

2018 #29

August 31, 2018

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## Outcomes of Restrictive vs. Liberal Transfusion Equivalent at Six Months in Cardiac Surgical Patients

Conflicting “long term” outcomes have been published in both observational and randomized studies of differing transfusion triggers during and after heart surgery, with concerns articulated including the potential adverse immunological effects of allogeneic red cell exposure. The merits of both liberal and restrictive transfusions have been debated for years with the latter thought to be as effective as the former and even superior in many settings. This latest [report](#) of the Transfusion Requirements in Cardiac Surgery (TRICS III) study in the *New England Journal of Medicine* extends [previously](#) described 28-day results to six months of postoperative follow up.

TRICS III was a randomized, controlled study of transfusion triggers in patients undergoing heart surgery with cardiopulmonary bypass. Restrictive transfusion was defined as transfusion at a hemoglobin trigger of < 7.5 g/dL, and liberal at < 9.5 g/dL intra- or postoperatively. The study included 5,243 patients who were randomized and evaluated using a composite primary outcome of death from any cause, myocardial infarction, stroke, or new-onset renal failure with dialysis within six months after surgery.

The primary outcome was reached by 17.4 percent and 17.1 percent of the restrictive and liberal cohorts respectively (odds ratio for non-inferiority 1.02, 95 percent confidence interval 0.87-1.18). Secondary outcomes included a composite of all the components of the primary outcome as well as emergency department visit, hospital readmission, or coronary revascularization occurring within six months after the index surgery, and the individual components of the two composites, for which there were no significant between-group differences.

The earlier report found that restrictive transfusion was non-inferior to liberal in both per-protocol and modified intention-to-treat analyses for the primary endpoint by hospital discharge or day 28.

**Citations:** Mazer, C.D., Whitlock, R.P., Fergusson, D.A. *et al.* Six-month outcomes after restrictive or liberal transfusion for cardiac surgery. *N. Engl. J. Med.* 2018. doi: [10.1056/NEJMoa1808561](https://doi.org/10.1056/NEJMoa1808561)

Mazer, C.D., Whitlock, R.P., Fergusson, D.A. *et al.* Restrictive or liberal red-cell transfusion for cardiac surgery. *N. Engl. J. Med.* 2017. doi: [10.1056/NEJMoa1711818](https://doi.org/10.1056/NEJMoa1711818). ♦



## OUR SPACE

Ruth Sylvester MS, MT(ASCP)SBB, ABC's Director, Regulatory Services

### Always Prepare – Are You Ready?

Seldom do disaster articles have positive spins to them, but today's an exception. Last week the Colorado State University Tropical Meteorology Project and the National Oceanic and Atmospheric Administration (NOAA) lowered their predictions for the Atlantic hurricane season. This increased the odds of a less active hurricane season, while lowering the chances of an active hurricane season.

Consider that an example in making statistics work for you. How can they be wrong? Regardless of the lowered chances, it only takes one hurricane to hit an unprepared area for the outcome to be catastrophic. Also last week, the last neighborhood in Puerto Rico finally had their power restored 11 months after Hurricane Maria devastated the island. An achievement worth celebrating, particularly as National Preparedness Month approaches with September's arrival.

This year's theme is [Disasters Happen. Prepare Now. Learn How.](#) The Department of Homeland Security's (DHS) [Ready.gov](#) website is dedicated to helping the American people prepare for and respond to disasters, both natural and man-made. An abundance of material exists to assist organizations, communities, and individuals in being prepared. The onus lies with us to take advantage of such resources. ABC also maintains a [disaster page](#) on our Member website to assist member blood centers.

I have said numerous times that plans are living documents and need to be reviewed, refreshed, and practiced. Both ABC and its membership have undergone changes over the past five years. Taking my own advice, we will begin undertaking a full review and revision of the ABC/Blood Centers of America, Inc. (BCA) disaster plan in the coming months.

Please stay tuned as we seek your input and volunteers to assist in this project.

Ruth Sylvester, MS, MT(ASCP)SBB  
Director of Regulatory Services

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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America's Blood Centers®  
It's About *Life*.

## INSIDE ABC

*The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.*

### SMT Journal Club Recording Available

A recording of the of August 2018 SMT Journal Club Webinar is [available](#) to ABC Members via ABC's listservs. The webinar included the review of three key scientific/medical articles, an editorial, and clinical evidence synopsis followed by open discussion by participants, presenters, and article authors. Members of ABC interested in accessing listservs may sign-up for an account [here](#). The publications can be found on the ABC Member [website](#):

- [Impact of Blood Type O on Mortality of Severe Trauma Patients](#)
- [How Do I Implement a Whole Blood Program for Massively Bleeding Patients?](#)
- [Pathogen-Reduced Platelets for the Prevention of Bleeding in People of Any Age](#)
- [Comparison of the Hemostatic Efficacy of Pathogen-Reduced Platelets vs Untreated Platelets in Patients with Thrombocytopenia and Malignant Hematologic Diseases-A Randomized Control Trial](#)
- [Pathogen Inactivation Strategies to Improve Blood Safety Let's Not Throw Pathogen-Reduced Platelets Out with Their Bath Water](#)

### Summer Meeting Presentations Available

ABC members can access [presentations](#) from the 2018 ABC Summer Meeting. The presentations have been posted to the [ABC Member Website](#). Members can download slides from the Medical Directors Workshop, Scientific, Medical, and Technical Forum, Business Forum, and ABC Members meeting. Please contact [Member Services](#) with any questions.

### Iron Depletion of Donors and Mitigation Strategies for Member Blood Centers Talking Points and Statement Available

ABC has provided its members with tools to assist with any inquiries regarding iron depletion of donors and mitigation strategies. [MCN 18-032](#): Donor Iron Update was distributed last week and includes links to both [talking points](#) and a [position statement](#). Members of ABC can access these documents through the [ABC Member Website](#). 💧

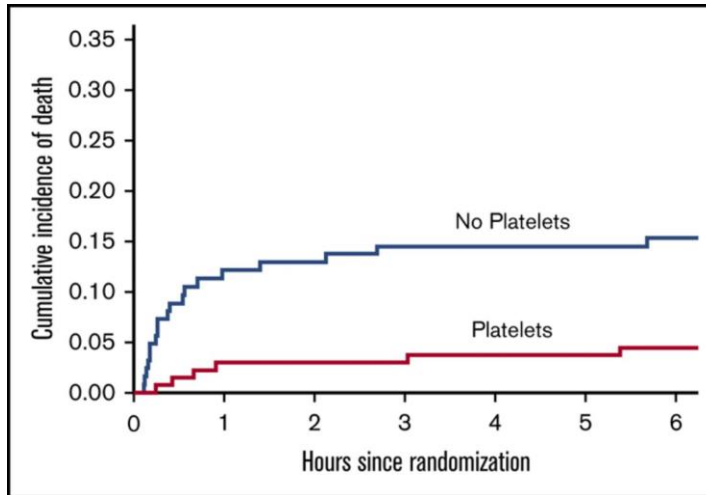
### Upcoming ABC Webinars – Don't Miss Out!

- **Quality Integration Part I** – September 18<sup>th</sup> at 3 p.m. EDT. Additional details forthcoming!
- **Development and Implementation of a Platelet Prediction Model** – October 25 at 3 p.m. EDT. Additional details forthcoming!
- **Quality Integration Part II** – November 29<sup>th</sup> at 3 pm. EST. Additional details forthcoming!



## RESEARCH IN BRIEF

**A substudy of the Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR) trial associates receipt of platelets with improved survival.**



Visual abstract courtesy of blood advances.

PROPPR was a randomized controlled trial that examined the influence of ratios of platelet and plasma to red blood cell (RBC) transfusion in severely injured patients. Due to the study design, patients receiving only the first cooler of blood products during their randomized treatment would have received a package that either did or did not include platelets. Twenty-four hour, 30-day mortalities, and deaths from exsanguination were 5.8 percent vs. 16.9 percent and 9.5 percent vs. 20.2 percent and 1.5 percent vs 12.9 percent respectively ( $p < .05$  for both timeframes and  $< .01$  for exsanguination). Total RBC transfusions were not different. These outcome comparisons

may be confounded by receipt of higher volumes of plasma in the platelet recipient group, which may have impacted hemostasis, inherent in the main study protocol.

**Citation:** Cardenas, J.C., Zhang, X., Fox, E.E. *et al.* Platelet transfusions improve hemostasis and survival in a substudy of the prospective, randomized PROPPR trial. *Blood Advances*. 2018. doi: [10.1182/bloodadvances.2018017699](https://doi.org/10.1182/bloodadvances.2018017699).

**A restrictive hemoglobin trigger in patients with pneumonia may be associated with higher mortality.**

Israeli investigators have reported a single center, retrospective, observational study of hospital mortality in patients with community-acquired pneumonia (diagnostic criteria not specified) who received RBC transfusion at liberal or restrictive triggers. The study included 177 patients with a median age of 80. Mortality was 56 percent with a trigger of  $\leq 7$  g/dL compared to 43.8 percent and 29.5 percent with triggers of 7-8 g/dL and  $> 8$  g/dL. Patients in the three trigger cohorts were well matched across a variety of clinical and laboratory metrics. Recognizing the issues with any observational studies, the authors conclude “prospective/randomized studies are needed to confirm our results.”

**Citation:** Rahimi-Levene, N., Koren-Michowitz, M., Zeidenstein, R. *et al.* Lower hemoglobin transfusion trigger is associated with higher mortality in patients hospitalized with pneumonia. *Medicine*. 2018. doi: [10.1097/MD.00000000000010192](https://doi.org/10.1097/MD.00000000000010192).

(continued on page 5)

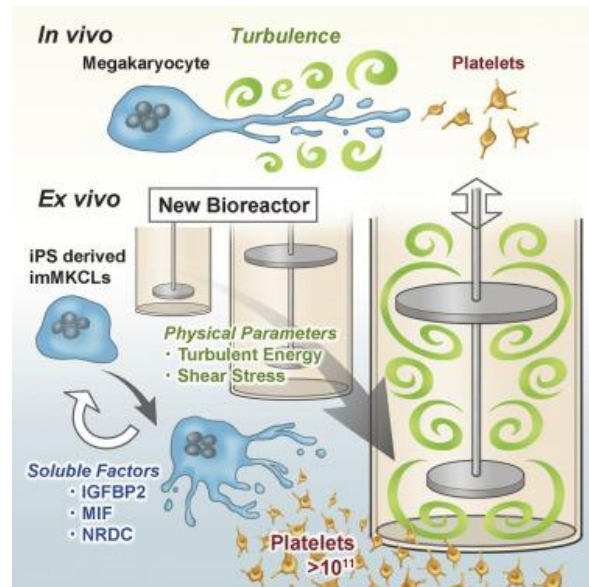





RESEARCH IN BRIEF (continued from page 4)

**Is turbulence a key to platelet farming?** Extending observations from murine models of thrombopoiesis to *in vitro* experiments suggests a path to “clinical scale” platelet manufacturing. Japanese scientists imaging platelet biogenesis in mice have found a role for turbulence in the production of platelets from megakaryocytes. They applied these findings to human-induced pluripotent stem cell derived megakaryocytes in 8-liter bioreactors to produce  $10^{11}$  (100 billion) platelets. The application of turbulence demonstrated the ability to promote megakaryocyte release of several soluble factors that “facilitate platelet shedding.” The resulting human platelets circulated and demonstrated *in vivo* hemostatic properties in animal models.

**Citation:** Ito, Y., Nakamura, S., Sugimoto, N. *et al.* Turbulence activates platelet biogenesis to enable clinical scale *ex vivo* production. *Cell*. 2018. doi: <https://doi.org/10.1016/j.cell.2018.06.011>. ♦



Graphical abstract courtesy of Cell.



**America's Blood Centers**  
It's About *Life*.

**A NATIONAL EFFORT WITH A LOCAL APPROACH**

**SAVE THE DATE!**  
**March 26, 2019**

AMERICA'S BLOOD CENTERS'  
CAPITOL HILL DAY  
WASHINGTON, D.C.

More details coming soon!



## REGULATORY NEWS

Both in-person and webcast [registration](#) is open for the upcoming U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Meeting. As previously reported, the meeting will take place on September 13<sup>th</sup> from 8 a.m. – 5 p.m. at the Crystal City Marriott at Reagan National Airport located at 1999 Jefferson Davis Highway in Arlington, VA 22202. The Committee will discuss “defining a tolerable risk for infectious diseases from a patient’s perspective” and will consider the history of combating infectious disease risks to the blood supply along with “ongoing” mitigation efforts and “emerging considerations.” The opportunity for public comments will be available at the meeting and limited to five minutes per speaker. Interested individuals must submit their name, email, and comment summary by the close of business on September 7<sup>th</sup>. For additional information, contact [ACBTSA@hhs.gov](mailto:ACBTSA@hhs.gov).

(Sources: Meeting Registration [Website](#), 8/31/18; *Federal Register* Meeting [Notice](#), 8/16/18) 💧

## BRIEFLY NOTED

United Kingdom (UK) authorities have recommended against the use of CAR-T therapy axicabtagene ciloleucel (Yescarta) for lymphomas on the grounds of lack of predefined cost-effectiveness. The National Institute for Health and Care Excellence (NICE) in the UK concluded that “cost-effectiveness estimates for axicabtagene ciloleucel compared with salvage chemotherapy...were above £50,000 [≈\$65,097] per year of quality adjusted life (QALY) gained, the upper limit of the specially extended range of cost-effectiveness for cancer treatments. The cost is therefore too high for it to be considered a cost-effective use of [National Health Service] resources.” The therapy is a CD19-directed genetically modified autologous T cell immunotherapy. The complete NICE analysis is available for [review](#). The Institute found the treatment promising, but unacceptable at the cost per patient set by the manufacturer. NICE has invited comments and further evidence that could lead to its being made available for use by the National Health Service. This product was [approved](#) by the U.S. Food and Drug Administration for adult patients with certain relapsed or refractory high grade B-cell lymphomas in October 2017.

(Source: NICE [Announcement](#), 8/28/18).

NATIONAL PREPAREDNESS MONTH 2018

**Disasters  
Happen**

**PREPARE NOW** **LEARN HOW**



National Preparedness Month begins in September with the theme of “Disasters Happen. Prepare Now. Learn How.” It serves as a reminder to organizations and individuals of the importance of updating and exercising their disaster plans. Tools and resources are [available](#) and provided the U.S. Department of Homeland Security. ABC members can access disaster preparedness materials on [ABC’s Member website](#).

(Source: DHS [Ready.gov](#)) 💧



### PEOPLE

Blood Systems Senior Vice President for Research and Scientific Programs and Blood Systems Research Institute (BSRI) Director **Michael Busch, MD, PhD** was honored with the Presidential Award from the International Society of Blood Transfusion (ISBT) during the recent ISBT Congress in Toronto, Canada. This award recognizes individuals who have made eminent contributions to transfusion medicine through original research, the practice of transfusion therapy, and significant service contributions to the field. During the meeting, Dr. Busch presented on estimating risk and evaluating the efficacy of risk reduction strategies.

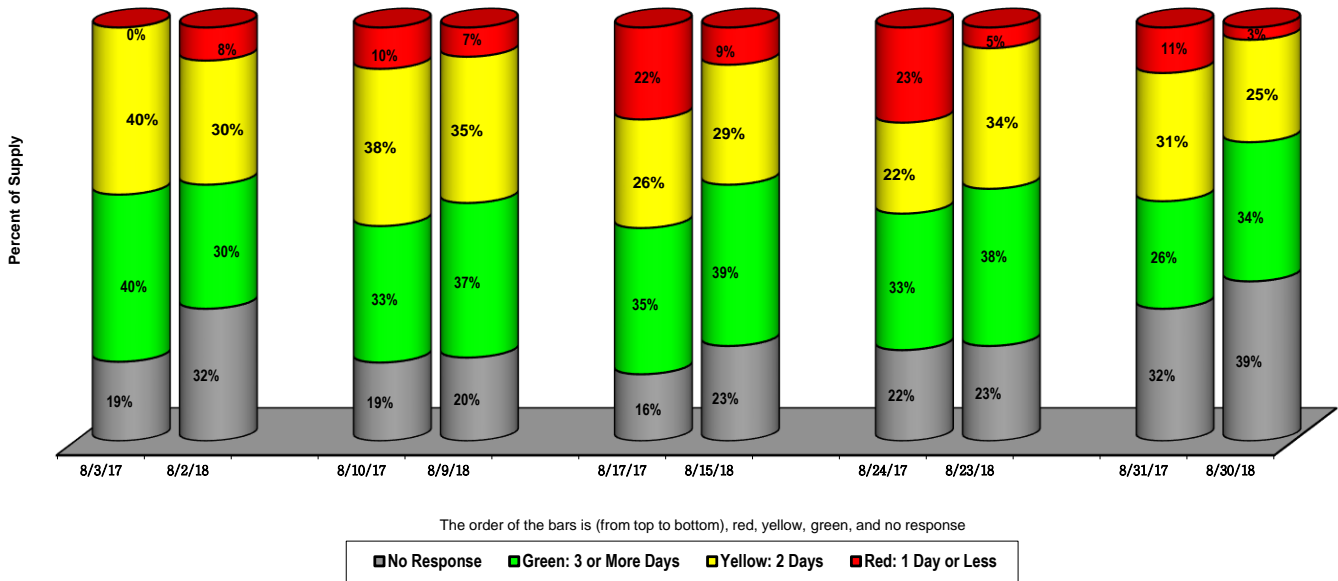


*Dr. Michael Busch (center) flanked by long-time colleagues and friends Ravi Reddy (left), ISBT president and COO of the South Africa National Blood Service and Paul Strengers (right), president of the ISBT Foundation and COO of the International Plasma Fractionation Association.*

(Source: Blood Systems Announcement, 8/28/18)



### STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply



Daily updates are available at:

[www.AmericasBlood.org](http://www.AmericasBlood.org)

### ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



## WORD IN WASHINGTON



Rep. Rodney Davis (R-Ill.) recently visited Community Blood Services of Illinois to donate. He was on the field when U.S. House of Representatives Majority Whip Steve Scalise (R-La.) was wounded during a shooting at a congressional baseball practice last year, “[b]eing on the field during the Congressional baseball attacks, I have a firsthand understanding how critical it is to have blood already donated, tested, on the shelf, and ready to go, when an emergency strikes.” Members of ABC can reach out to their congressional members individually at any time using the [ABC Action Center](#).

(Source: Community Blood Services of Illinois Announcement, 8/24/18) ◆

## CALENDAR

**Note to subscribers:** Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail ([lmaundy@americasblood.org](mailto:lmaundy@americasblood.org)) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

### 2018

Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available [here](#).

Sept. 11. **37<sup>th</sup> Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available [here](#).

Sept. 12. **8<sup>th</sup> Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD.** More details available [here](#).

Sept. 13. **Advisory Committee Meeting on Blood and Tissue Safety and Availability, Arlington, VA.** More details available [here](#).

Sept. 24-26. **The MedTech Conference, Philadelphia, PA.** More details available [here](#).

Oct 15-16. **510(k) Submissions Workshop, Washington, D.C.** More details available [here](#).

(continued on page 9)

## We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to the Editor at [newsletter@americasblood.org](mailto:newsletter@americasblood.org) or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.





## CALENDAR (continued from page 8)

May 22-23. **IPFA/PEI 26th International Workshop on “Surveillance and Screening of Blood-Borne Pathogens, Krakow, Poland.** More details available [here](#). ♦

## CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: [lmaundy@americasblood.org](mailto:lmaundy@americasblood.org).

## POSITIONS

**Director, Donor Recruitment.** LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Donor Recruitment position. This position is responsible for developing and directing the blood center’s donor recruitment department/plans to achieve collection goals. Scope of responsibilities includes oversight of all mobile and fixed site recruitment. Requires the ability to oversee the daily operations, as well as strategically work toward the long-term goals. Must be able to facilitate all operational activities related to recruitment of donors and management of recruitment staff within the expected budget guidelines. Must be an effective leader and have the ability to adapt to change. Excellent salary (with bonus program) and benefits including relocation package. Bachelor’s degree required. Demonstrated experience in sales/territory management skills, strong leadership and team building skills, excellent verbal and written communication and public speaking skills and computer literacy. Prior blood center experience preferred. Minimum three years management experience. Successful candidate must demonstrate ability to work closely with Marketing and Collections Managers/Directors to facilitate efficient and effective blood drives. This position reports to the Vice President/Operations. LifeStream is an Equal Opportunity Employer, M/F/D/V. Apply online at: <https://www.lstream.org/careers/>.

**Blood Services Technical Manager.** Unyts, Western New York’s ONLY Organ, Eye, Tissue and Community Blood Donation Center has an immediate opening for a Blood Services Technical Manager. This position is responsible for the administrative and technical management of blood processing and distribution. Ensures compliance with the standards of the FDA, NYSDOH and for all other pertinent industry standards. Manages process for proficiency testing for the QC lab to meet CLIA requirements. Responsible for implementing and maintaining policies and procedures relevant to transfusable blood and blood products. Manages current and potential future technology needs of blood lab. Performs testing and other component processing procedures as necessary. Qualified individuals will have a bachelor’s degree, plus a NYS Clinical Laboratory Science license with a minimum of six years experience as a Med Tech, with a minimum of two years in blood banking experience including component preparation preferred. Please visit this job listing at [www.unyts.org/about/careers/](http://www.unyts.org/about/careers/) for full details and to submit your application. ♦