loss during procedures, provision of real-time education for physicians and the adoption of data-driven decision support tools. The success of PBM programs hinges on collaboration across medical specialties and the support of frontline providers.

Physician education is key for breaking entrenched habits and fostering adherence to guidelines.

A keen focus on perioperative management is vital to reducing the need for transfusions. Access to data is critical for monitoring and assessing transfusion practices. Clinician decision support tools, such as computerized physician order entry (CPOE) systems with alerts, are beneficial in solidifying adherence to both institutional and national transfusion guidelines.

Transfusion Utilization Review:

Transfusion utilization review plays a crucial role in PBM by providing rigorous peer reviews of an organization's transfusion practices. It is a crucial component of modern healthcare quality control program in hospital settings. Its objectives encompass the development, implementation and monitoring of adherence to institutional and national transfusion guidelines while offering feedback for continuous quality improvement. The review may also examine various factors such as blood products expiration and wastage, the monitoring of patient safety, the scrutiny of adverse events, as well as the exploration of potential cost-saving opportunities.

Implementing these tactics can lead to reduced transfusion risks and costs as well as improved quality outcomes.

The transfusion utilization review committees should include representatives from major departments engaged in blood transfusions, such as medicine, surgery, emergency medicine, pediatrics, hematologic oncology and anesthesiology. Additionally, the committee should include key personnel like the transfusion service medical director, blood bank supervisor manager, as well as representatives from hospital administration, nursing, quality assurance, IT and the institution's blood supplier. Regular committee meetings, organized at least quarterly, are essential with reports from these meetings being communicated with the medical staff, thereby promoting transparency and perpetuating a culture of continuous improvement.



Conclusion:

The evolution of blood transfusion practices in modern healthcare, characterized by a decline in RBCs administration, can be partly attributed to the transformative impact of PBM. PBM's patient-centric approach, with emphasis on the principle of evidence-based care, has successfully redirected the focus from transfusion practices to patient outcomes. Achieving PBM's objectives involves adopting complex strategies, including physician education and the use of data-driven tools. Transfusion utilization review, an integral component of PBM, allows healthcare facilities to develop and monitor adherence to transfusion guidelines as well as to provide feedback for ongoing improvement in institutional transfusion practice.

Editorial:

Transfusion Reactions

By: Felicia Hill Davis, BS, MLS(ASCP), SBB

Felicia Hill Davis worked as the blood bank and general laboratory supervisor at Hunt Regional Medical Center in Greenville, TX for more than 20 years. Felicia earned her Bachelor of Science degree from Texas A&M University Commerce and graduated from the Specialist in Blood Banking Program at the University of Texas Southwestern Medical School. She now serves as a COLA Surveyor specializing in Transfusion Services.



When the nurses called and began asking questions... I was terrified.

Fresh out of school as a new Medical Technologist, I grabbed the procedure manual to determine what our next steps should be and to honestly figure out if I was the one that had caused the issue. It was a transfusion reaction. As you know, working with blood and blood products is necessary for sustaining life when bodily functions are compromised due to blood loss; they also come with adverse complications, hence the terminology. But because of their infrequency, medical professionals often don't feel as comfortable and may panic as I did those 40+ years ago. Use this information to help you remember how to navigate and, more importantly, recognize them the next time you see one.

It's critical that you're aware that any symptom occurring within 24 hours of a blood transfusion should be considered a transfusion reaction until proven otherwise. For precautionary purposes, it's even recommended all be suspected as severe during the initial management due to the overlap of mild and acute cases.

Signs often include fever, chills, itching, and hives.

Other less frequent symptoms are low blood pressure, labored breathing, or blood in the urine, indicating a more serious reaction. During this time, it's essential to retain an open line of communication with nurses within the first few minutes and throughout, given the sometimes fluctuating nature of the patient's conditions. After appropriate identification, classifying is the next step.

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Common categories include:

✓ Acute Hemolytic Reactions:

Occur when patient antibodies attach to red blood cells, causing them to burst. They can also happen due to a compromised blood unit hemolyzed before transfusion. For example, a malfunctioning blood warmer used to warm units or IV fluids other than saline introduced into the unit can cause hemolysis.

✓ Allergic Reactions:

This is when a patient's immune response is directed to allergens in the unit, such as IgA. Anaphylactic reactions are more severe and may require more treatment support.

✓ Delayed Reactions:

Caused by an anamnestic response due to previous sensitization or graft-versus-host disease caused by donor lymphocytes.

✓ Febrile Reactions:

The most common febrile reactions occur when blood donor white blood cells release proteins.

✓ Septic Reactions:

Results from bacteria in the donor unit leading to infection, shock, or death.

✓ Transfusion-Associated Circulatory Overload (TACO):

a collection of signs and symptoms of acute pulmonary edema with or without peripheral edema due to circulatory overload occurring within 6 to 12 hours of transfusion. Risk factors include patients with liver, heart or kidney failure, patients requiring multiple transfusions and patients of extremes of age.

✓ Transfusion-Related Acute Lung Injury (TRALI):

characterized by symptoms and signs of pulmonary edema without evidence of peripheral edema within 6 hours after transfusion. complication of blood product transfusion. It is thought to be immune mediated with donor antibodies directed toward human leukocyte antigens (HLA) or human neutrophil antigens (HNA) expressed on pulmonary epithelial cells.



Next, stop the transfusion and maintain venous access with isotonic saline. Depending on the severity and progress of the diagnosis, specific cardiac, respiratory, and renal support should be initiated. Blood product labeling and patient identification should be checked, and every incident must be reported to the transfusion center.

The cornerstone of transfusion reaction prevention is a restrictive attitude towards transfusion indications.

Healthcare providers, blood banks, and hospitals should take many precautions to help minimize the chance of a reaction occurring to ensure optimal patient care.

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The Return of Whole Blood Transfusion

By: **Runyararo M. Munyikwa**, MSTM, MLS(ASCP)^{CM} SBB^{CM}

Runyararo M. Munyikwa joined COLA in 2022 as a surveyor before taking the role of a Technical Advisor in 2023. Ru has over 20 years of clinical laboratory experience especially in the field of blood bank. Prior to COLA, she worked as a Blood Bank Lead Technologist at Quest Diagnostics in Maryland. She also Worked at American Red Cross Immunohematology Reference Laboratory (IRL) Baltimore, Maryland. Ru's interest in the field of Transfusion Medicine began while working in the blood bank, reference laboratory and hospital-based donor room at Brigham and Women's Hospital in Boston, Massachusetts 2006-2008. She went on to earn the Specialist in Blood Bank in 2017 and Master of Science in Transfusion Medicine in 2021 at University of Texas Medical Branch (UTMB), Galveston Texas. Ru had an Abstract Poster Presentation at AABB 2021 annual meeting, and she also published a peer-reviewed article in the field of Transfusion Medicine in 2022.



The field of transfusion medicine (TM) is not static. Recently, an explosion of clinical trials and new scientific evidence, combined with advanced technology, has TM back in the limelight again. This article will highlight some of the changes in the way we manage massive transfusion; specifically, the return of whole blood as a preferred product for trauma cases.

Whole Blood Transfusion: **Full Circle**

Following advancements in human blood group identification and blood typing, whole blood transfusion was popularized in World War I. At that time, blood was stored in glass bottles with citrate solution to prevent clotting. The introduction of new anticoagulants and plastic collection bags allowed for longer storage of blood, and whole blood was soon routinely separated into its components, each of which could benefit many recipients in treating different medical conditions. The use of component therapy showed less wastage, and most individual components had a longer shelf life than whole blood. With the increased use of blood components, colloids and crystalloids in heavily bleeding patients, the practice of whole blood transfusion declined.

Component therapy with packed red blood cells (PRBCs), fresh frozen plasma (FFP), platelets and cryoprecipitate became the standard of practice

Whole Blood Reintroduced: **Low Titer Group O Whole Blood**

In a typical massive transfusion protocol, where a patient is in life-threatening hemorrhagic shock, more than 10 units of red cells are transfused in a 24-hour period. In many facilities, a component ratio of 1:1:1 of plasma, platelets, and red cells is used in MTPs in an attempt to mimic the benefits of whole blood transfusion; this normally requires 6 PRBCs, 6 plasma units and 1 apheresis platelet unit to be ready at the time of need to resuscitate a trauma patient..

Recent wars in Iraq and Afghanistan have revived the interest in whole blood transfusion in treating life threatening hemorrhagic shock. In the battlefield, managing component therapy requires resources and time that are not always available. Using whole blood for severely injured soldiers simplifies the processing and storage of donor units: the blood does not need to be separated into components prior to use and there is no need for specialized equipment such as freezers, platelet rotators and plasma thawers.

In addition, time is saved because the product can be administered quickly through one intravenous line, and there is no need to wait for products to thaw.

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As whole blood transfusion showed promising results in war settings, many US hospitals implemented their own whole blood transfusion study protocols for severely injured or trauma patients. Current data shows that the use of whole blood transfusion in treating life threatening bleeding has better outcomes and many advantages. As a result, use of cold stored low titer group O whole blood (LTOWB) is steadily being accepted in many civilian trauma centers in U.S. The American Red Cross has seen a growing number of civilian hospitals across the country use LTOWB since 2018 when they first made this blood product available.

Cold-Stored Low Titer Group O Whole Blood

Group O whole blood can be transfused to any ABO group patient. However, group O whole blood has anti-A and anti-B antibodies present in the plasma that are incompatible with non-group O recipients. This creates a safety concern. The plasma of LTOWB donors is tested for anti-A and anti-B using antibody titration and must have levels that fall below a set threshold. There is no standard “low” titer and there is no “safe” titer that can effectively prevent a hemolytic transfusion reaction. Transfusing facilities must have policies and procedures in place to define an acceptable titer cut-off for anti-A and anti-B for their LTOWB, specific indications for use and a defined maximum number of units to be transfused to each patient.

Cold stored low titer group O whole blood (LTOWB) is FDA approved.

Because group O Rh negative whole blood remains a limited resource, most of it comes from group O Rh positive donors preferably males to mitigate the risk of transfusion-related acute lung injury (TRALI). Hospitals should evaluate the use of Rh positive LTOWB in certain patient populations such as Rh-negative females of childbearing age and pediatric patients. LTOWB is stored at 1 to 6 degrees Celsius for 21 days in citrate phosphate dextrose (CPD) and up to 35 days in citrate phosphate dextrose adenine-1 (CPDA-1). Most U.S hospitals or trauma centers limit use to 14-21 days, because platelet function drops after 14 days and significantly after 21 days.

Advantages Over Component Therapy

LTOWB offers practical and theoretical advantages over component therapy. The process to collect, prepare and store blood components versus LTOWB is costly. LTOWB takes less storage space and is easier to store and transport. LTOWB is one product readily available and easy to administer with speed using one intravenous line especially in pre-hospital settings and can be transported on vehicles and helicopters in coolers.

Recipients of LTOWB end up with lower quantities of additive solutions and anticoagulants compared to those transfused with individual blood components. This has clinical implications, as additional fluid from additives and anticoagulants in individual components may cause dilutional coagulopathy and raise a patient's blood pressure.

One important disadvantage of LTOWB is its short shelf life. It can only be stored up to 14 days to preserve platelet function viability, which creates a waste concern. To maximize use and reduce waste, LTOWB can be separated to create a PRBC unit after a predetermined date of storage. In addition, setting appropriate thresholds for anti-A and anti-B in donor units is a fine balance: higher titer thresholds may increase the possibility of hemolytic transfusion reactions and too low titer thresholds may exclude many safe eligible donors.

Published papers show a titer range of <50 to <256 is used by most civilian trauma centers.

Conclusion:

The growing interest in the use of LTOWB in trauma protocols is certainly changing the use of blood in transfusion medicine and expanding blood bank inventories. While blood component therapy is useful in specific patient conditions and the products generally have a longer shelf life, LTOWB has shown that it is cost effective to prepare and store, and it is quickly becoming the product of choice in treatment of trauma and hemorrhagic shock.

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