

CareForum 2022

The WellSky® Conference

Post-pandemic blood system: Resilient/Sustainable?

Jay E. Menitove, M.D.

9/14/2022

CareForum 2022

The WellSky® Conference

Today's speaker



Jay Menitove
CEO
JEM Consulting

Conflict of Interest

Independent contractor, CSL Plasma

Independent contractor, Accumen Clinical Optimization

Agenda

1. Background

- 2008/09 recession
- PBM
- Financial instability
- Hospital system purchase power greater than that of regional blood centers
- BC consolidation

2. Reports & Stake Holder Activities

- RAND
- Stakeholder discussions post-RAND
- Section 209 report

3. Pandemic & the Lessons Learned

4. Driving Forces and Future Actions

- Donors
- Data
- Discovery/innovation
- D'Supply Chain
- Dollars

Consider dual and multi-sourcing directly with manufacturers and distributors.

Develop product prioritisation approvals with each supplier in preparation of the next disaster.

Develop a broader contract portfolio of domestic-based suppliers to provide more control of access to critical products when international supplies may not be reliable.

Re-evaluate just-in time inventory management levels. Increase the critical items' supply-on-hand in the event of a disaster for both suppliers and blood center.

Address resistance at the local blood center level to funding the expense of maintaining inventories of supplies in excess of immediate need.

Establish a strategic stockpile of PPE and other supplies designated as critical that is prepositioned and managed by an appropriate entity and supported by HHS or other governmental agencies to accelerate capability.

Create and access the national stockpile of PPE products as needed such as with the EU model^{45,46}

Consider the potential value of pathogen reduction of blood products as technologies become available. Future emerging infections may be transfusion transmitted and, even if this is not the case,

Gammon R, Katz LM, Strauss D, et al.
Beyond COVID-19 and lessons learned in the United States.
Transfusion Medicine. 2022;1-10. doi:10.1111/tme.12896

Background

2008-2015:

Red Cross Blood utilization ↓26.4%

National utilization ↓ 24.4%

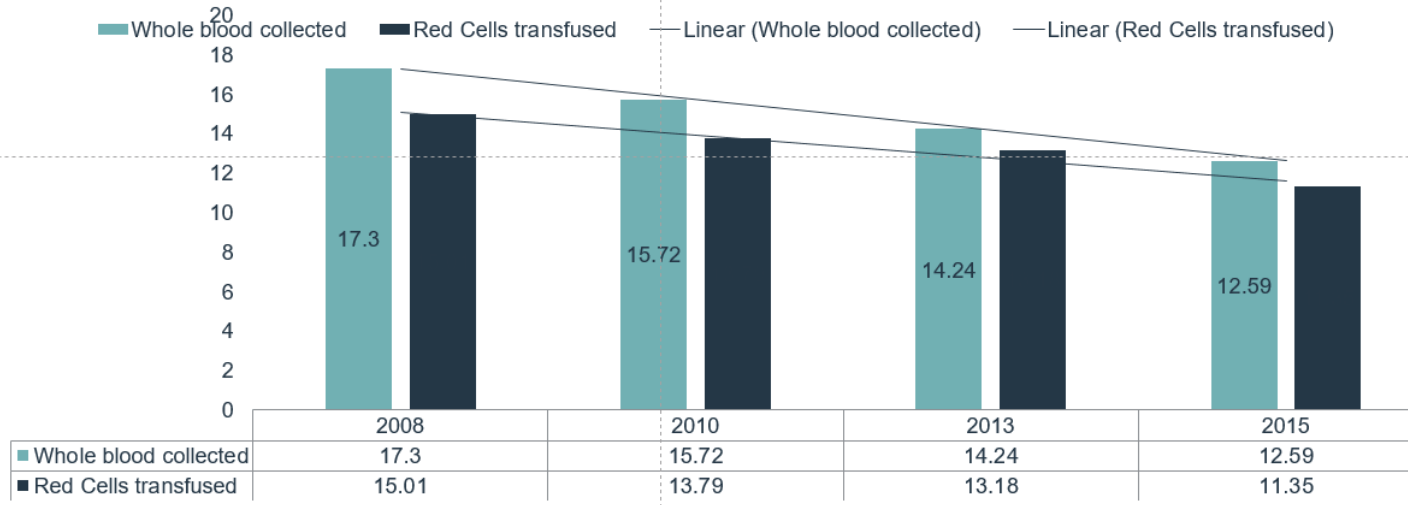
- Recession
- Patient blood management programs



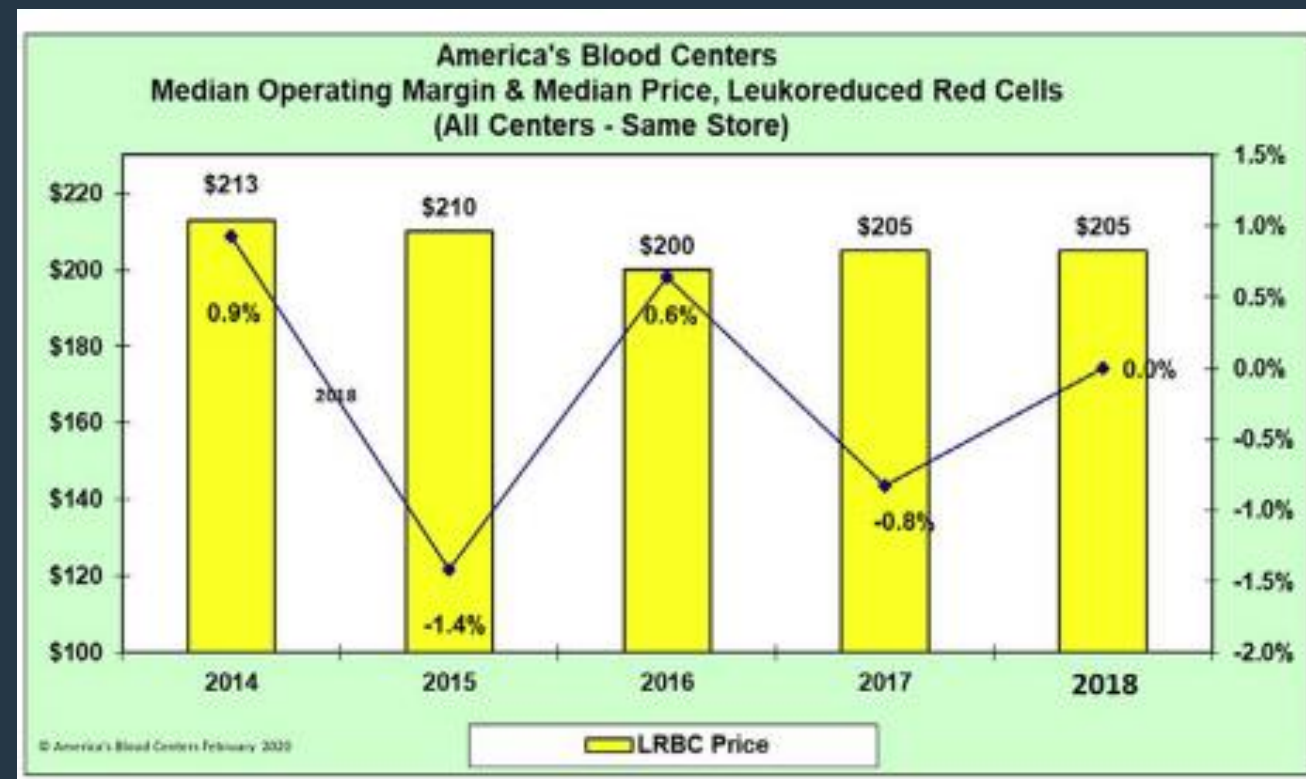
N Engl J Med 377;15 nejm.org October 12, 2017

National Blood Collection and Utilization Survey Data

• 2008-2015



Blood Center revenues ↓
 ↓ blood units distributed
 Cost of testing, etc ↑
 Prices ↓
 blood center competition
 hospital system leverage ↑
 Blood Center \$ margins ↓
 ~90% of blood centers:
 negative margins



Report

The U.S. blood system is in a period of flux and uncertainty.

There are unlikely but possible scenarios where the supply of blood would be disrupted.

The current system is not conducive to private investments in innovation.

Suppliers to blood centers face significant uncertainty and contribute to concerns on sustainability.

Services provided by local blood banks may be at risk.

The U.S. blood system under the status quo operates effectively and, in many cases, efficiently.

Offeror to prepare an independent study report, *“Toward a sustainable blood supply in the United States: an analysis of the current system and alternatives for the future.”*

- Describe the current business model and reimbursement structure underlying the non-profit, private sector supply of blood and blood components, **with particular reference to its ability to sustain technological advances and responses to safety threats and surge capacity.**

RAND REPORT

Fall, 2016



RAND Criticisms

Blood is a public good, built on the altruism of non-remunerated donors. Simple supply and demand economic principles do not fully address the societal value of this critical national resource. Consequently, there are unique considerations with respect to sustainability of the blood system.

48th meeting Advisory Committee on Blood and Tissue Safety and Availability,
November, 2016

Minimum input from those aware of the rapidly changing environment (arms length)

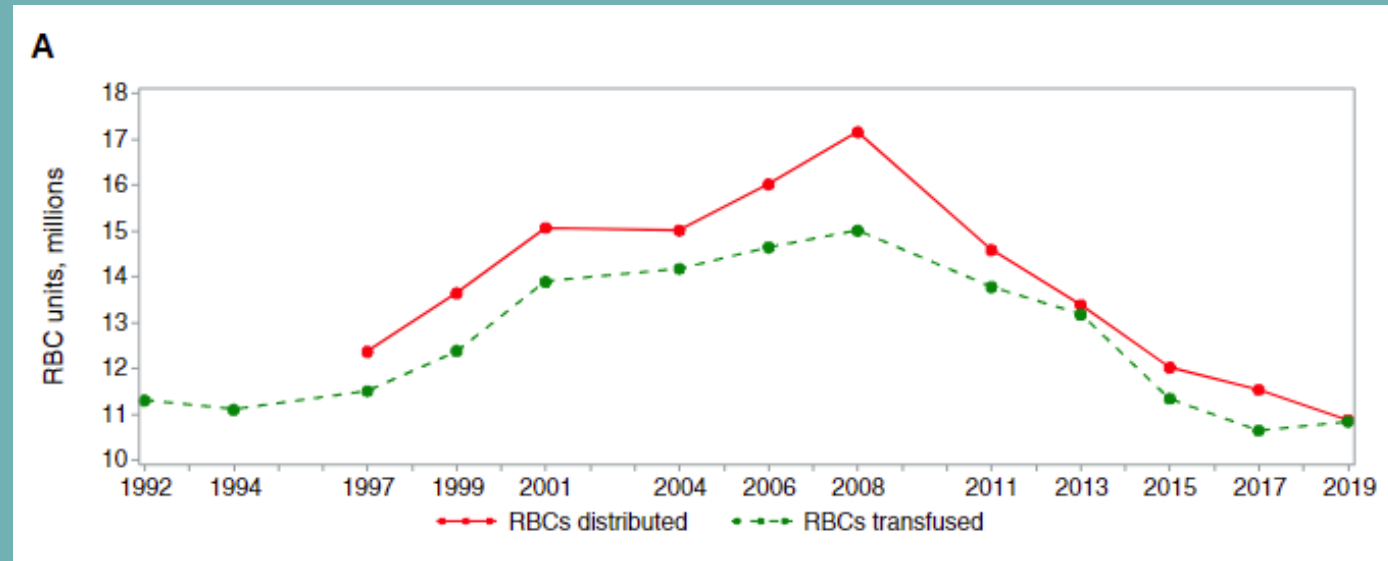
Recommendations based on dated data

“Snap shot”

short term economic perspective

systemic change

not cyclic downturn




Jones JM, Sapiano MRP, Mowla S, Bota D, Berger JJ, Basavaraju SV. Has the trend of declining blood transfusions in the United States ended? Findings of the 2019 National Blood Collection and Utilization Survey. *Transfusion*. 2021;61:S1–S10.

Stakeholders Perspective 2019

- Blood Centers consolidated
(ABC: 77 → 47 centers)
- \$1.3B expense reduction
- System remained **resilient**

COMMENTARY

Strategic issues currently facing the US blood system

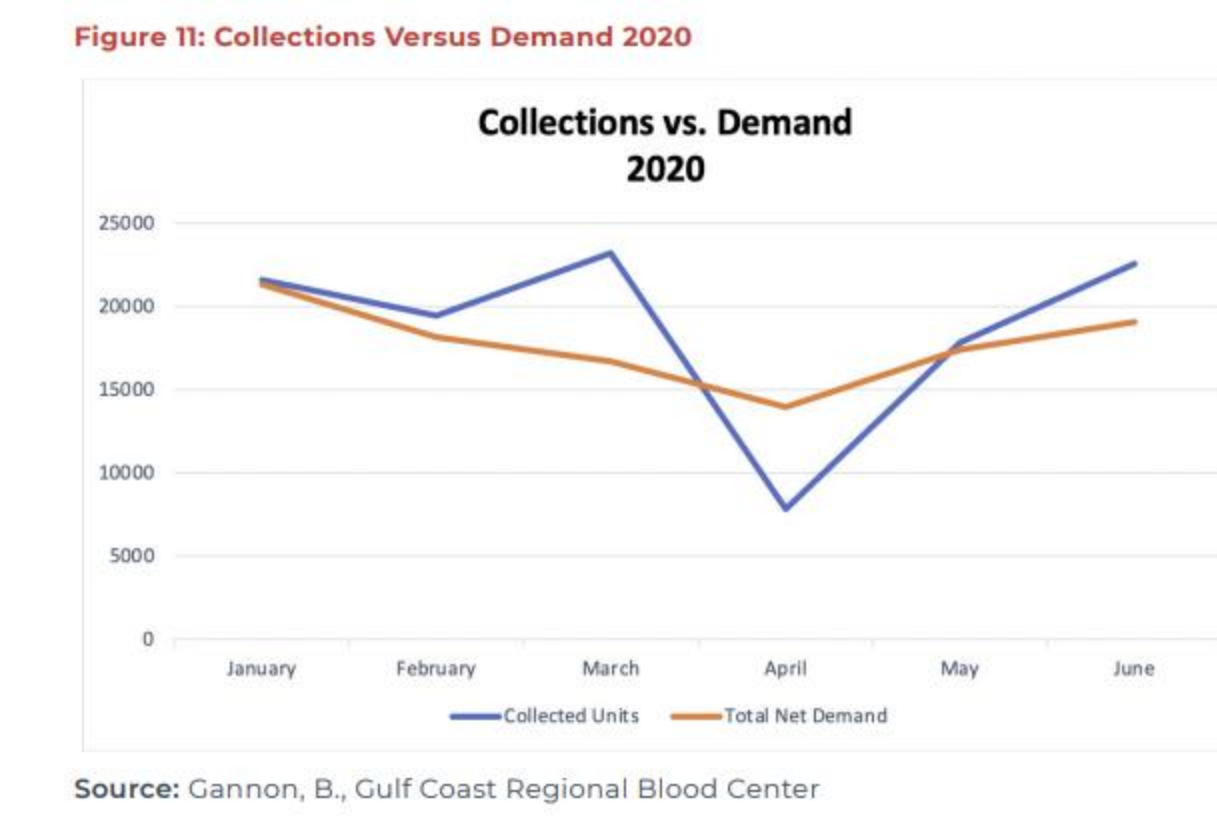
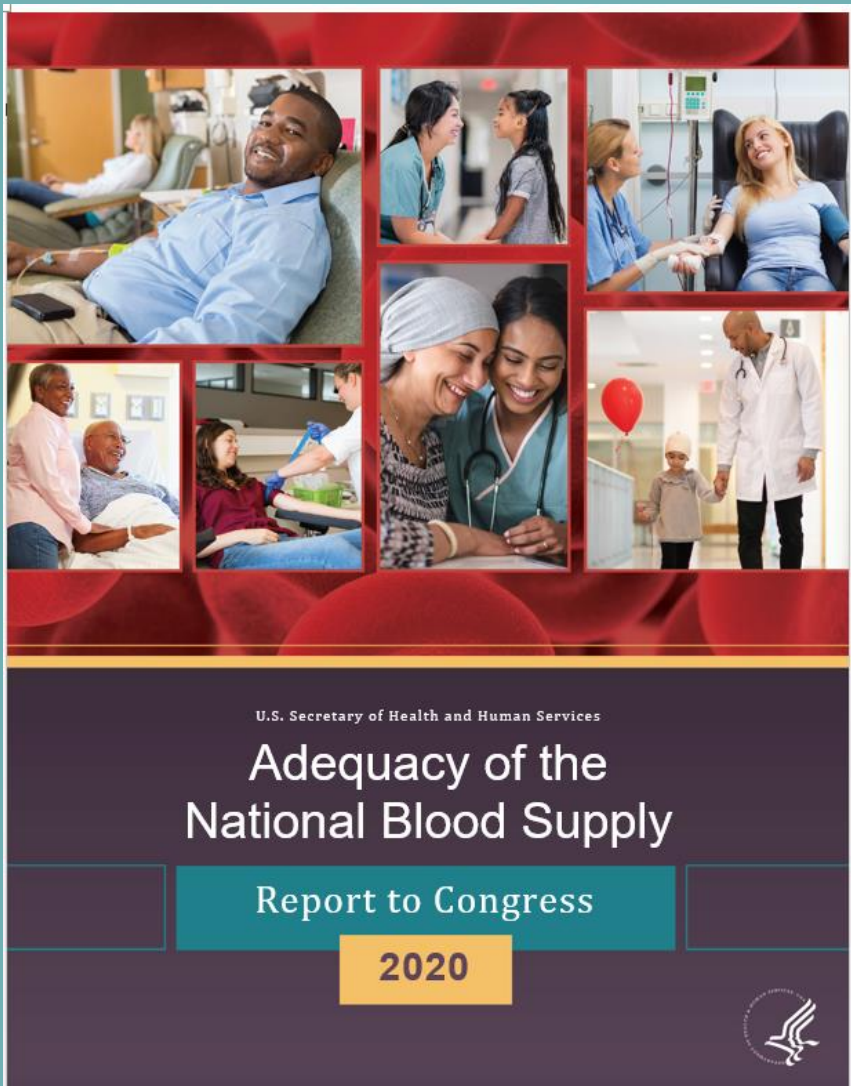
Jacquelyn Fredrick,¹ James J. Berger,² and Jay E. Menitove ³

TRANSFUSION 2020;60;1093–1096

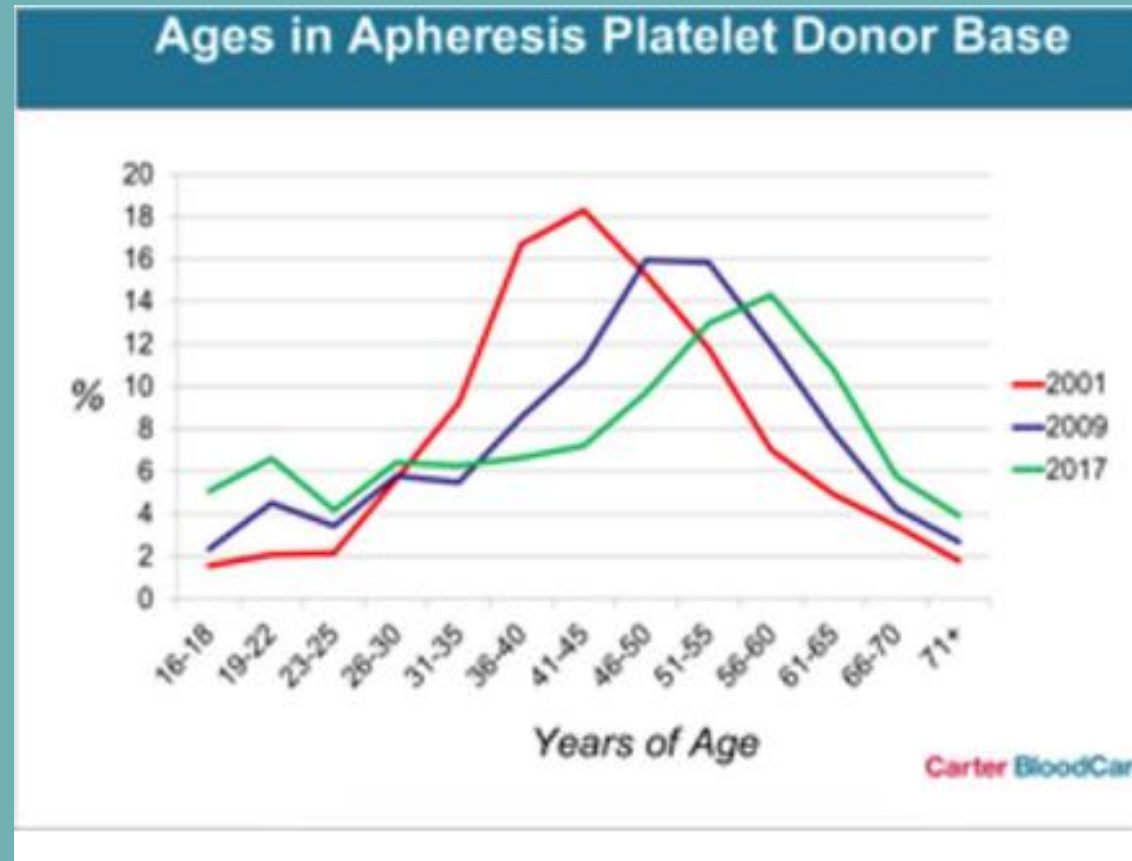
- Enhance critical transfusion medicine, blood, and safety innovation
focused on **outcomes**
- Establish a data collection system supported by data analytics across
the supply chain from suppliers to vein-to-vein
- Assure transfusion medicine preparedness

Pandemic and All-Hazards Preparedness and Advancing Innovation Act (reauthorized—2019)

(Sec. 209) This section requires the Department of Health and Human Services (HHS) to report about the adequacy of the national blood supply in the case of a public health emergency, the recruitment of blood donors, and other procedures related to the safety and reliability of the national blood supply.



Collecting real-time data for meeting everyday needs, responding to public health emergencies, monitoring the safety of transfusion therapy, and establishing research agendas to improve patient outcomes

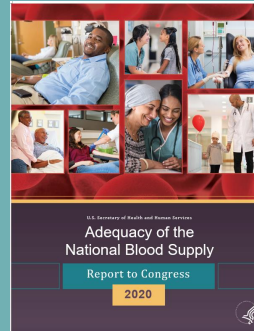


Expanding the blood donor base by creating a culture of blood donation and engagement—particularly among young people and people of color—by understanding donor motivation and improving access to donation

Consolidation and concentration of testing laboratories has also increased the vulnerability of the U.S. blood supply during a pandemic or natural disaster. There are currently only six testing organizations and 22 laboratories. Figure 13 shows the six organizations and their dependence on aerial and road infrastructure to collect and test blood.



Blood Center Shipping to Testing Labs:

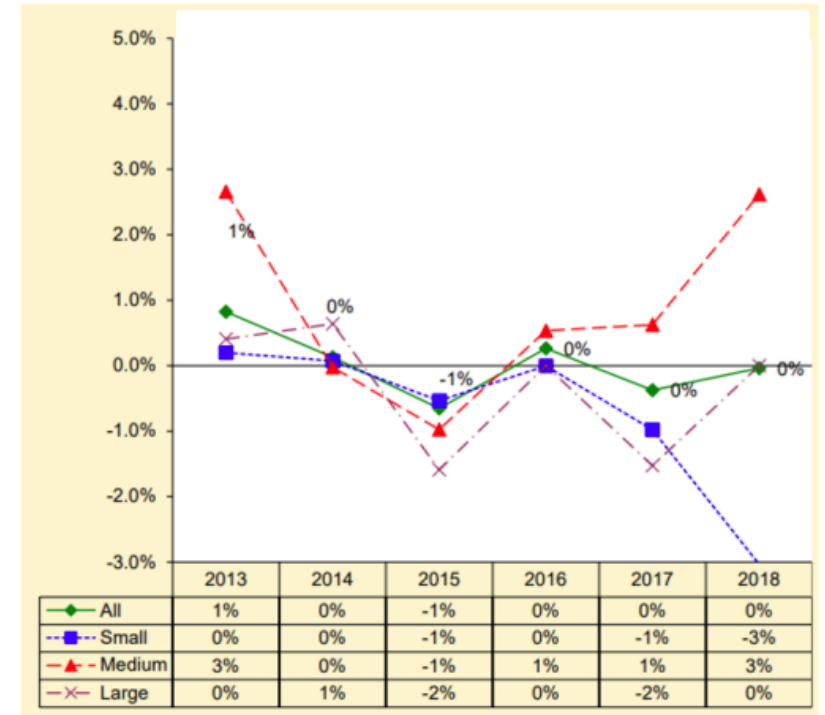


BARDA and Operation Warp Speed – **Critical Support**

- Strong communication with FDA, BARDA, Armed Services Blood Program, ABC, AABB, ARC, CEO's, and stakeholder clinicians (Dr. Mike Joyner, Dr. Arturo Casadevall, Dr. Nigel Paneth)
 - Should consider forming Coordination Response Team to be regularly meeting and be the Quick Reaction Force for the next Pandemic
 - Community Engagement with networks like Chaim Lebovits representing the Orthodox Jewish Community, and Survivor Corps led by Diana Berrent
- Centers ramping up to >20,000 CCP doses/week from zero with help from BARDA
- Development of new cost recovery model that factored in all relevant cost to the blood centers and accounted for Opportunity Cost (multiple components not collected)
- Surgeon General reminder on importance of donating – data to support advocacy

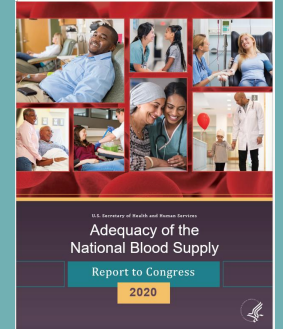
Stakeholder involvement to address: Modernizing the current business model for blood collection, innovation, and adoption of new technology

Figure 2: Median Operating Margin (Operating Income Percent) by Year



Source: Fry, K., America's Blood Centers, 2020

Section 209 Executive Summary (Summer 2020)

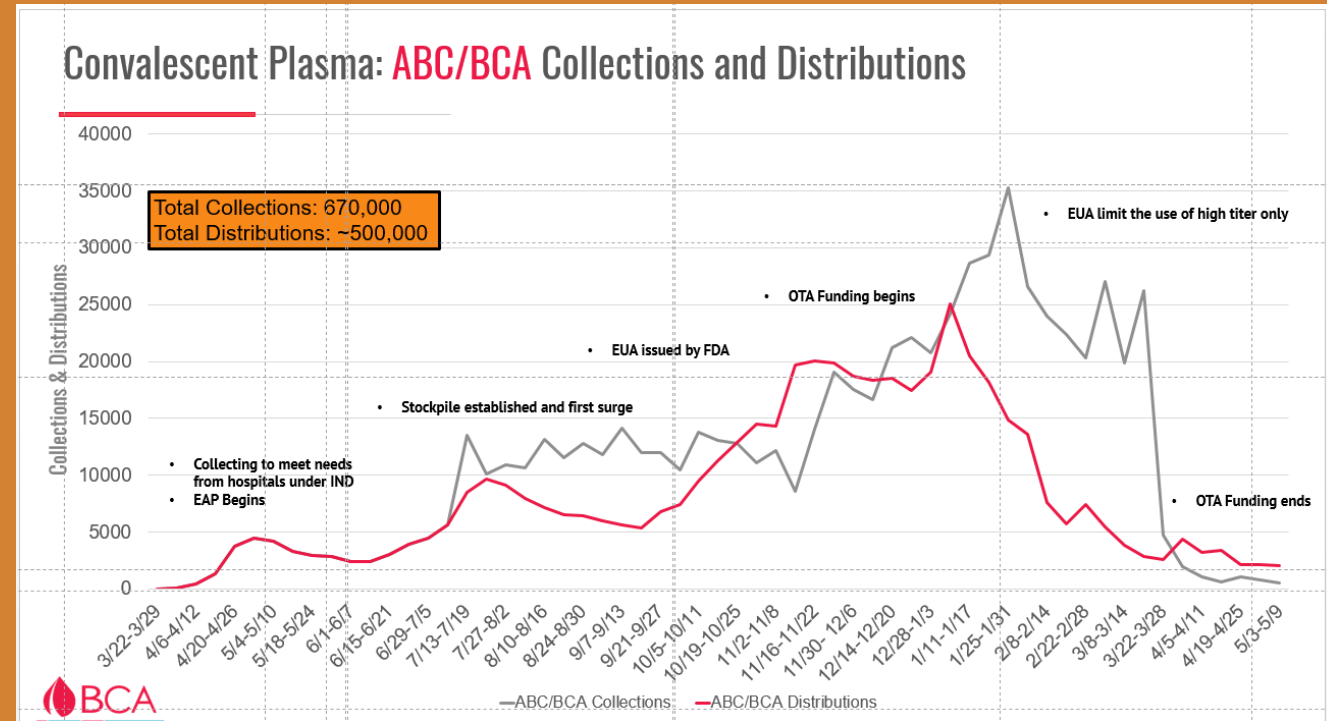


The COVID-19 pandemic focused attention on the strengths and weaknesses of the U.S. blood system. The system responded rapidly, robustly, and reliably to the dramatic swings in the blood supply, from shortages to surpluses to shortages. It adapted to the dramatic redirection of venues for blood collection, from mobile blood drives to fixed-site locations. The system brought online a new product with life-saving potential, COVID-19 convalescent plasma, utilizing a public-private partnership model.

Pandemic & Lessons Learned

COVID Convalescent Plasma (CCP) New Product

- inventory distribution
- **> 23,000 units per week at pandemic peak**
- Supplies
- Regulatory issues (EUA)
- New donor communication
- Efficacy?

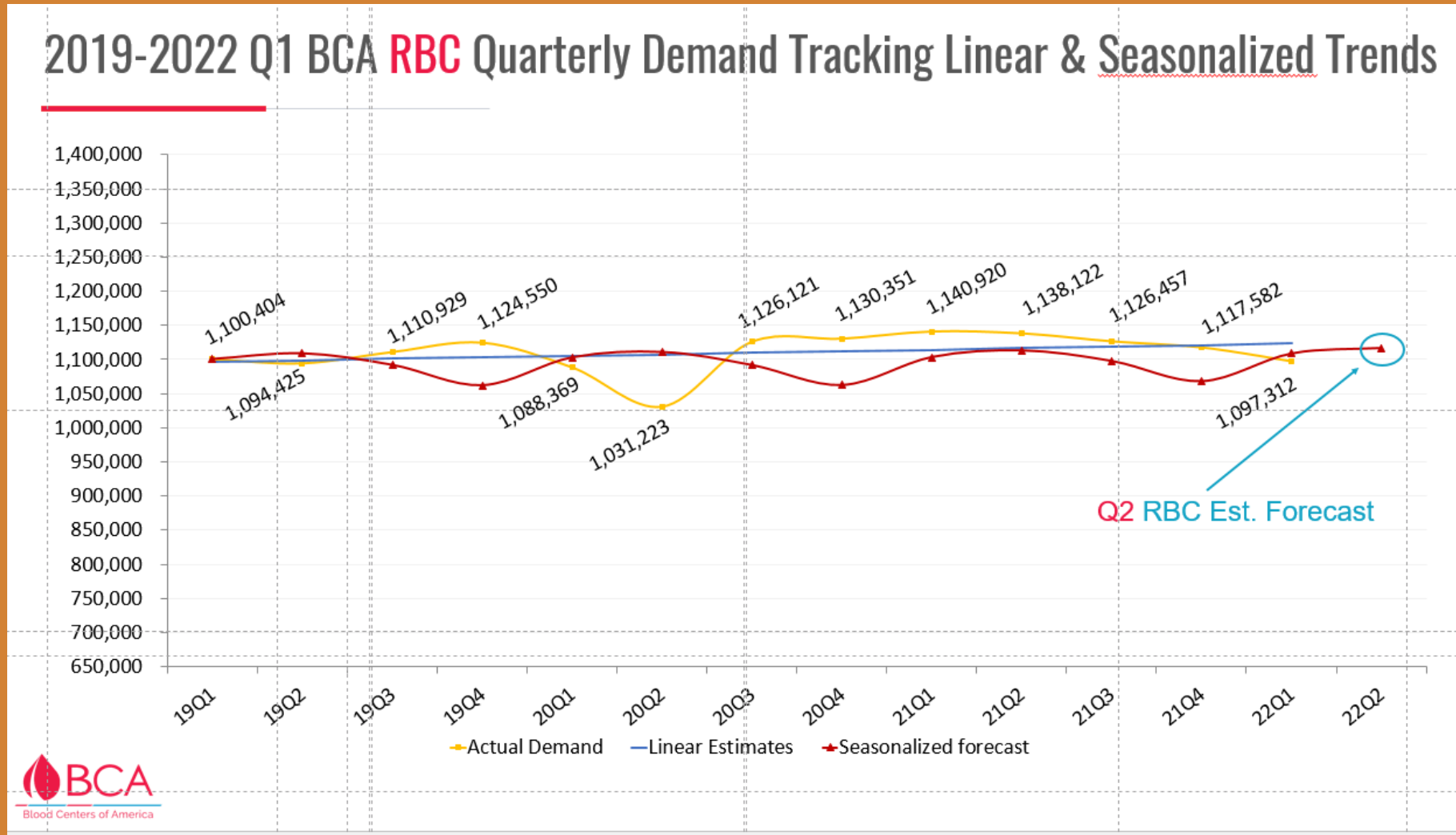


Reimbursement

>\$500M for *production*
vs *distribution*

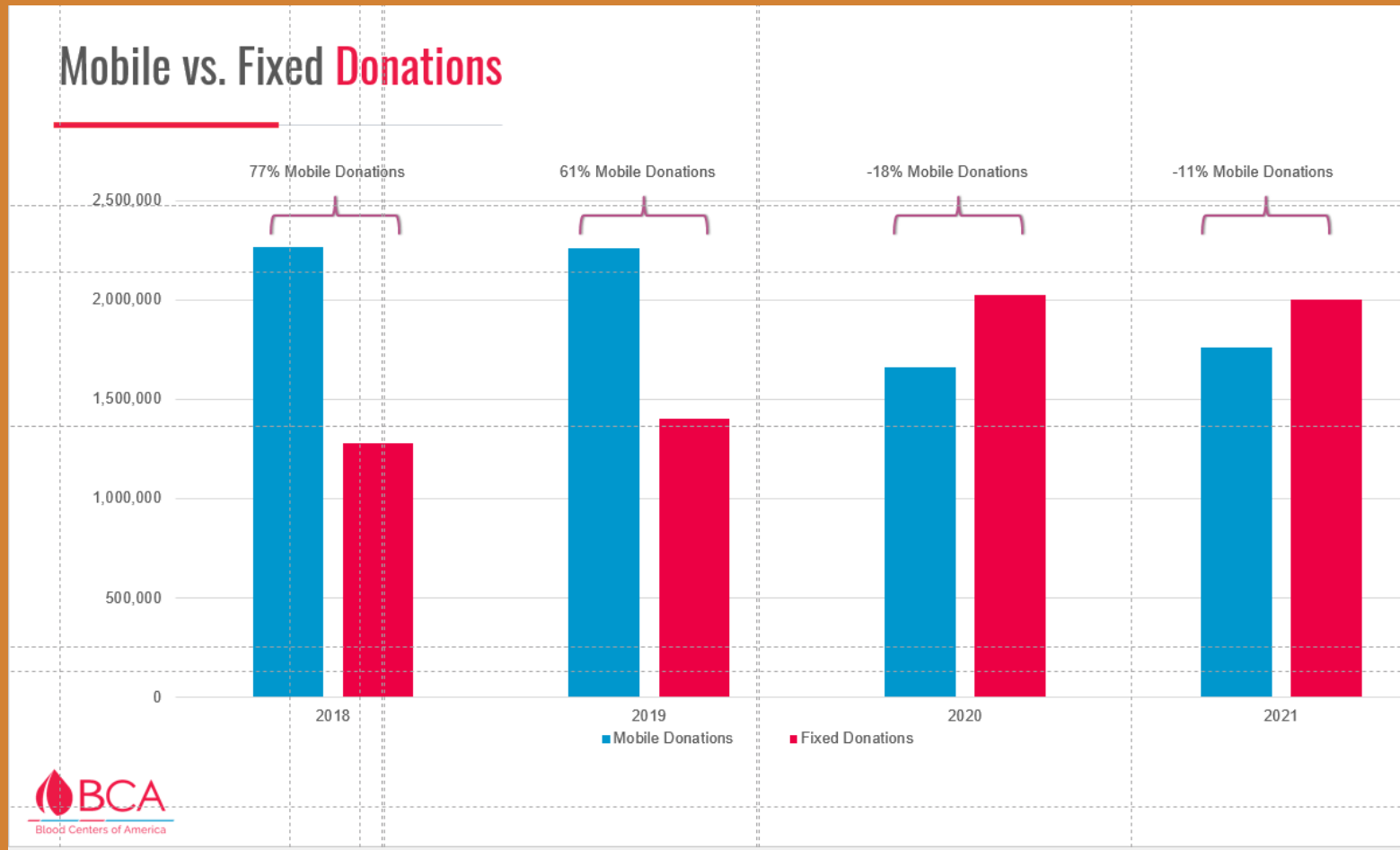
Pandemic & Lessons Learned

Blood Collection and Utilization



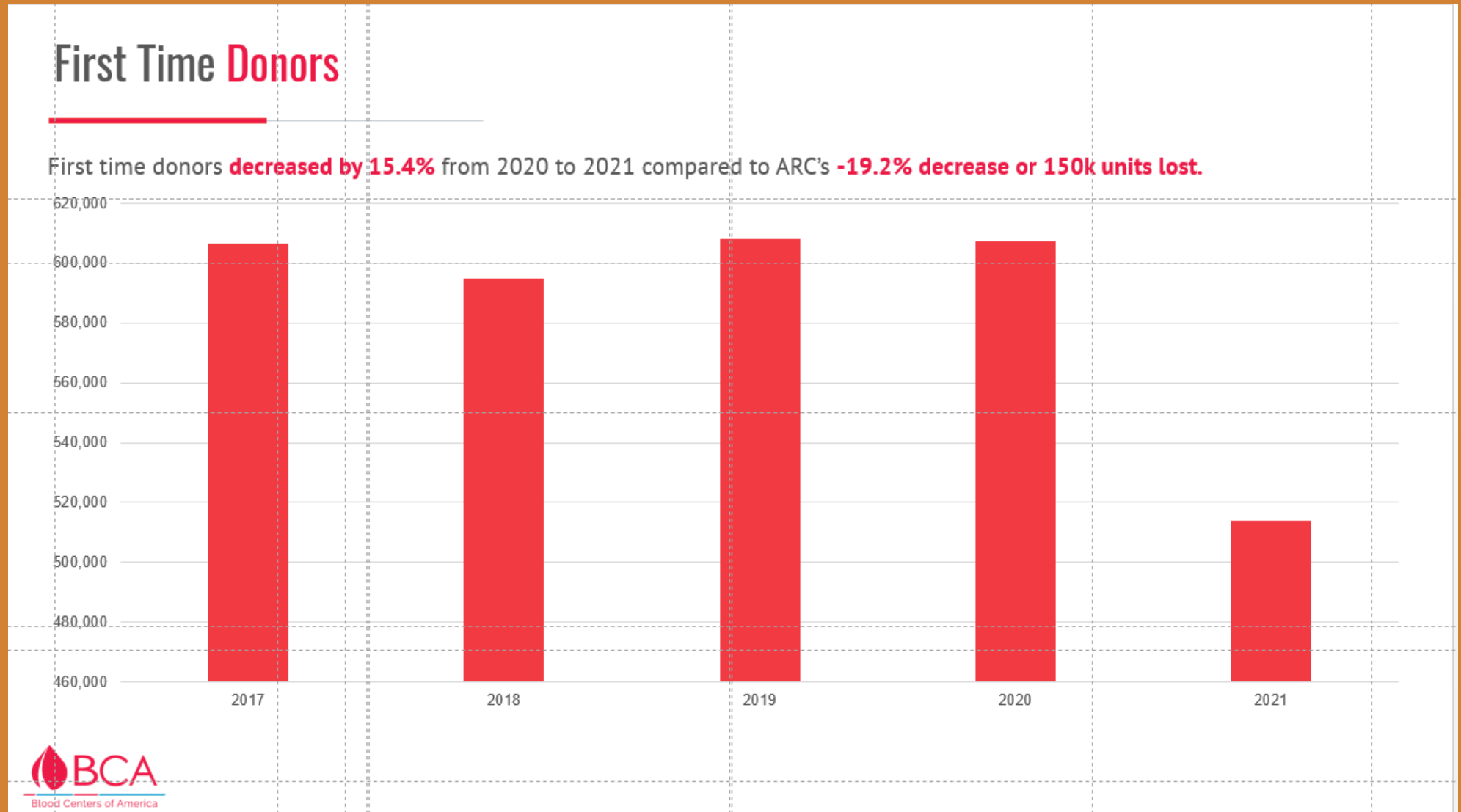
Pandemic & Lessons Learned

Blood Collection and Utilization



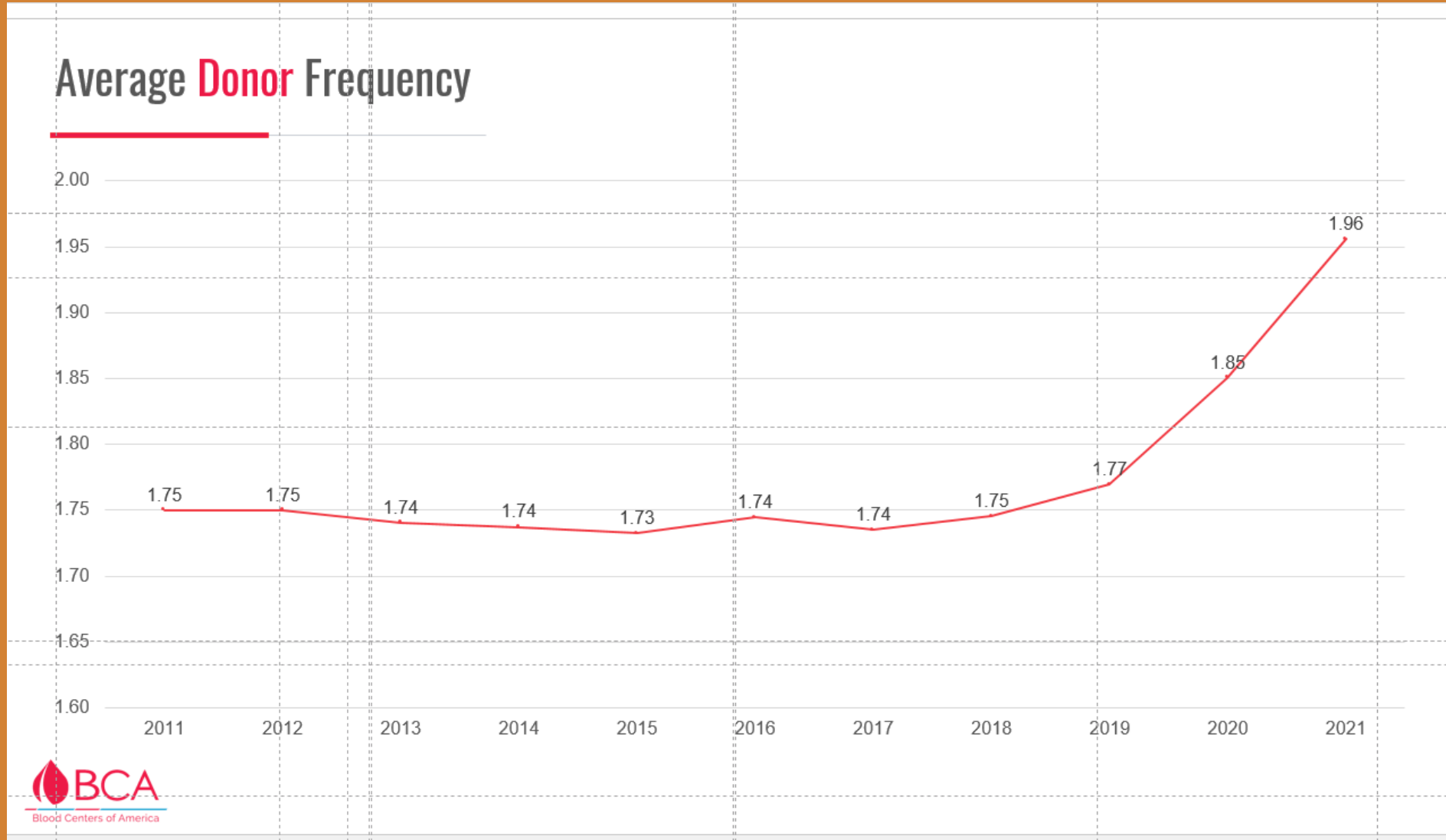
Pandemic & Lessons Learned

Blood Collection and Utilization



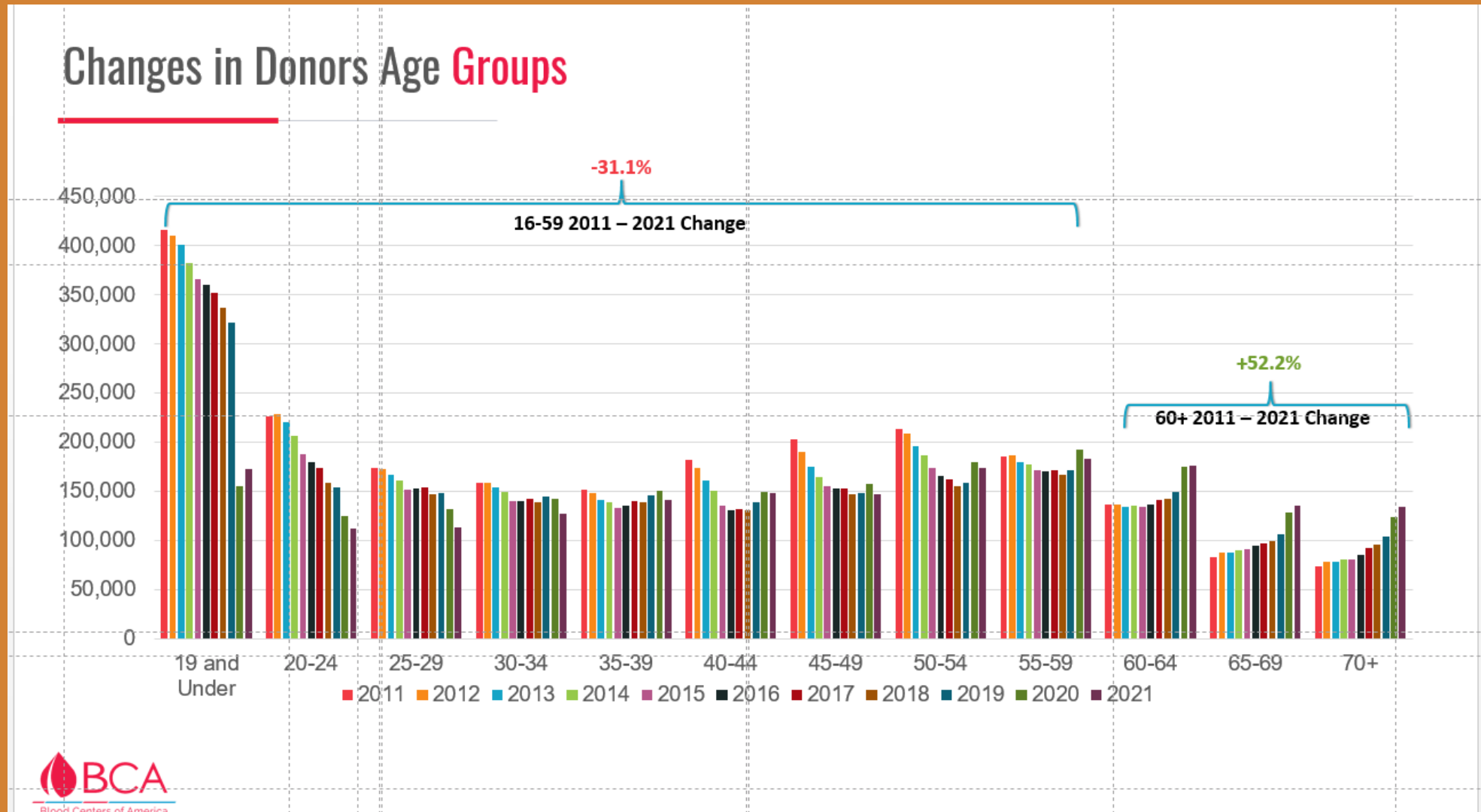
Pandemic & Lessons Learned

Blood Collection and Utilization



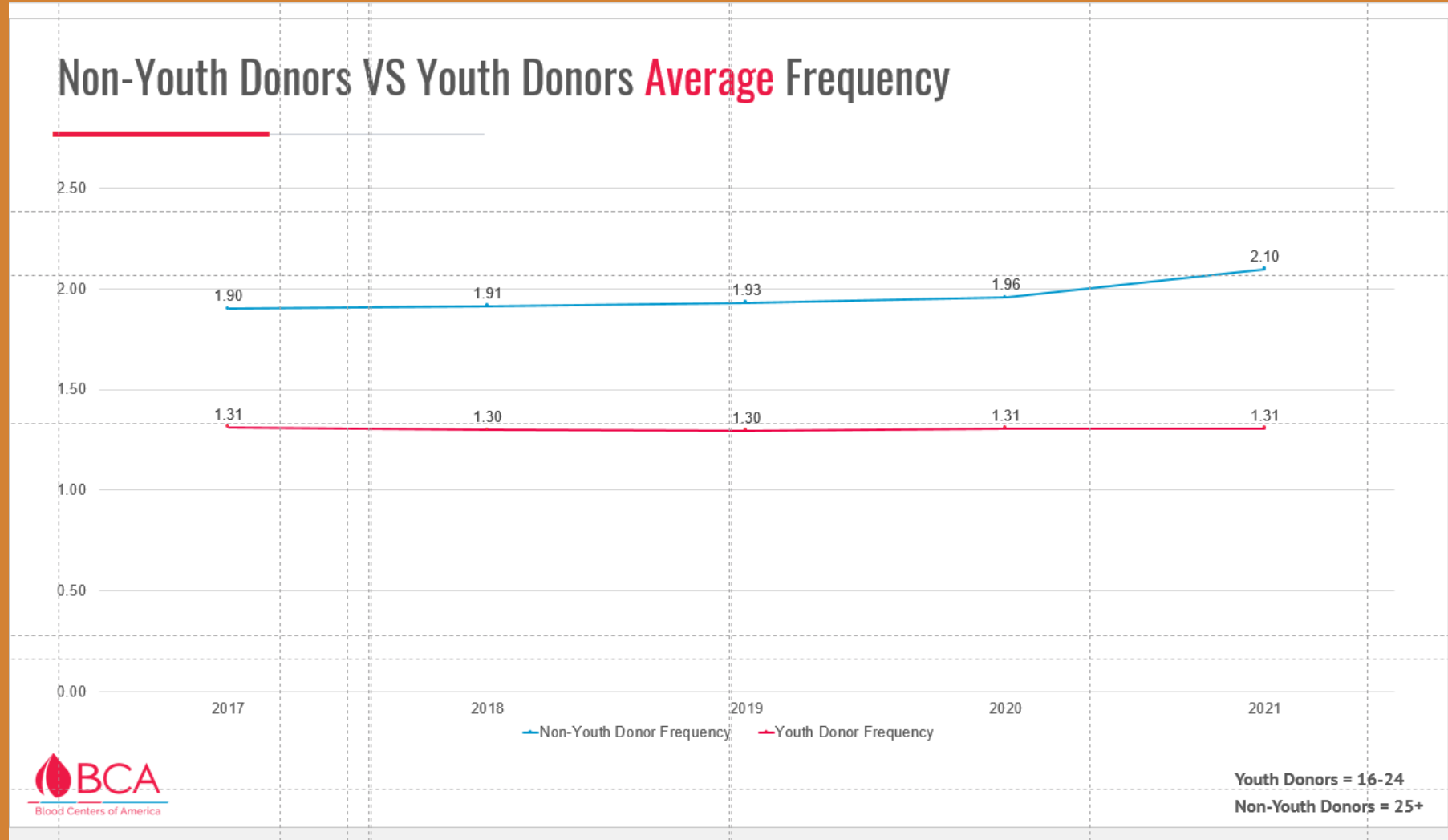
Pandemic & Lessons Learned

Blood Collection and Utilization



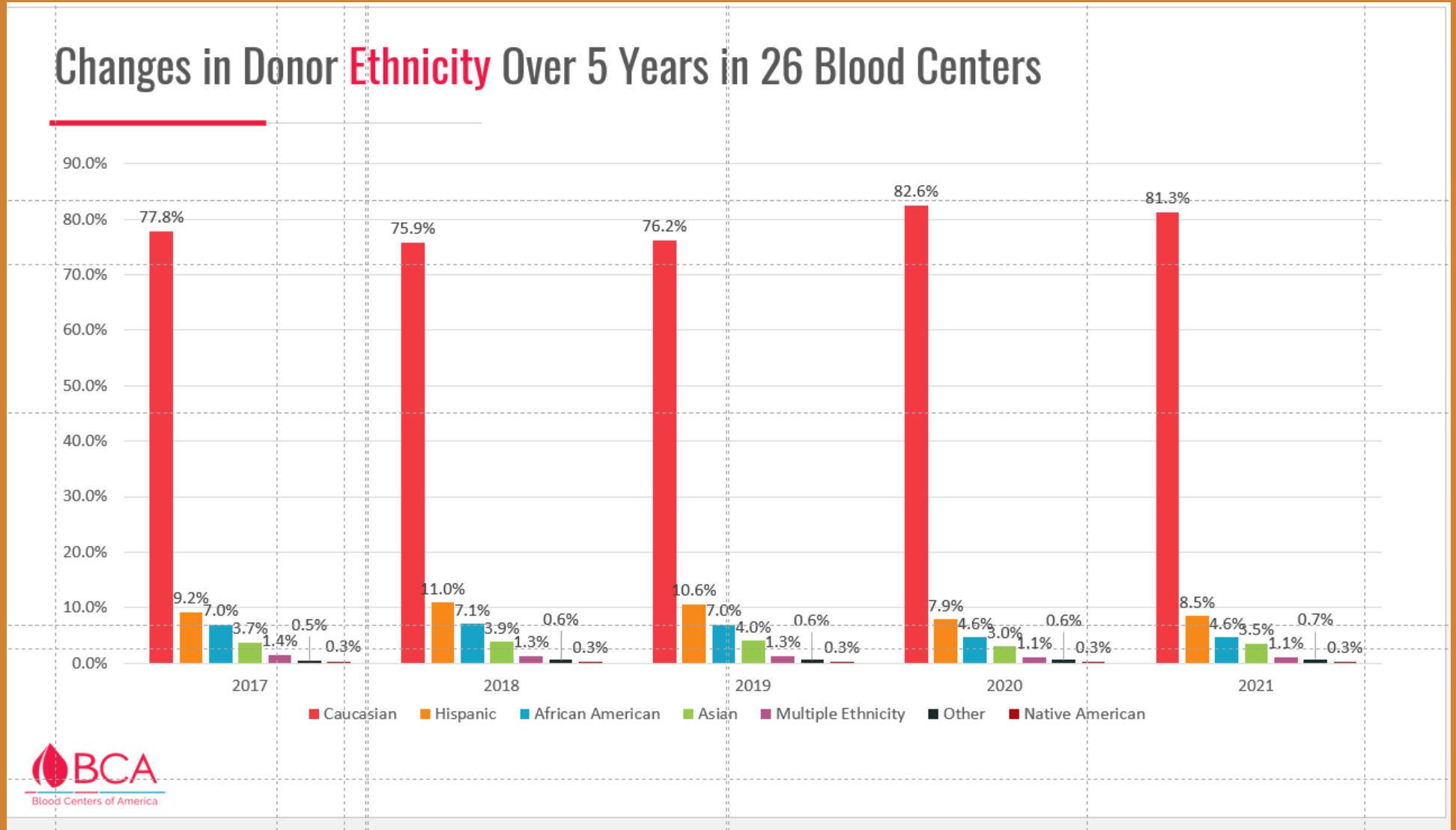
Pandemic & Lessons Learned

Blood Collection and Utilization



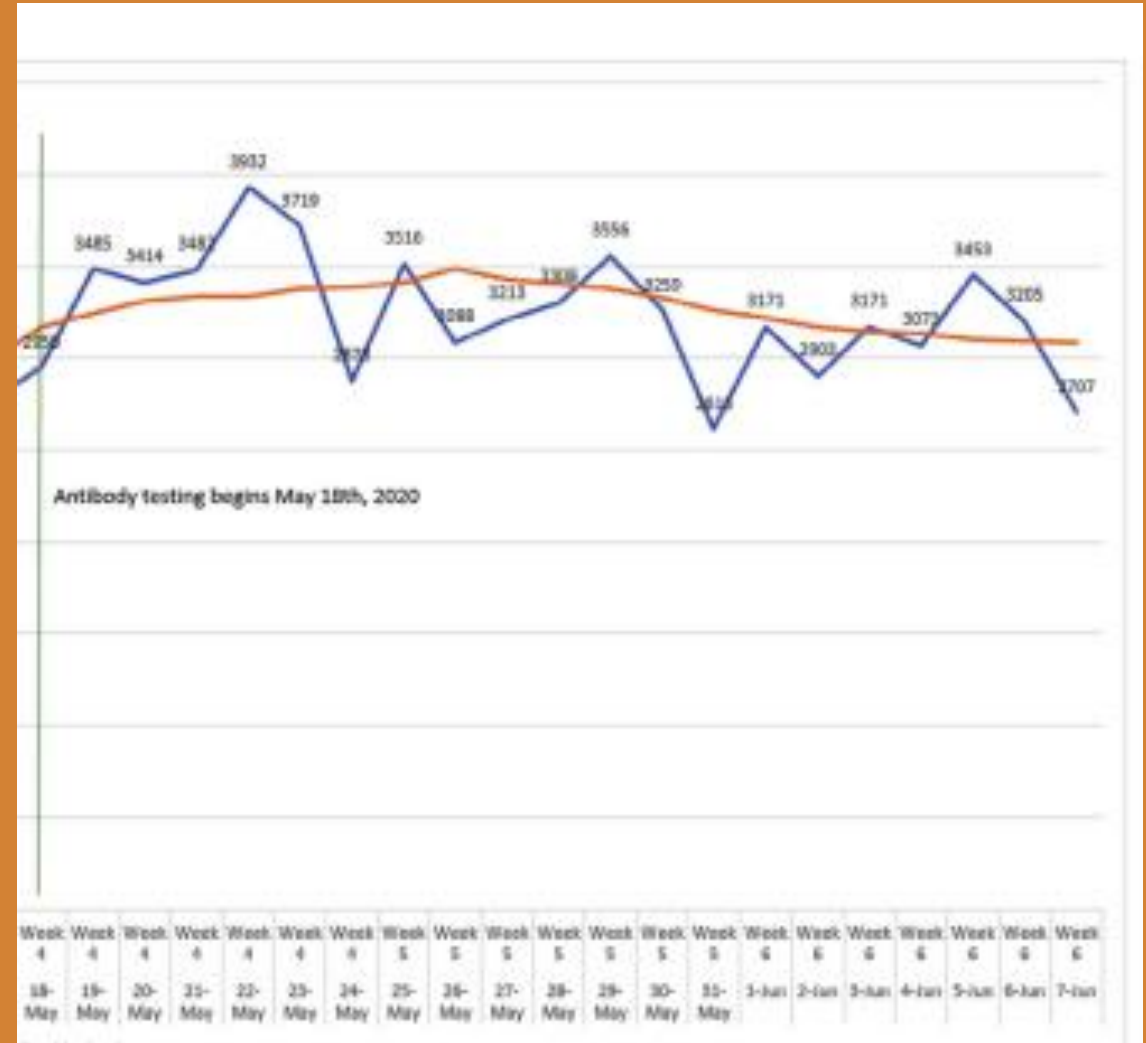
Pandemic & Lessons Learned

Blood Collection and Utilization



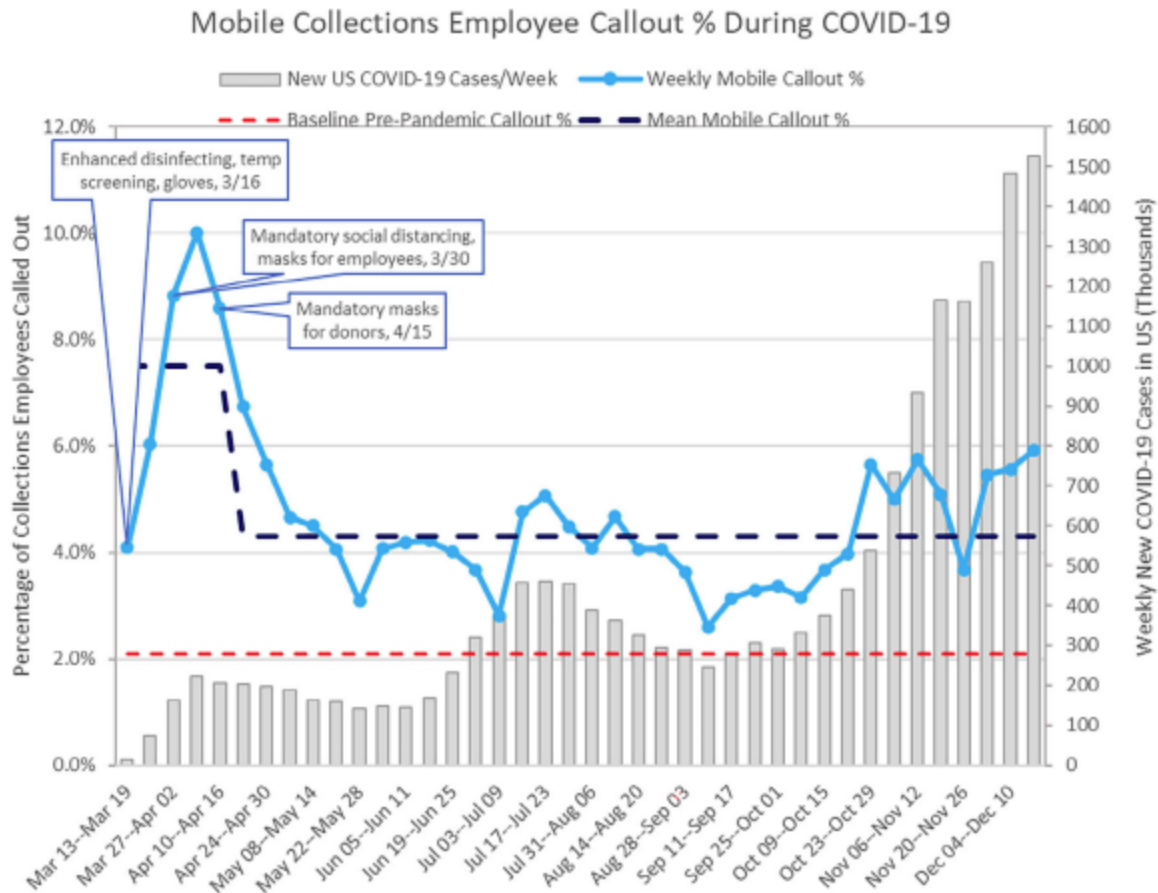
Pandemic & Lessons Learned

- Donor incentives
- COVID Antibody testing



Pandemic & Lessons Learned

Staffing issues

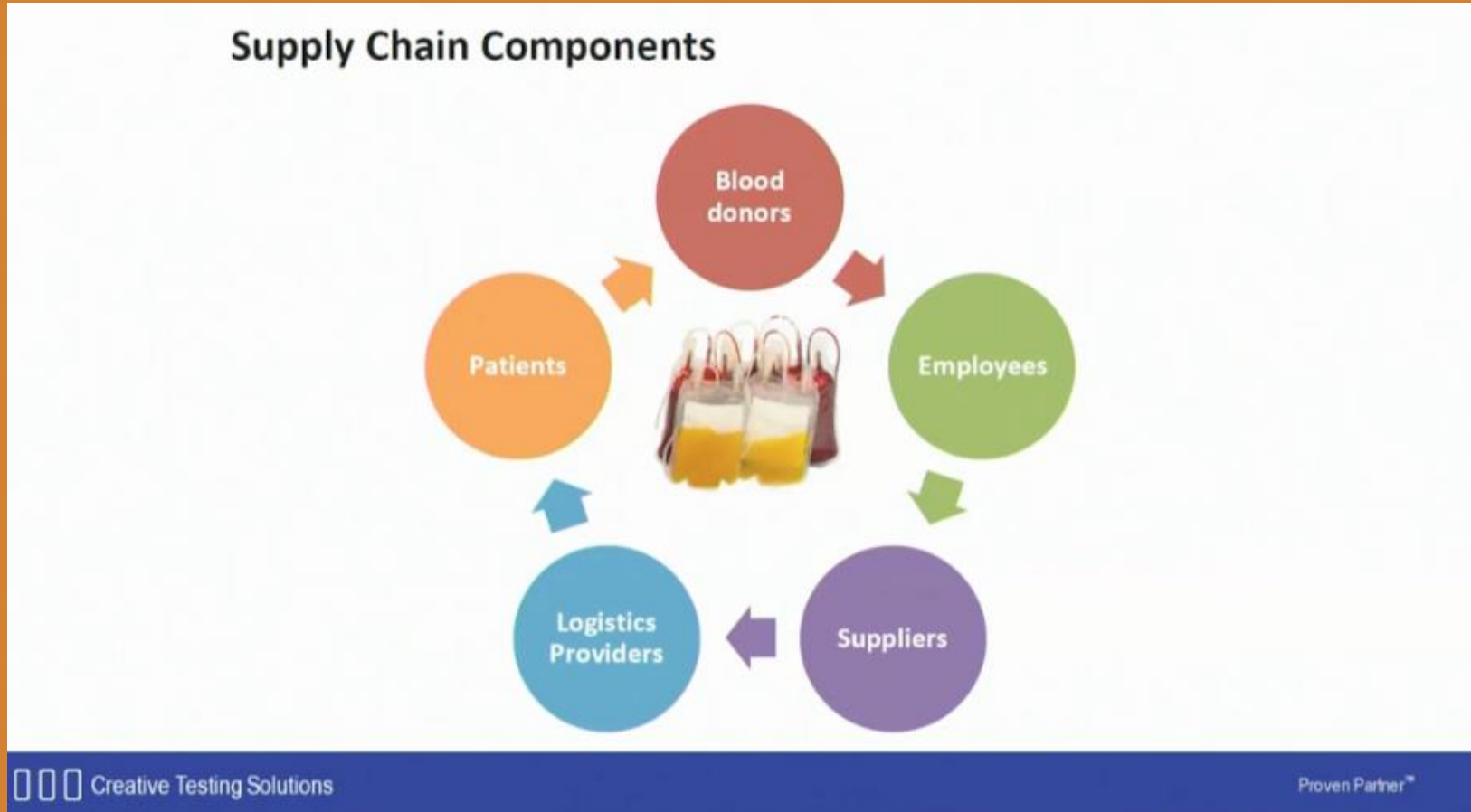


Conclusion: Callouts for BCC employees during the COVID-19 pandemic initially increased, but subsequently declined and stabilized after implementation of safety measures. Since multiple interventions were implemented simultaneously, it is not possible to determine the individual impact of each measure on callout rate.

Coberly E, Korich E, Henesy M, Doerksen K, Young P. Implementation of measures to improve blood collection center employee safety and reduce callouts during the 2019 novel coronavirus pandemic. *Transfusion*. 2021;1–6. <https://doi.org/10.1111/trf.16426>

Pandemic & Lessons Learned

Supply chain issues



Caglioti, S Advisory Committee on Blood and Tissue Safety and Availability 53rd meeting, August 2021

Pandemic & Lessons Learned

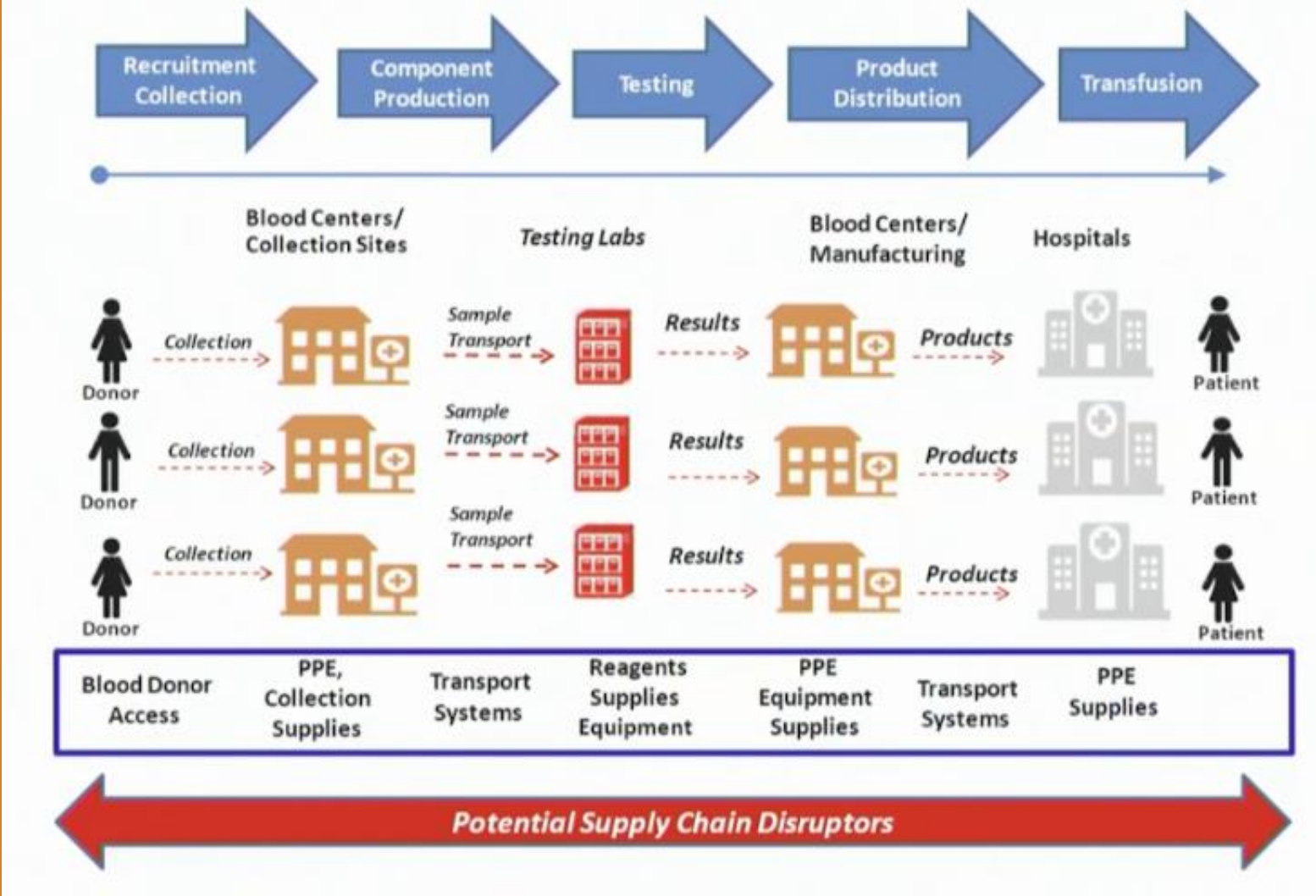
Supply chain issues

- Reagent/bag suppliers played a significant concentration



Caglioti, S Advisory Committee on Blood Safety and Availability 53rd meeting, August 2021

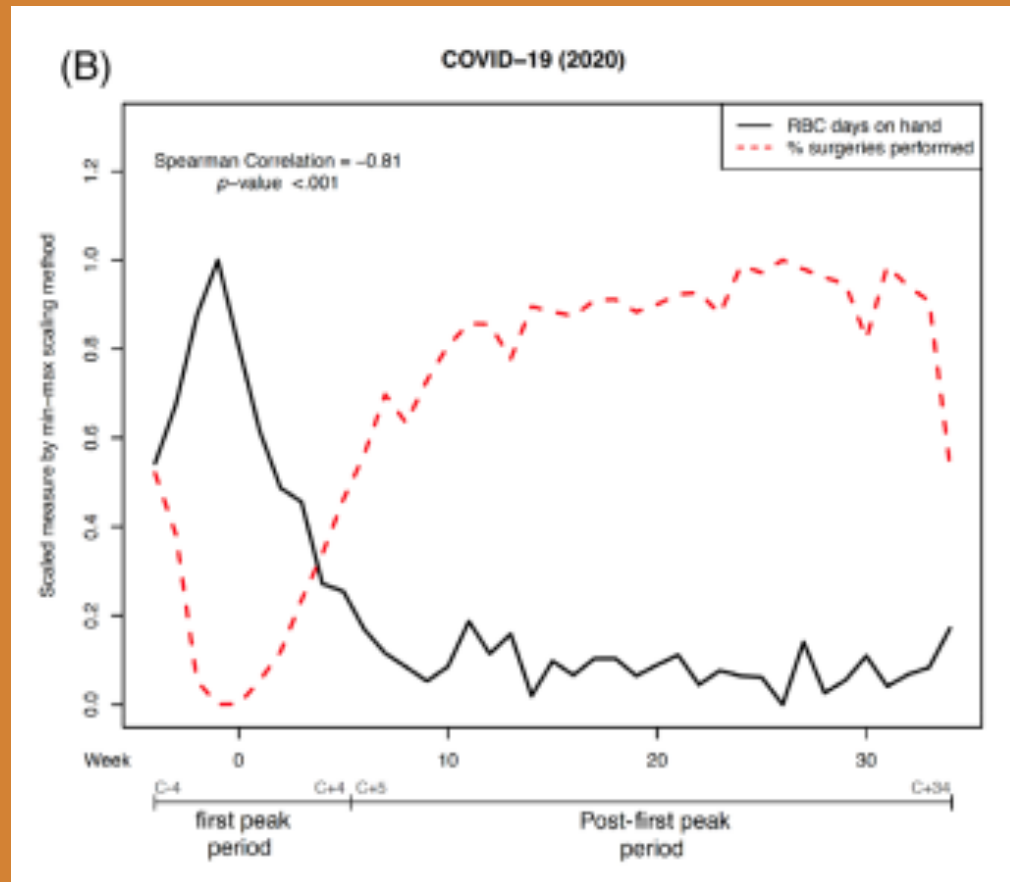
Pandemic & Lessons Learned



Supply chain issues

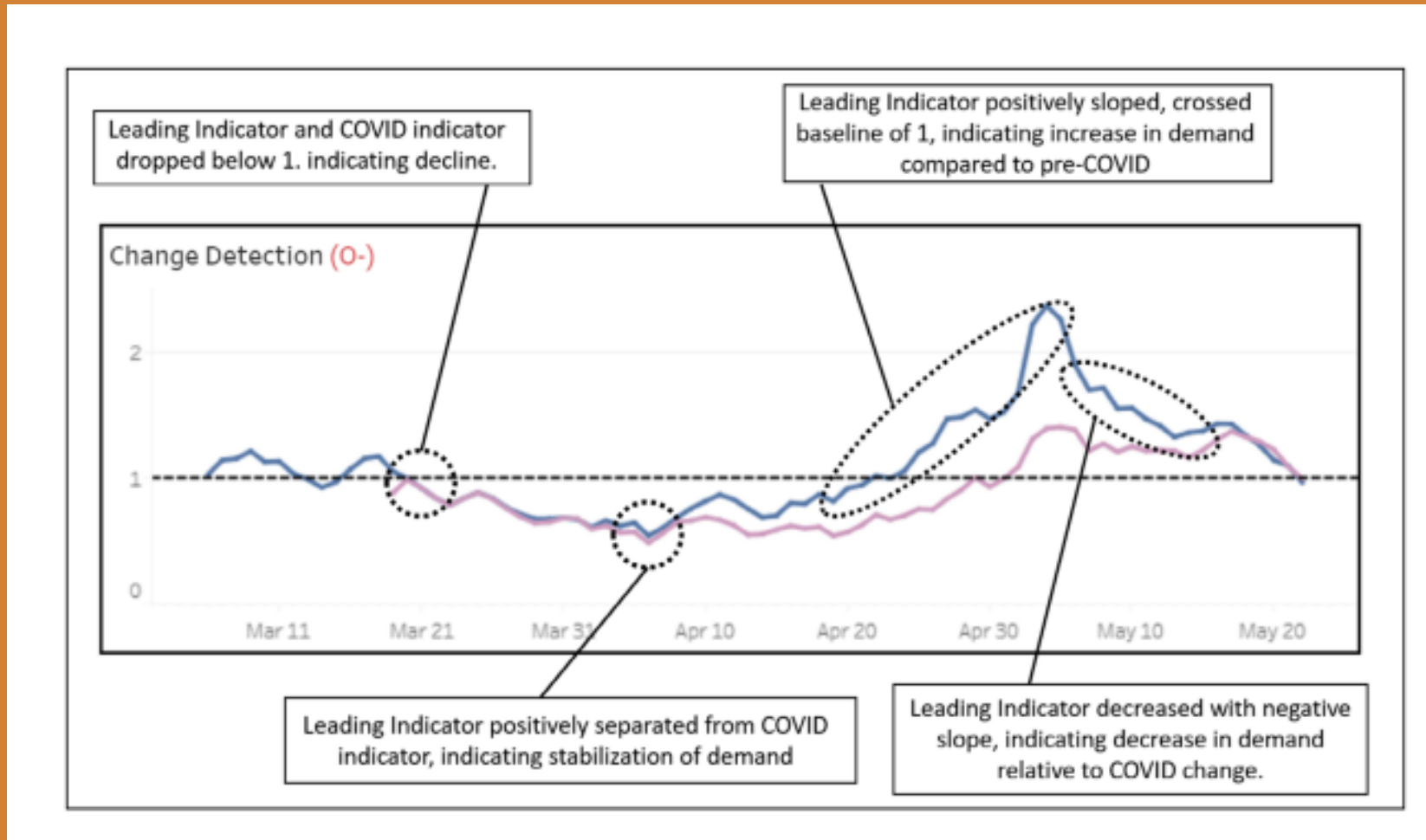
Pandemic & Lessons Learned

- Big data
 - lack of visibility between blood centers and hospital transfusion service inventories



Lu W, Yazer M, Li N, Ziman A, Wendel S, Tang H, et al. Hospital red blood cell and platelet supply and utilization from March to December of the first year of the COVID-19 pandemic: The BEST collaborative study. *Transfusion*. 2022. <https://doi.org/10.1111/trf.17023>

Predicting demand with big data



Gammon R, Katz LM, Strauss D, et al.
Beyond COVID-19 and lessons learned in the United States. *Transfusion Medicine*. 2022;1-10. doi:10.1111/tme.12896

Pandemic & Lessons Learned

Regulations (FDA)

Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

Guidance for Industry

Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria

Guidance for Industry

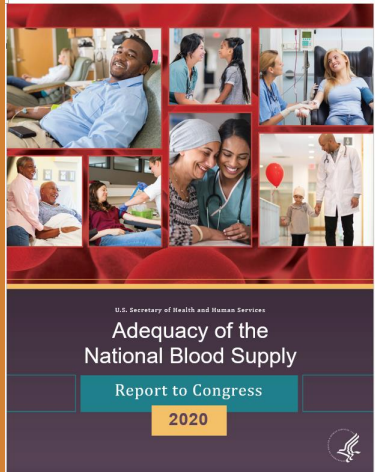
This guidance is for immediate implementation.

- Defer for 3 months from the most recent event, an individual who has exchanged sex for money or drugs.
- Defer for 3 months from the most recent event, an individual who has engaged in non-prescription injection drug use.
- Defer for 3 months from the most recent sexual contact, an individual who has had sex with a person who has ever had a positive test for HIV.

We recommend that you defer for 3 months after the last departure from a malaria-endemic area (as defined in section III of this guidance) a donor who is a

April 2020
Updated August 2020

Pandemic & Lessons Learned



On the other hand, the pandemic exposed weaknesses that require remediation in order to address current needs and respond to future public health emergencies (Figure 16). These vulnerabilities include the following:

- Lack of current, real-time data for decision making;
- Uncertainty about modern business models for blood centers and appropriate remuneration for their services;
- Gaps in understanding of blood donor motivation to ensure adequate blood donations from current and future generations of blood donors; and
- Barriers and an uncertain environment that stifles innovation and new technology adaptation.
- Ambiguity about the role of cost/benefit analyses in decision-making without compromising safety.

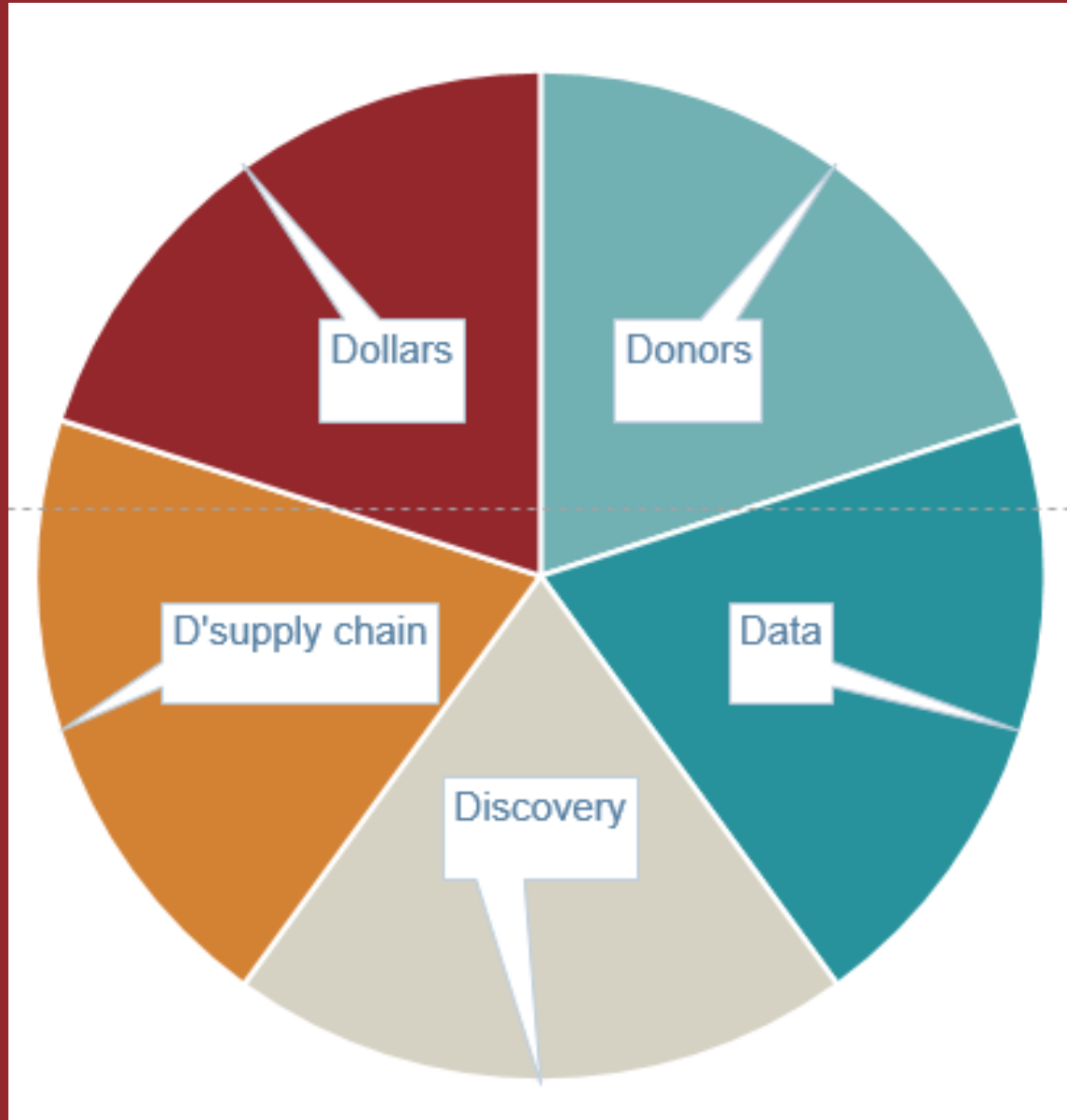
Figure 16: Magnitude of Risk, United States

Magnitude of risk, US

Agent	Risk	Comment
HBV	1:2,300,000	By WP estimation
HCV	1:2,600,000	By WP estimation
HIV	1:1,500,000	By WP estimation
HTLV	~0	No known cases
Syphilis	~0	No known case (1960)
vCJD	~0	4 known cases globally
WNV	<1:10,000,000	14 reports in 15 years
<i>T. cruzi</i>	~0	0 in 11 years
<i>B. microti</i>	0:390,000 (with testing)	IND study, of 1:50,000
ZIKV	?	Likely zero

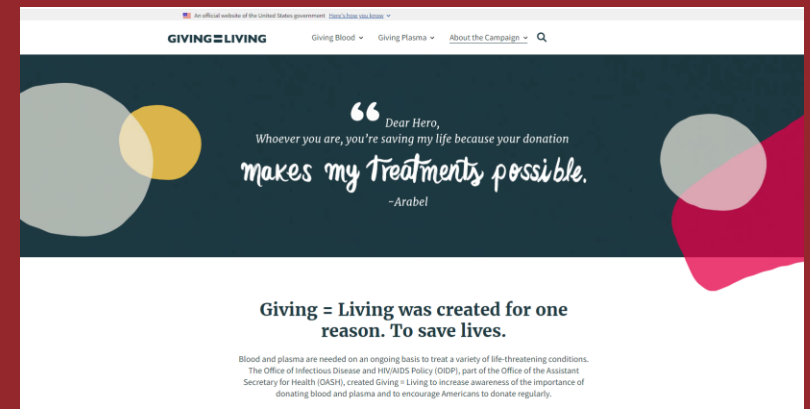
Dodd RY. Presentation to the Advisory Committee on Blood and Tissue Safety and Availability, August 26, 2020

Driving Forces/Future Actions



Donors

- Engage donors
 - Younger
 - diverse
 - current
- Identify effective incentives
 - Monetary \$\$
 - Non-monetary
 - Altruism only
- Mitigate donor attrition
 - Fear → ↑ vasovagal reaction
 - Vasovagal reactions → donor attrition
 - Deploy distraction strategies



Bruers S. Blood donation and monetary incentives: A meta-analysis cost-effectiveness. *TransfMedRev*2022;36: 48-57.

Sayers M. Donor motivation and psychosocial research. *Transfusion*. 2022 Jul 10. doi: 10.1111/trf.17024. Epub ahead of print. PMID: 35811303.

France CR, France JL, Himawan LK, Duffy L, Kessler DA, Rebosa M, Rehmani S, Frye V, Shaz BH. Fear is associated with attrition of first-time whole blood donors: A longitudinal examination of donor confidence and attitude as potential mediators. *Transfusion*. 2021 Dec;61(12):3372-3380. doi: 10.1111/trf.16671. 2021

Chell K, Masser B, Davison TE, Ferguson E. A typology of strategies that recognize, reward, and incentivize blood donation. *Transfusion*. 2022. <https://doi.org/10.1111/trf.17053>

Gilchrist PT, Masser BM, Horsley K, Ditto B. Predicting blood donation intention: the importance of fear. *Transfusion*. 2019 Dec;59(12):3666-3673. doi: 10.1111/trf.15554. PMID: 31663615

Data

- **Communicate with donors/donor groups**
 - Develop digital targeting
 - Migrate mobiles to “fixed sites”
- **Coordinate blood center and hospital inventories**
 - Local, regional, and national levels
 - ↓ shortage/outdating/hoarding
- **Attain visibility to supplier inventories**

Lu W, Yazer M, Li N, Ziman A, Wendel S, Tang H, et al.

Hospital red blood cell and platelet supply and utilization from

March to December of the first year of the COVID-19 pandemic: The BEST collaborative study. *Transfusion*. 2022;62(8):1559–70. <https://doi.org/10.1111/trf.17023>

<https://doi.org/10.1111/trf.17023>

Ning S, Li n, Barty R, Arnold D, Heddle NM. Database-driven research and big data analytic approaches in transfusion medicine. *Transfusion* 2022; 62; 1427-34.

Data (cont'd)

- **Expand Hemovigilance**
 - Mitigate donor adverse events
 - Improve recipient (patient) *outcomes*
- **Support Discovery/innovation**
 - Maximize use of Big Data

Fink RV, Fisher L, Sulaeman H, Dave H, Levy ME, McCann L, et al. How do we...form and coordinate a national serosurvey of SARS-CoV-2 within the blood collection industry? *Transfusion*. 2022;62(7): 1321–33. <https://doi.org/10.1111/trf.16943>

Thijsen A, Gemelli CN, Davison TE, Masser B. Using the Health Action Process Approach to predict blood donation intentions and return behavior following a vasovagal reaction for whole blood and plasma donors. *Transfusion*. 2022. <https://doi.org/10.1111/trf.17052>

Senefeld JW, Johnson PW, Kunze KLRS, et al. Access to and safety of COVID-19 convalescent plasma in the United States Expanded Access Program: A national registry study. *PLoS Med*. 2021 Dec 20;1e1003872003872. PMID: 34928960; PMCID: 8(12):PMC8730442

Discovery/Innovation

- **Identify “Better donors”**
 - metabolomics
 - donor/recipient demographic interactions, e.g. impact of gender mismatch
- **Define benefits of Phenotype → genotype matching**
 - Patients with Sickle Cell Disease
 - Chronically transfused patients
 - Routine transfusion practice

Alshalani A, Uhel F, Cremer OL, Schultz MJ, de Vooght KMK, van Bruggen R, Acker JP, Juffermans NP. Donor-recipient sex is associated with transfusion-related outcomes in critically ill patients. *Blood Adv.* 2022 Jun 14;6(11):3260-3267. doi: 10.1182/bloodadvances.2021006402. PMID: 35286383; PMCID: PMC9198942

Hadley JB, Kelher MR, Coleman JR, Kelly KK, Dumont LJ, Esparza O, Banerjee A, Cohen MJ, Jones K, Silliman CC. Hormones, age, and sex affect platelet responsiveness in vitro. *Transfusion.* 2022 Aug 5. doi: 10.1111/trf.17054. Epub ahead of print. PMID: 35929193.

Josephson CD, Glynn S, Mathew S, et al. National Heart, Lung, and Blood Institute (NHLBI) Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric (REDS-IV-P). The Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric (REDS-IV-P): A research program striving to improve blood donor safety and optimize transfusion outcomes across the lifespan. *Transfusion.* 2022 May;62(5):982-999. doi: 10.1111/trf.16869. Epub 2022 Apr 19. PMID: 35441384; PMCID: PMC9353062

Shih AW, Yan MTS, Elahie AL, Barty RL, et al. Utilising red cell antigen genotyping and serological phenotyping in sickle cell disease patients to risk-stratify patients for alloimmunisation risk. *Transfus Med.* 2020 Aug;30(4):263-274. doi: 10.1111/tme.12685. Epub 2020 May 20. PMID: 32432400.

Discovery/Innovation (cont'd)

- **Improve products/devices/tests**

- Implement universal pathogen reduction technology

- *Next emerging pathogen could be transfusion-transmitted*

- Determine DEHP plasticizer replacement

- Optimize processing/storage/manufacturing procedures

Grebe E, Yu EA, Bravo MD, et al. Vaccine effectiveness against SARS-CoV-2 infection in the United States prior to the Delta and Omicron-associated surges: a retrospective cohort study of repeat blood donors. *J Infect Dis.* 2022 Aug 3;jiac318. doi: 10.1093/infdis/jiac318. Epub ahead of print. PMID: 35921537.

Escolar G, Diaz-Ricart M, McCullough J. Impact of different pathogen reduction technologies on the biochemistry, function, and clinical effectiveness of platelet concentrates: An updated view during a pandemic. *Transfusion.* 2022 Jan;62(1):227-246. doi: 10.1111/trf.16747. Epub 2021 Dec 6. PMID: 34870335; PMCID: PMC9300014

Santa Maria F, Laughhunn A, Lanteri MC, Aubry M, Musso D, Stassinopoulos A. Inactivation of Zika virus in platelet components using amotosalen and ultraviolet A illumination. *Transfusion.* 2017 Aug;57(8):2016-2025. doi: 10.1111/trf.14161. Epub 2017 Jul 3. PMID: 28671343.

Razatos A, Acker JP, de Korte D, Bégué S, Noorman F, Doyle B, Zia M, Min K; Biomedical Excellence for Safer Transfusion Collaborative. Survey of blood centre readiness regarding removal of DEHP from blood bag sets: The BEST Collaborative Study. *Vox Sang.* 2022 Jun;117(6):796-802. doi: 10.1111/vox.13258. Epub 2022 Feb 14. PMID: 35157317

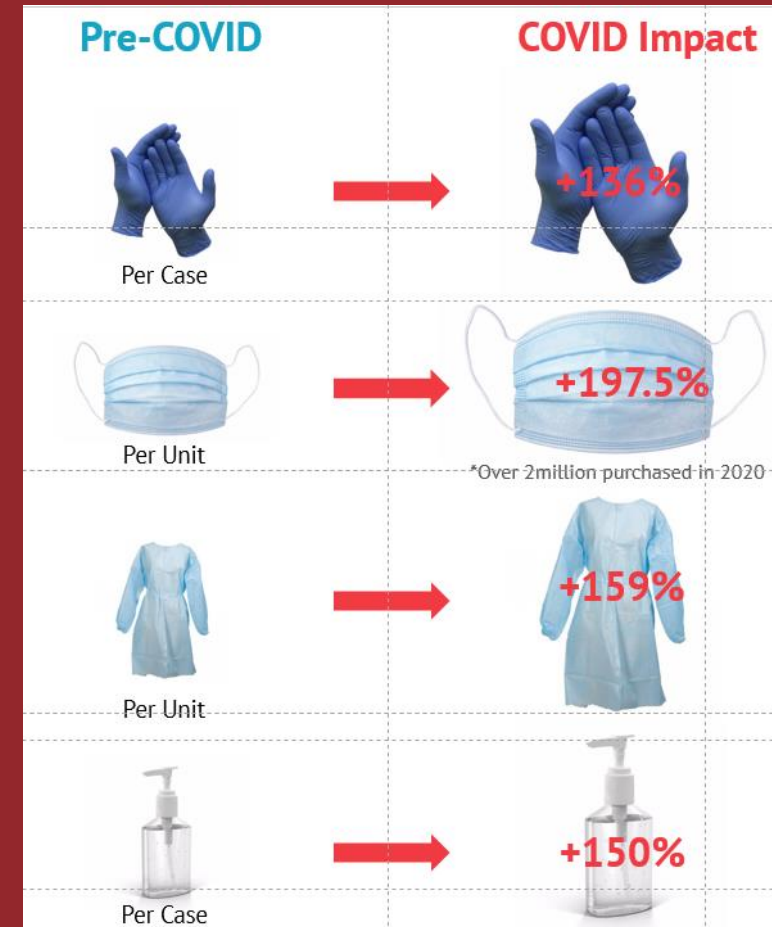
D'supply Chain

- **Obtain visibility into suppliers' contingency plans**
- **Obtain visibility into suppliers' suppliers contingency plans**
- **Consider multi-sourcing, duplicate technologies**
 - Less efficient
 - Additional training
 - More costly
- **Re-evaluate just-in-time inventory**
 - Increase critical supply inventory levels
- **Encourage entrance of new suppliers**
 - Significant supplier consolidation
 - Significant supply chain interruption risk
- **Enhance business continuity plans**



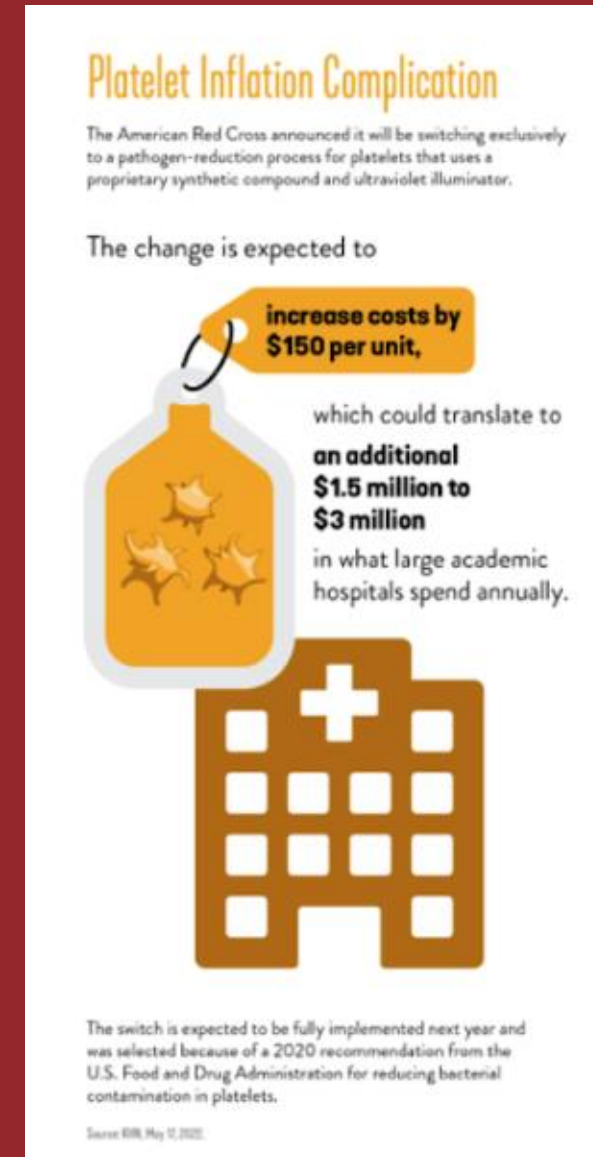
D'supply Chain (cont'd)

- **ESTABLISH STRATEGIC STOCKPILE**
 - Where/what products/how much?
 - Virtual vs physical
 - Rotate products
- **Maximize staff retention**
 - Recruit staff to augment aging work force
 - Vary shifts/hours
 - Increase per diem workers
 - Offer work-from-home/hybrid options
 - Encourage better work-life balance
 - Shift operational focus to “mobiles”
- **Encourage regulatory flexibility**
 - Evaluate benefits of international harmonization



Dollars

- **Implement cost-recovery pricing**
 - Attain stakeholder consensus that blood system is a *Public Good* (and/or Commodity)
- **Allocate \$\$ for donor recruitment/retention, plant modernization, IT infrastructure, and salary adjustments**
- **Assign \$\$ for dual and multi-sourcing technologies**
 - Safeguards the supply chain
- ***Pay for production rather than distribution***
 - Public health emergencies
 - ? new product/process implementation



Conclusion

Resilient: YES!

Sustainable? Still under discussion

Unfailingly supply the right blood
to the right patient
in a timely manner
regardless of location

Responsive!!

\$\$ Dependent

- maintains or improves on current safety levels for blood and blood products
- provides blood for the full range of clinical applications consistent with standard
- delivers blood in a timely fashion such that patient health and preparedness are not unduly compromised

Mulcahy et al., Toward a Sustainable Blood Supply in the United States



Learn more about
WellSky Blood and Biotherapies



Request a consultation today!



CareForum 2022

The WellSky® Conference

Thank you.

Contact:

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