Walking Blood Bank

A strategic blood reserve?

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Disclosures & Disclaimer

- Hematology Consultant supporting HHS/ASPR/BARDA (Tunnell Government Services)
- Board of Directors, Velico Medical
- Scientific Advisory Board, Seragene Therapeutics

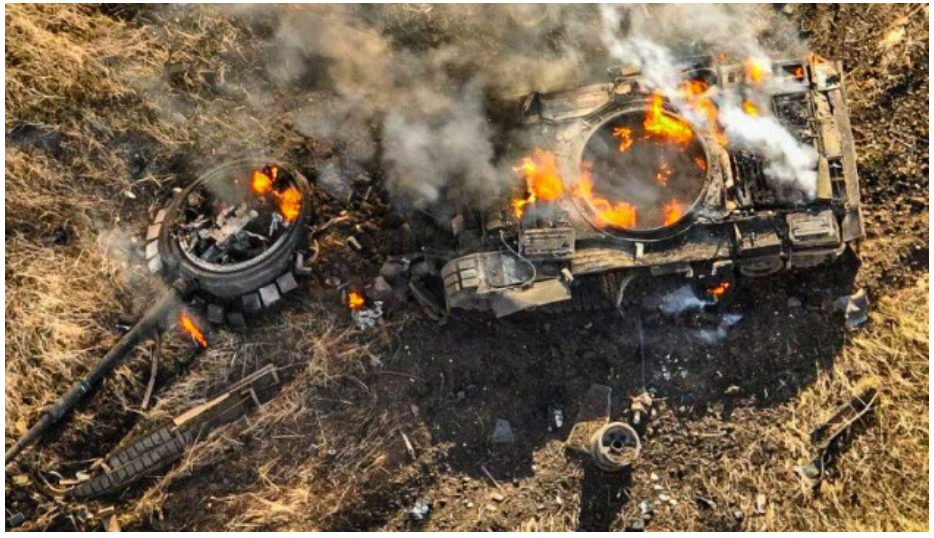
- My spouse, Becky Cap, is SVP Biotherapies, Vitalant.

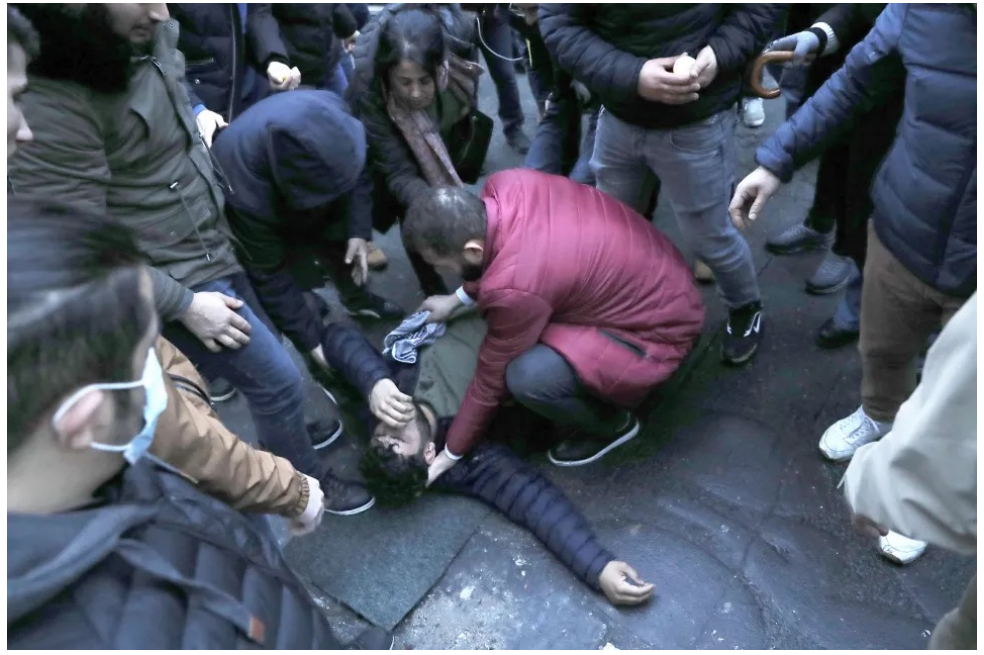
- The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the U.S. Department of the Army, the U.S. Defense Health Agency, the U.S. Department of Defense, or the Department of Health and Human Services.

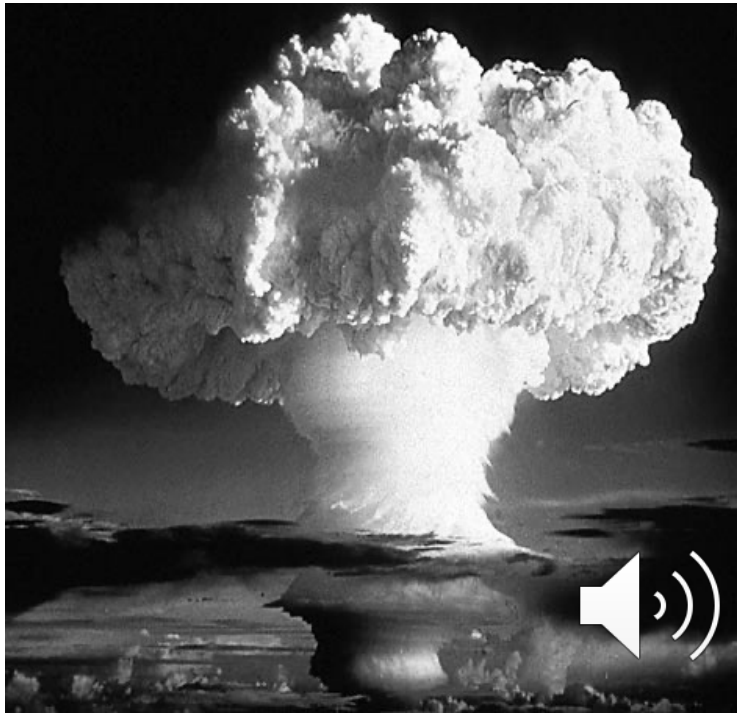
Overview

- Current threats to U.S. population drive need for blood supply readiness
  - Peer-to-Peer Large Scale Combat Operations (LSCO)
  - Mass Casualty Incidents (MCI; terrorism, mass shootings, etc.)
  - Nuclear Detonation (strategic nuclear weapons, terrorism)
- Current blood supply is inadequate; need options
  - MCI history & modeling indicates inadequate supply
  - Getting the most from stored products: “cold” storage, whole-blood derived platelets, dried products
  - Walking blood bank (WBB) is the obvious and proven answer
- Build the Strategic Blood Reserve
  - Build infrastructure for producing, stockpiling & using dried products
  - Build emergency donor panels (EDPs); plan for WBB; implement NOW!

The threats are very real…







As are the vulnerabilities…

- Supply chain shocks
  - Blood collection equipment production highly concentrated
  - Recent blood bag sterility failures, manufacturing interruptions
  - Vulnerability to weather/natural disasters/climate change
- Demand extremes
  - Major peer-peer war
    - During peak Vietnam, U.S. shipped up to 10,000 WB units per week (about 4-5% of current total U.S. collection rate – ***DO WE HAVE THE MARGIN TO SUPPORT THAT?***)
    - Ukraine has suffered more severe military traumas in 2 years than U.S. military had in past 20! ***(Not counting civilians!)***

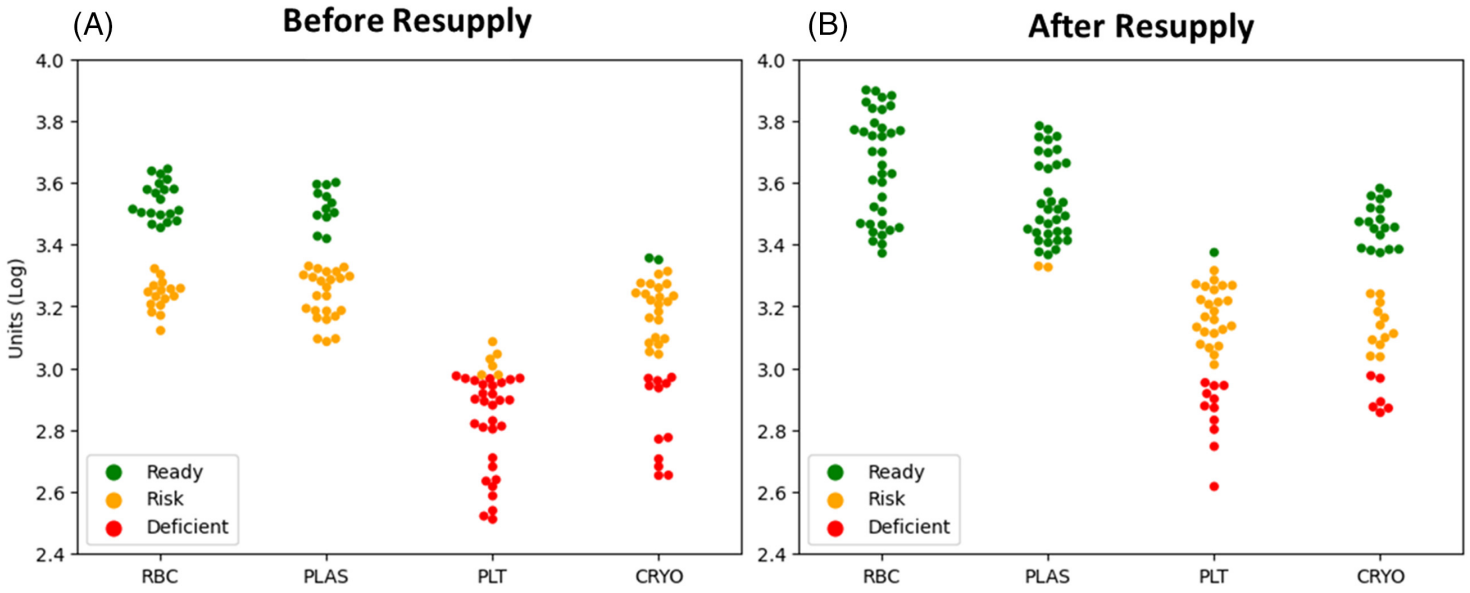
Neel S. Medical Support of the U.S. Army in Vietnam. Dept. of the Army. 1991.

The blood donor crunch

- 3% of the U.S. population donates (1-2 times/yr)
- Between 6-7 million donors give about 12 million WB and 2.5 million aPLT units per year
- ¾ of donations are from repeat donors
  - Only 1% of units rejected after collection for positive TTD markers (mostly first-time donors)
- 12% from minority donors (vs. 41% of U.S. population & growing)
- Loss of male and minority donors (and overall) during COVID
- ***BUT…*** 62% of U.S. population theoretically eligible (205 million)

America's Blood Centers. *Blood donation statistics and public messaging guide*. January 2024.

MCIs: we're not prepared…



	Before Resupply (N = 36)				After Resupply (N = 36)			
	RBC	PLAS	PLT	CRYO	RBC	PLAS	PLT	CRYO
Ready	20	12	0	2	36 (33-36)	34 (33-34)	1	18
Risk	16	24	6 (4-7)	22 (22-26)	0 (0-3)	2 (2-3)	24	12 (11-14)
Deficient	0	0	30 (29-32)	12 (8-12)	0	0	11	6 (4-7)

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DISASTER PREPAREDNESS

TRANSFUSION

U.S. cities will not meet blood product resuscitation standards during major mass casualty incidents: Results of a THOR-AABB working party prospective analysis

Jeremy W. Cannon[1,2,3] | Noah M. Igra[1,4] | P. Dayand Borge[5] | Andrew P. Cap[6] | Dana Devine[7] | Heidi Doughty[8] | Zhi Geng[1] | Jessica F. Guzman[9] | Paul M. Ness[10] | Donald H. Jenkins[11] | Srijana Rajbhandary[12] | Daniela Schmulevich[1] | James R. Stubbs[13] | Douglas J. Wiebe[2,14,15] | Mark H. Yazer[16] | Philip C. Spinella[17,18]

- Mass casualty event modeling in 36 U.S. cities
- 1000-pound conventional blast, crowded area
- Target transfusion ratio of 1:1:1, sensitivity analysis using 2:1:1 (typical of recent MCIs)

We're not ready to provide quality DCR in MCIs.

This analysis didn't even consider prehospital blood transfusion…

We routinely accept high trauma mortality because of inadequate prehospital supply. We PLAN TO FAIL in MCIs.

2:1:1 was the ”standard” arm in PROPPR with double mortality (20% vs. 10%) due to not enough platelets

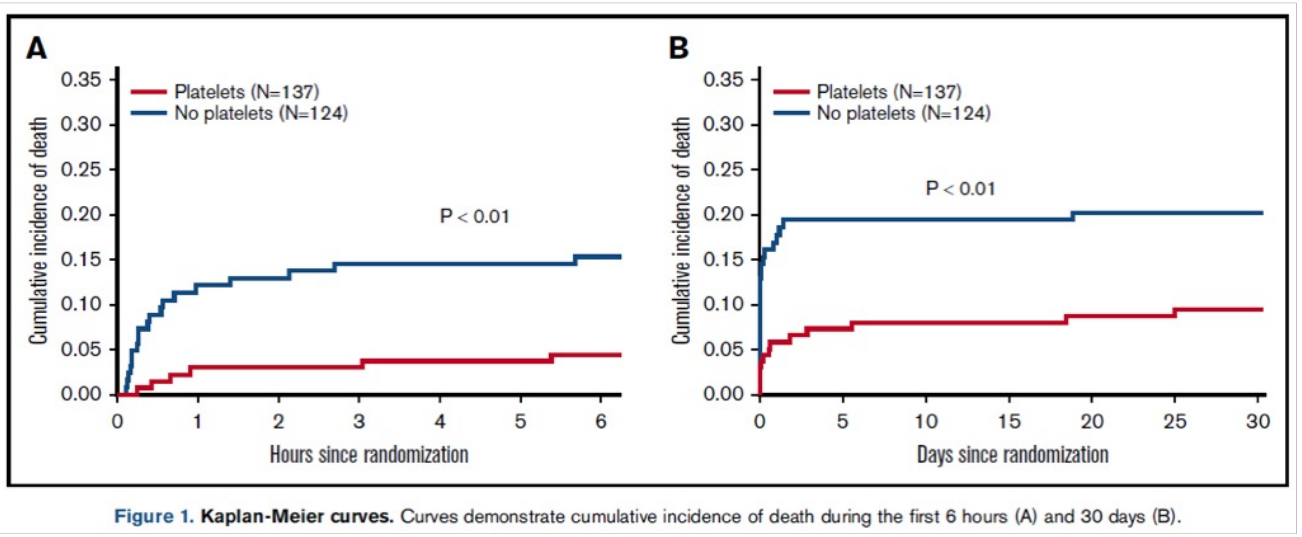


Figure 1. Kaplan-Meier curves. Curves demonstrate cumulative incidence of death during the first 6 hours (A) and 30 days (B).

REGULAR ARTICLE

blood advances

Platelet transfusions improve hemostasis and survival in a substudy of the prospective, randomized PROPPR trial

Jessica C. Cardenas,[1,2] Xu Zhang,[3] Erin E. Fox,[1-3] Bryan A. Cotton,[1-3] John R. Hess,[4] Martin A. Schreiber,[5] Charles E. Wade,[1-3] and John B. Holcomb,[1-3] on behalf of the PROPPR Study Group

[1]Division of Acute Care Surgery, Department of Surgery, McGovern School of Medicine, [2]Center for Translational Injury Research, and [3]Center for Translational and Clinical Studies, University of Texas Health Science Center, Houston, TX; [4]Department of Laboratory Medicine, Harborview Medical Center, University of Washington, Seattle, WA; and [5]Division of Trauma, Critical Care and Acute Care Surgery, Department of Surgery, Oregon Health and Science University, Portland, OR

Table 3. Outcomes by treatment group

Outcome	Platelets (n = 137)	No platelets (n = 124)	P
24-h mortality, n (%)	8 (5.8)	21 (16.9)	<.01*
30-d mortality, n (%)	13 (9.5)	25 (20.2)	<.01†
Time to death, median (IQR), h	13.8 (0.9-69.5)	0.6 (0.3-5.7)	.02‡
Achieved hemostasis, n (%)	130 (94.9)	91 (73.4)	<.01*
Anatomic, median (IQR), min	81.5 (46-135)	59 (36-109)	.14§
Hospital-free days, median (IQR)	13 (0-22)	15 (0-22)	.77§
Ventilator-free days, median (IQR)	28 (23-29)	28 (9-29)	.03§
ICU-free days, median (IQR)	25 (15-27)	25 (7-27)	.09§
Disposition location, n (%)			.07‖
Home	65 (47.5)	51 (41.1)	
Other¶	33 (24.1)	31 (25.0)	
Remained hospitalized	26 (19.0)	17 (13.7)	
Morgue	13 (9.5)	25 (20.2)	

Table 4. Cause of death by treatment group

	First 24 hours			30 days		
	Platelets (n = 137)	No platelets (n = 124)	P*	Platelets (n = 137)	No platelets (n = 124)	P*
Total number of deaths	8	21		13	25	
Cause of death, n (%)†						
Exsanguination	2 (1.5)	16 (12.9)	<.01	2 (1.5)	16 (12.9)	<.01
Traumatic brain injury	4 (2.9)	5 (4.0)	.63	8 (5.8)	9 (7.3)	.64
Respiratory, pulmonary contusion, or tension pneumothorax	0 (0)	0 (0)	—	1 (0.7)	0 (0)	.32
Multiple organ failure	0 (0)	0 (0)	—	0 (0)	1 (0.8)	.32
Myocardial infarction	1 (0.7)	1 (0.8)	.94	1 (0.7)	1 (0.8)	.94
Pulmonary embolism	0 (0)	1 (0.8)	.32	0 (0)	1 (0.8)	.32

*P value was based on the Wald test for comparing 2 proportions.
†Patients may have had >1 cause of death.

So, how are we going to be ready???

- MUST get better at recruiting donors!
- INNOVATE!
  - Get more out of existing products – e.g., longer shelf life to expand access
  - Get ”new” products into “circulation” 😉
- BUILD the strategic reserve: the WBB!
  - >200M potential donors
  - Recent precedents: military AND London Olympics planning AND Norway!
  - Pilot projects to identify challenges (e.g., rural areas/low blood availability)
  - Goals:
    1. Ability to provide blood now in high risk areas
    2. Ability to surge blood supply by 10% within one week (extra 20-25K WB units/week)

Getting more out of existing products

CHILLED PLATELET STUDY
CHIPS

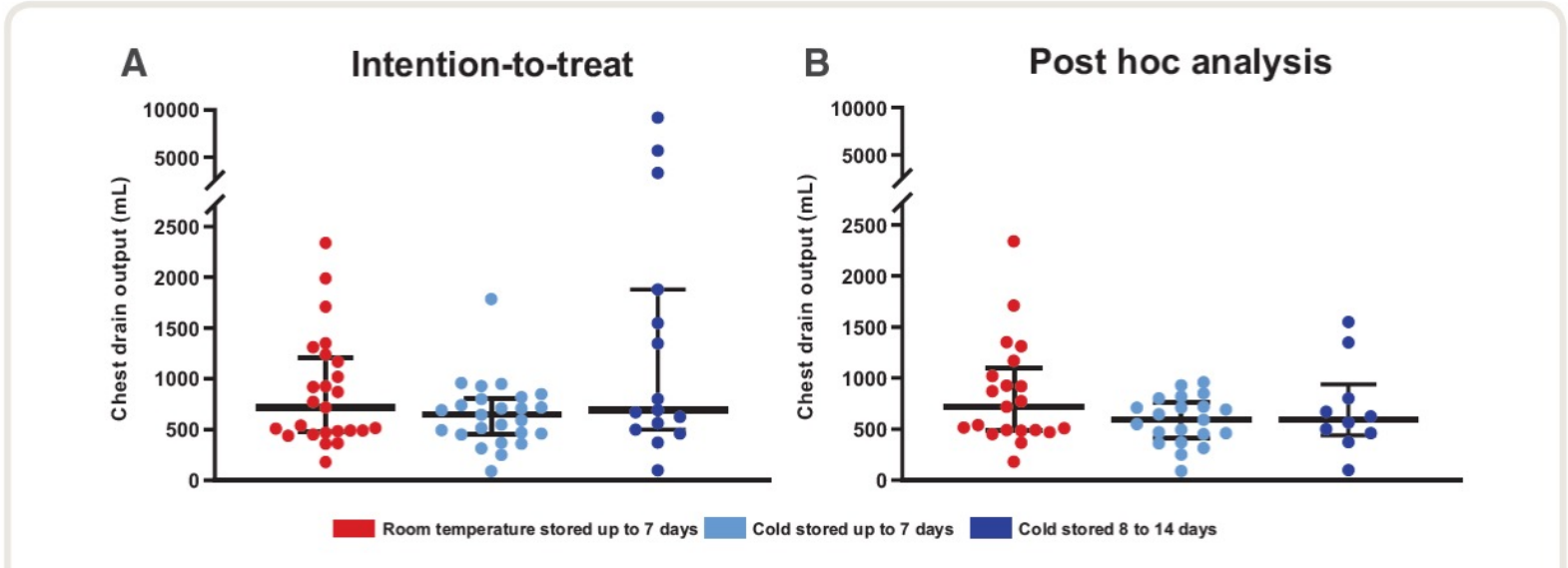
- Platelets: put them in the refrigerator!
  - 14-day shelf life (CHIPS testing out to 21 days) vs. 5-7 days at RT
  - No need for expensive bacterial testing per FDA guidance
  - Use for active bleeding when “conventional” (room temp) platelets not available or use inconvenient
- *Also: need to stop throwing PLT away: make WB-derived PLT*

ANESTHESIOLOGY

A Pilot Trial of Platelets Stored Cold *versus* at Room Temperature for Complex Cardiothoracic Surgery

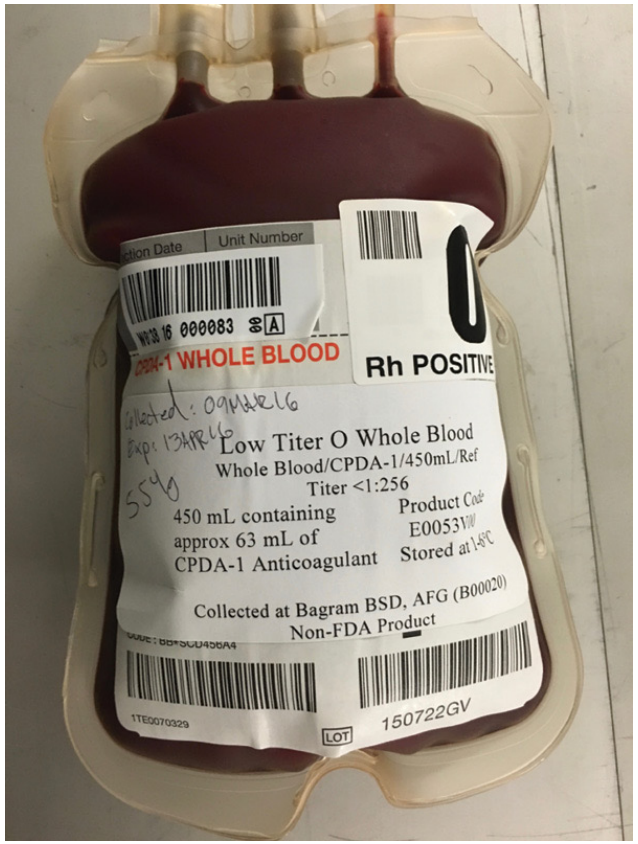
Geir Strandenes, M.D., Joar Sivertsen, B.Sc., Christopher K. Bjerkvig, M.D., Theodor K. Fosse, M.D., Andrew P. Cap, M.D., Ph.D., Deborah J. del Junco, Ph.D., Einar Klæboe Kristoffersen, M.D., Ph.D., Rune Haaverstad, M.D., Ph.D., Venny Kvalheim, M.D., Ph.D., Hanne Braathen, B.Sc., Turid Helen Felli Lunde, M.Sc., Tor Hervig, M.D., Ph.D., Karl Ove Hufthammer, Ph.D., Philip C. Spinella, M.D., Torunn Oveland Apelseth, M.D., Ph.D.

Anesthesiology 2020; XXX:00–00



Getting more out of existing products

- **Whole Blood: cancel the leukoreduction!**
  - Platelet-sparing LR only available in one kit using CPD; designed for component preparation
    - LR thus limits to 21-day shelf life, waste of component bags
  - **Collection in CPDA-1 yields 35-day shelf life, greater access for patients**
  - No benefit to trauma patients from LR: no reduction in mortality, infection, febrile episodes, LOS, ALI/organ dysfunction… not even reduced microchimerism
  - Eliminating LR would reduce kit and labor costs



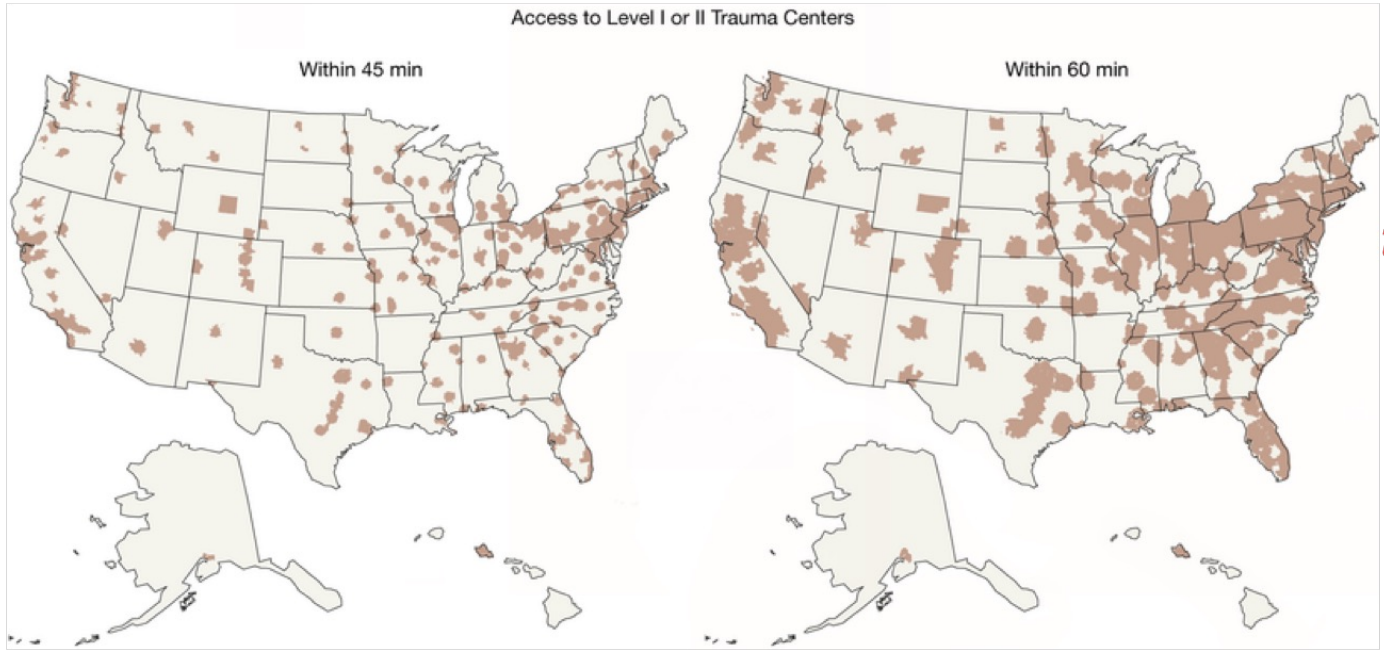
Nathens et al. Shock. 2006.
Phelan et al. J Surg Res. 2007.
Watkins et al. CCM. 2008.
Bloch et al. Transfus Med Rev. 2013.

Dried plasma you say? A “new” product!

- Not available yet in the U.S. but hopefully coming soon…
  - Not ”new” exactly: used throughout WWII & Korea
  - Current/near term products (will) conform to modern regulatory standards
- Europe: lyophilized single donor plasma, lyophilized pooled S/D plasma (all centralized production)
- U.S. development efforts funded by DoD, HHS/BARDA
  - Lyophilized single donor plasma (centralized production, single manufacturer)
  - Spray-dried single donor plasma (de-centralized production in U.S. blood centers)
  - **Blood centers may have opportunities to supply plasma for lyophilization or acquire system to spray-dry plasma in-house**
  - **Dried plasma can be stockpiled**

U.S. geography suggests dried plasma as bridge to whole blood (U.S. military practice in WWII, Korea)

Whole Blood is ideal… but requires rotation to trauma centers to reduce waste.



Most of the U.S. is too far from a trauma center to make this feasible.

(Even NE: 37% in 45min, 70% in 60min)

***Dried plasma* is the bridge to whole blood.**

Access to **trauma centers** in the United States.
Branas CC, MacKenzie EJ, Williams JC, Schwab CW, Teter HM, Flanigan MC, Blatt AJ, ReVelle CS.
JAMA. 2005 Jun 1;293(21):2626-33. doi: 10.1001/jama.293.21.2626.
PMID: 15928284

Maybe also dried platelets? Cryo-preserved platelets?

New (dried) products will help but WBB is vital

- Fresh WB outperforms components
- Large scale donor panels are feasible (London Olympics)
- Norwegian experience: vital blood supply to remote, underserved populations

WBB delivers safe & efficacious resuscitation

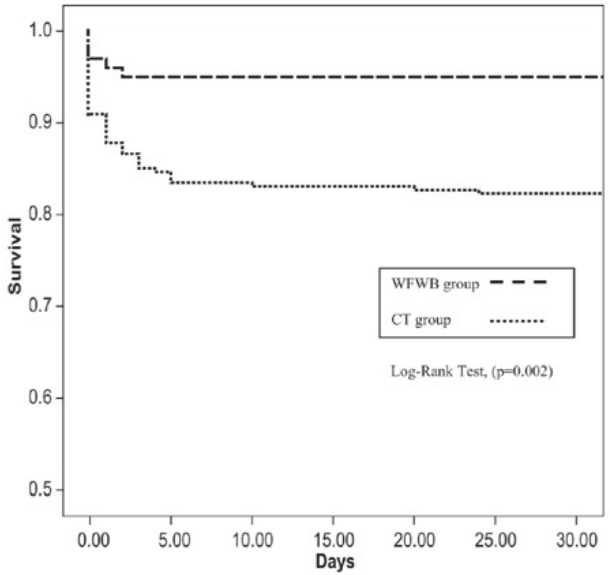
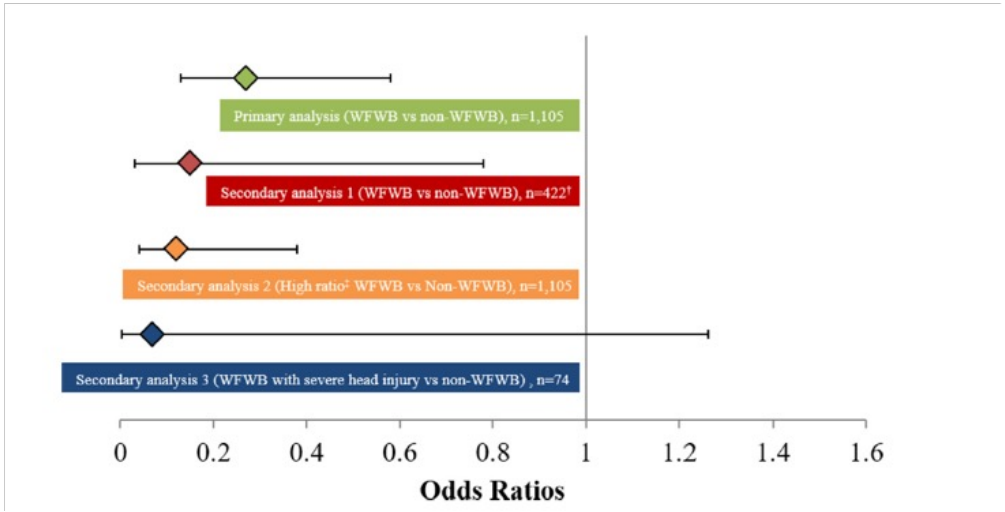


Fig. 1.
Kaplan-Meier curve of 30-day survival according to study group.

Warm fresh whole blood is independently associated with improved survival for patients with combat-related traumatic injuries.Spinella PC, Perkins JG, Grathwohl KW, Beekley AC, Holcomb JB.J Trauma. 2009 Apr;66(4 Suppl):S69-76. doi: 10.1097/TA.0b013e31819d85fb.PMID: 19359973

FWB looks pretty good…

Whole blood at the tip of the spear: A retrospective cohort analysis of warm fresh whole blood resuscitation versus component therapy in severely injured combat casualties.**Gurney JM**, Staudt AM, Del Junco DJ, Shackelford SA, Mann-Salinas EA, **Cap AP**, Spinella PC, Martin MJ.Surgery. 2022 Feb;171(2):518-525. doi: 10.1016/j.surg.2021.05.051. Epub 2021 Jul 10.PMID: 34253322



London Olympics 2012: massive EDP

TRANSFUSION MEDICINE
Official Journal of the British Blood Transfusion Society
Transfusion Medicine | REVIEW ARTICLE

Going for gold: blood planning for the London 2012 Olympic Games

S. M. Glasgow,[1] S. Allard,[2,3] R. Rackham[3] & H. Doughty[3]

[1] *Trauma Sciences, Blizard Institute, Barts and the London School of Medicine & Dentistry, Queen Mary University of London, London, UK,* [2] *Department of Haematology, Royal London Hospital, London, UK, and* [3] *NHS Blood and Transplant, Birmingham, UK*

Received 6 September 2013; accepted for publication 20 February 2014

- Plan for extra 10,000 WBE on-hand for games
- 13,000 donors on standby for MCI
- Call-in by SMS on day one: 4,000 appointments

Norway: delivering for vulnerable populations

Received: 15 February 2022 | Revised: 2 May 2022 | Accepted: 2 May 2022

DOI: 10.1111/trf.16968

TRANSFUSION

DISASTER PREPAREDNESS

The Norwegian blood preparedness project: A whole blood program including civilian walking blood banks for early treatment of patients with life-threatening bleeding in municipal health care services, ambulance services, and rural hospitals

Torunn Oveland Apelseth[1,2,3] | Mirjana Arsenovic[4] | Geir Strandenes[1]

The recipe:

- **EDP/WBB for FWB**
- **Stored LTOWB**
- **Dried plasma**

TABLE 1 An overview of the Norwegian blood preparedness project

	Rural hospital with hospital-based blood bank	Prehospital health care services	Municipal health care
Emergency blood transfusion program	Stored blood. Emergency collection of fresh whole blood from regular blood donors if needed.	Stored LTOWB provided by civilian blood bank. Dried plasma.	Fresh LTOWB collected from preplanned walking blood bank. Dried plasma.

Abbreviation: LTOWB, low titer group O whole blood.

Norway has the plan…
No need to re-invent the wheel!

TABLE 2 Comparison between the walking blood bank and the hospital based whole blood program in the Norwegian blood preparedness pilot project

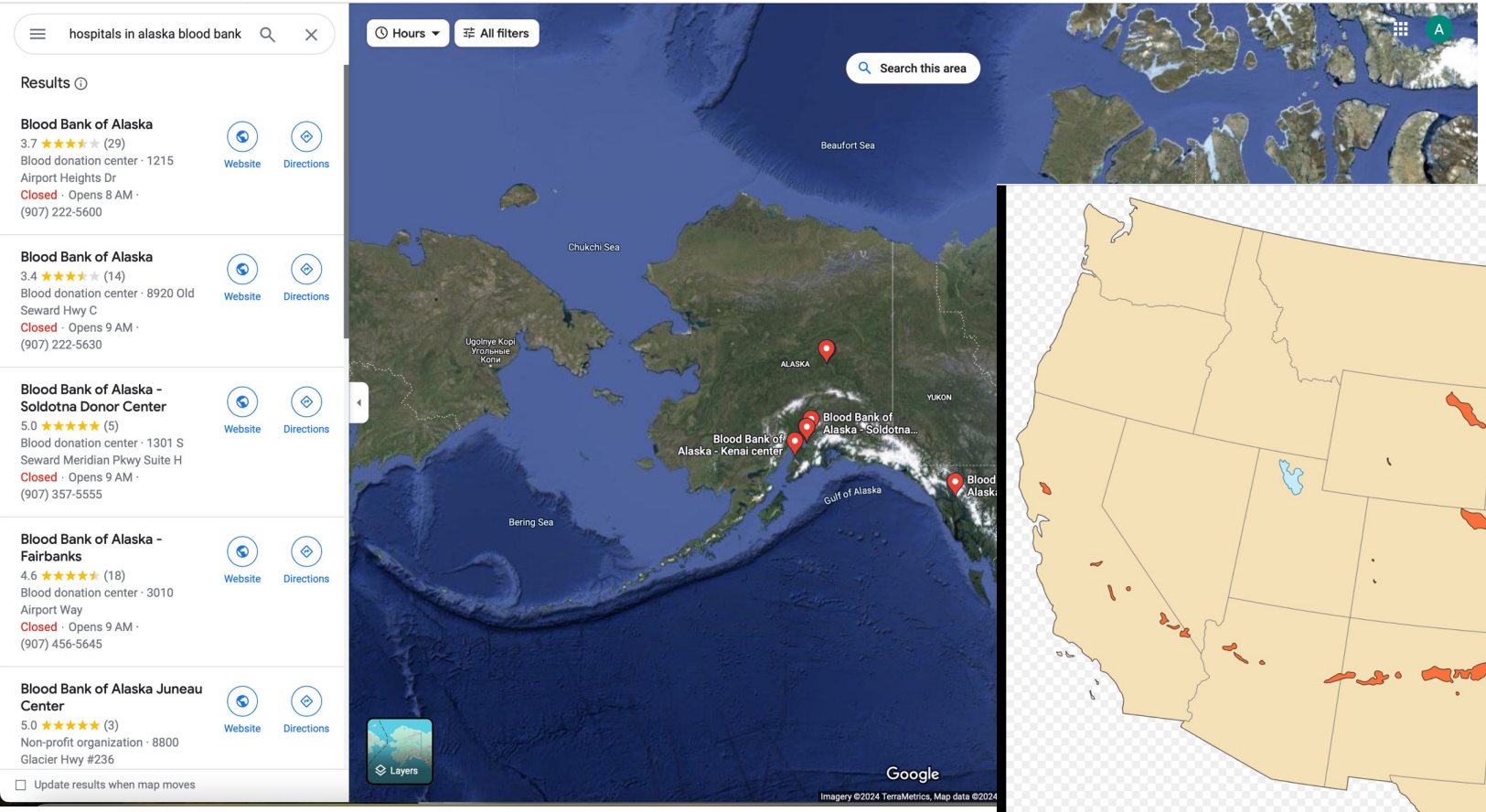
	Preplanned walking blood Bank	Hospital based blood Bank
Blood donor		
Donor status	Emergency whole blood donor	Regular whole blood donor
Blood type[a]	Low titer O High titer O considered if needed.	Low titer O ABO-type like considered if needed.
Donor gender[b]	Both male and female	Both male and female
Transfusion transmittable disease testing[c]	At inclusion, every 6 months, and at donation (sample taken at donation but results not available before emergency transfusion of whole blood, posttransfusion testing)	At inclusion and at donation.
Interview	At inclusion, every 6 months, and at donation. Before an emergency donation a screening interview are performed.	At inclusion and at donation.
Documentation of donation	Screening interview form and standard interview form filled out and signed by donor and interviewer. Donation documented by use of donation form at WBB collection site. Postdonation registration performed electronically by Mother Blood Bank.	Interview form filled out by donor and signed by donor and interviewer. Interview and donation documented electronically at donation.
Whole blood unit		
Volume	450 ml	450 mL
Anti-coagulant[d]	CPDA-1	CPD
Processing of whole blood unit after collection	No further processing	Leukoreduced with a platelet-sparing filter
Storage	No storage	21 days without agitation
Storage temperature	Not applicable	2–6 °C
Transfusion transmittable disease (TTD) testing[c]	Posttransfusion (Only donors with negative TTD tests within the past 6 months are accepted for donation)	Before transfusion

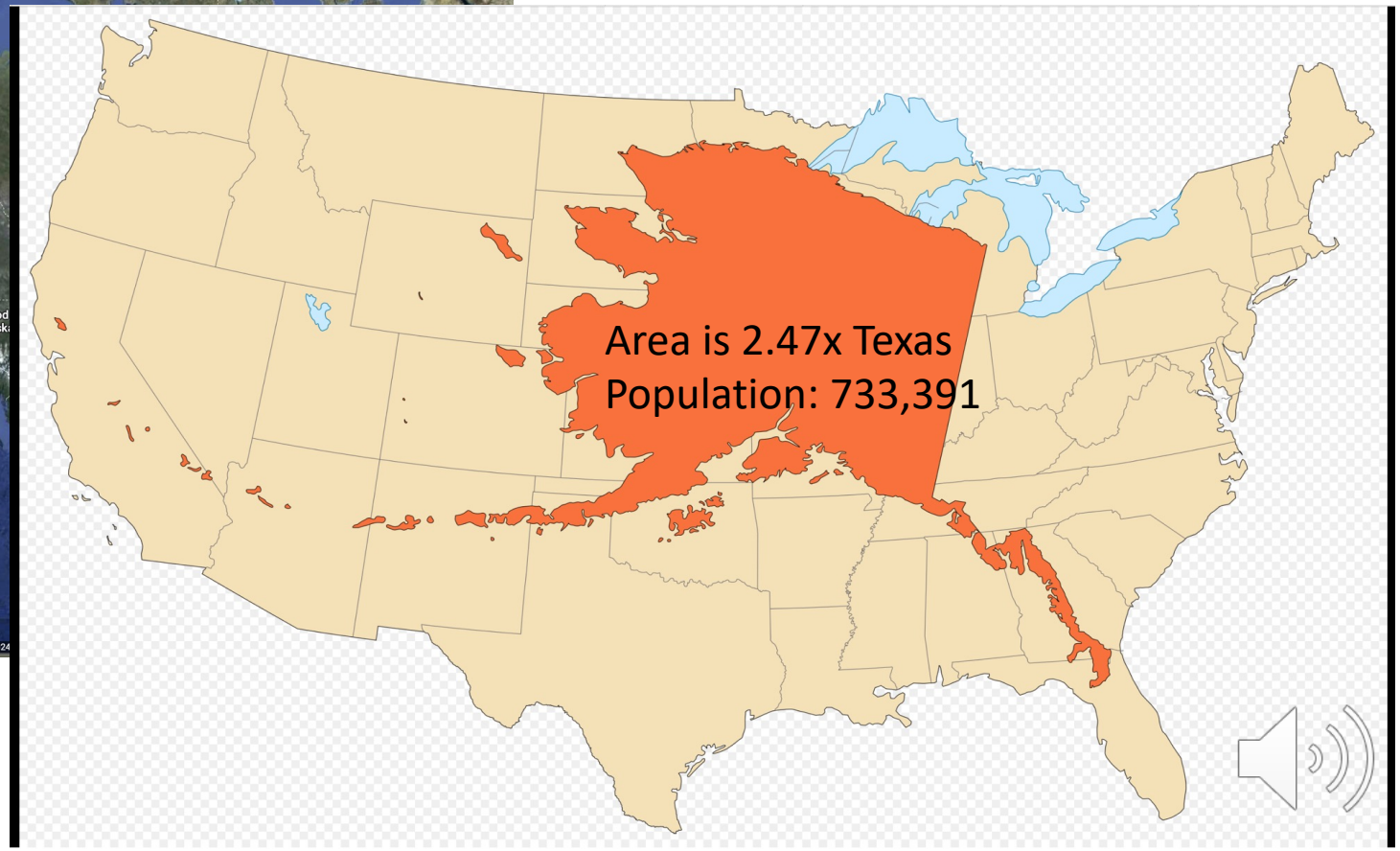
[a]Low titer defined as <256 for IgM and IgG anti-A and anti-B.
[b]Additional testing of female donors: anti-HLA, anti-HNA and anti-HPA.
[c]HIV, hepatitis B and hepatitis C.
[d]CPDA-1, citrate–phosphate-dextrose-adenine-1; CPD, citrate–phosphate-dextrose.

WBB investments needed

- Donor recruitment
- EDP activation protocols
- Collection/transfusion kits
- WBB blood storage capability for rural/emergency environments
- Improved POC blood grouping, TTI rapid tests
- Telehealth support
- Pre-positioned stocks, drone resupply

Pilot WBB project here?





Questions?

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