Compensation-Based Platelet Collection Program

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History of Compensated Donation

- Compensating donors was standard practice decades ago
- In 1978 the FDA required labeling units as "paid" vs volunteer
- Labeling change led to almost disappearance of compensated donors
- Increased safety of blood supply
  - NAT (2002) and Pathogen Reduction (2016)
- Few small programs persisted with compensated donors until early 2000
  - Iowa and Mayo Clinic

The Mayo Experience: 1981-2002

- Paid $50 in cash per platelet donation
- Required 7 non-compensated whole blood donations prior to being eligible for a compensated platelet donation

Mayo Clinic used compensated donors for two decades in Rochester MN without any safety or quality adverse effects

Taswell H, Part III. Directed, paid and self donors. In: Clark GM, editor. Competition in blood services. Arlington, TX: American Association of Blood Banks, 1987; p. 137–148.

Mayo Data: Blood Donor Pool HBsAg Incidence was Lower with Carefully Selected Compensated Donors

	Reimbursed Donors	Volunteer Donors	P Value
Number of Units:			
1970-1985	282,227		
1980-1985		32,828	
HBsAg Positive	0.007%	0.027%	0.0002

	Reimbursed Donors	Volunteer Donors	P Value
Number of Units 1980-1985	94,516	32,828	
HBsAg Positive	0.004%	0.027%	0.0004

Taswell H, Part III. Directed, paid and self donors. In: Clark GM, editor. Competition in blood services. Arlington, TX: American Association of Blood Banks, 1987; p. 137–148.

Secure Transfusion Solutions

- Founded in 2018
- Mission to improve outcomes by increasing the quality and availability of hard to source components
- Operating in 3 cities
  - Edina, MN
  - Raleigh, NC
  - Beaverton, OR
- 9 contracted hospital systems (large quaternary care centers)
- 3 research customers

Platelet usage increases while shortages translate into real clinical impact

- Recent NBCUS Survey revealed an **8.0% increase** in apheresis platelet units transfused in the U.S. between 2017 to 2019 and a **15.8% increase** in total platelet units transfused between 2017 to 2019

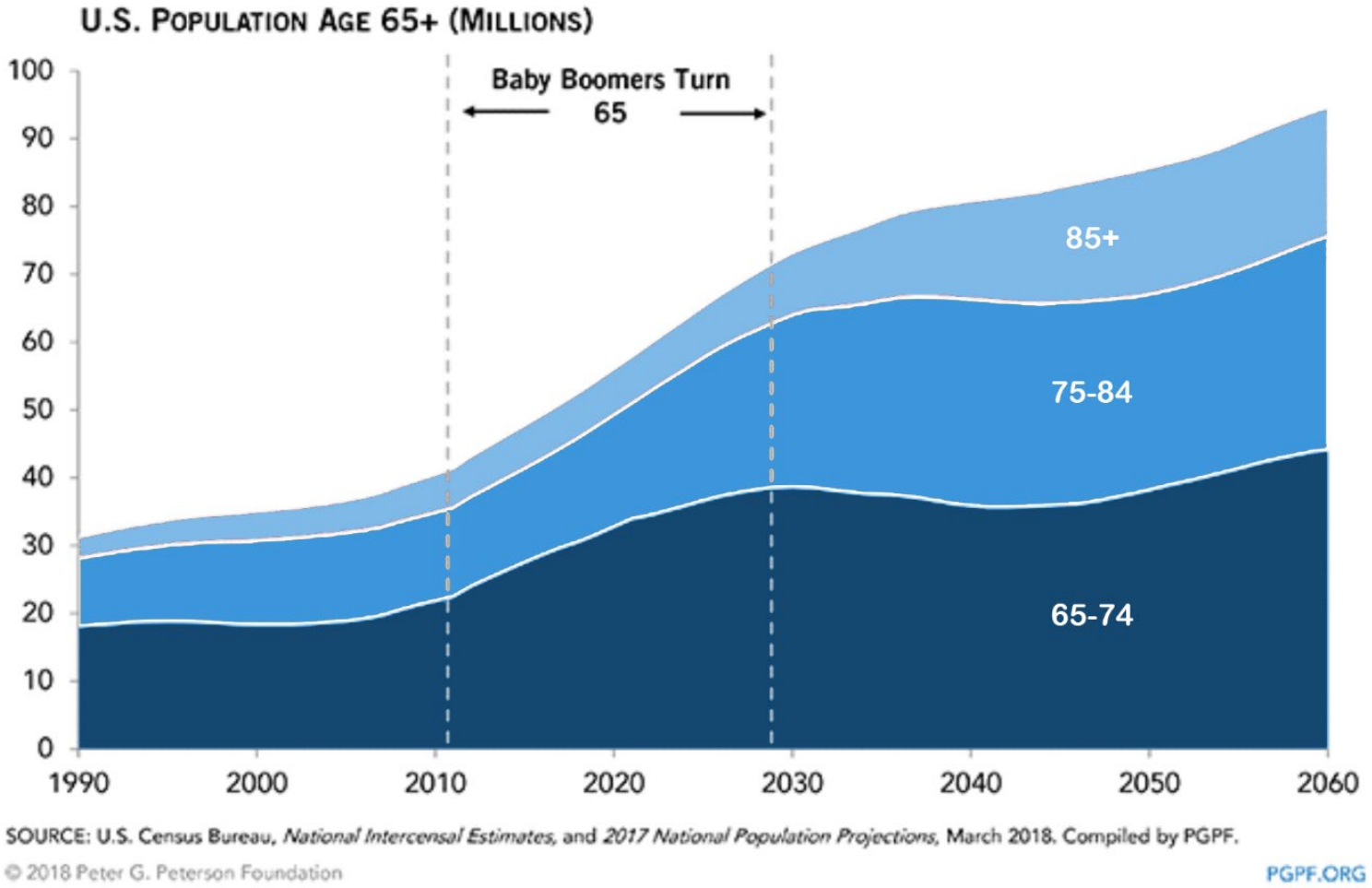
- A recent survey of 481 U.S. hospitals found that **22.3%** of hospital **experience platelet supply challenges** at least once per month and **47.2%** of high transfusion volume hospitals **report supply challenges** once or more per month

- **18.7%** of U.S. hospitals report experiencing **delayed surgeries** and **31.8%** report **delayed outpatient transfusions** due to platelet supply challenges over the past 12 months

Jones, JM, et al. 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 Suppl 2:S1-S10.
Pandey S, et al. A survey of US hospitals on platelet inventory management, transfusion practice, and platelet availability. Transfusion. 2021; 61:2611-2620.

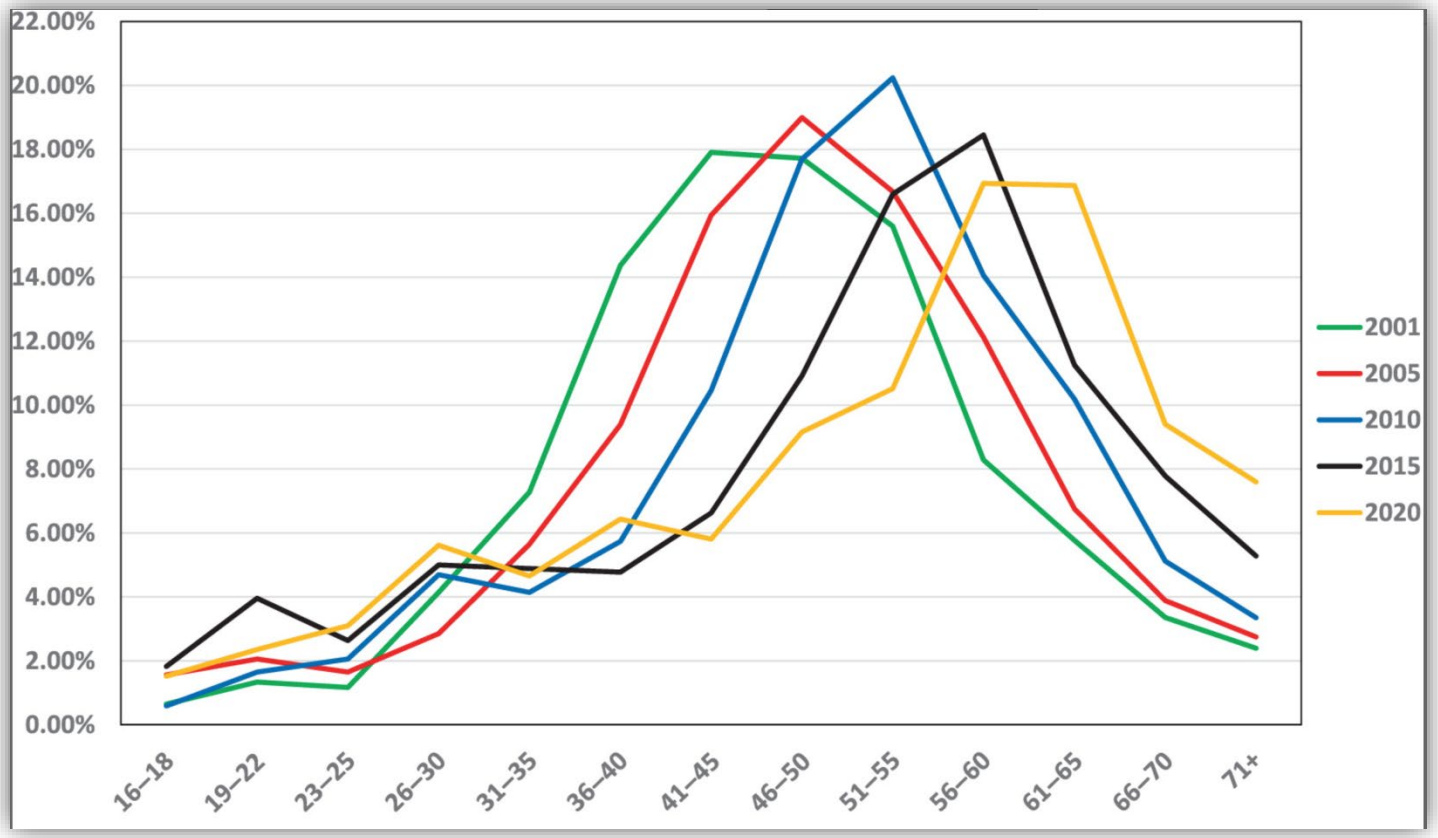
Demand for platelets grows as the population ages

- Since cancer generally, and hematologic malignancies specifically, disproportionately affect older individuals, unsurprisingly 81% of US patients receiving platelets are aged >50 years, and 33% are aged ≥70 years. (Gottschall, Wu et al. 2020)
- Next 10 years-20M more > 65 yr old



Platelet Donors Aging Rapidly

Ages in Apheresis Platelet Donor Base (Males)



Sayers M. Donor Motivation and Psychosocial Research. Transfusion. 2022

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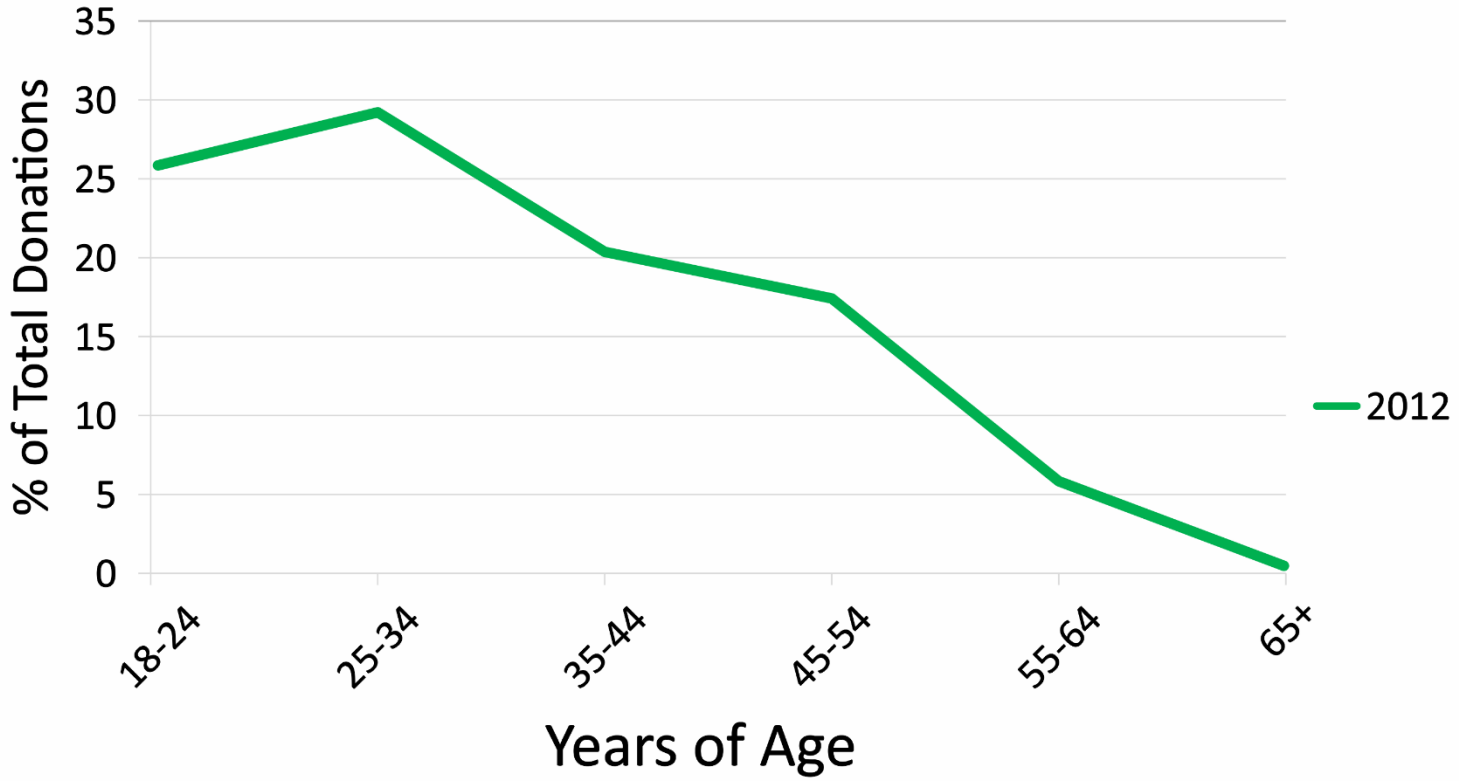
Compensated Donors can be Harnessed to Solve the Problem of Platelet Availability

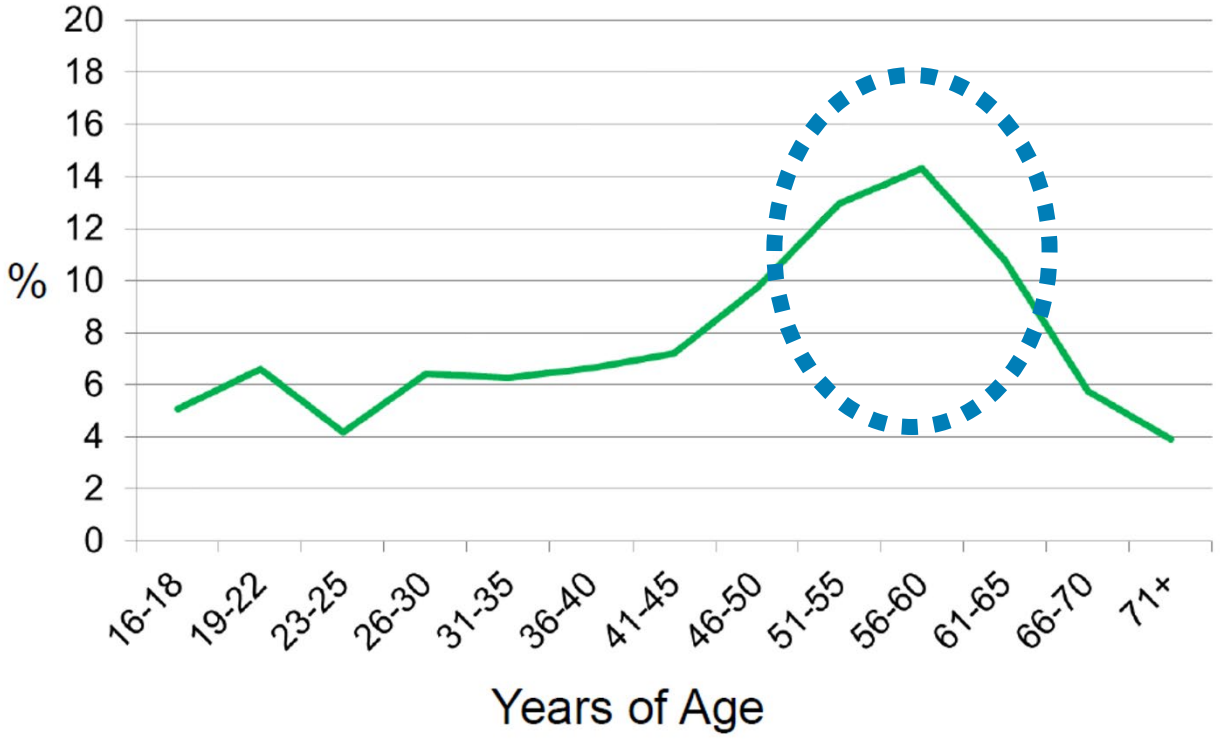
Donor Age Distribution – Source Plasma



Source: Transfusion 2017 Vol. 57 Supplement 53 (p 110A)

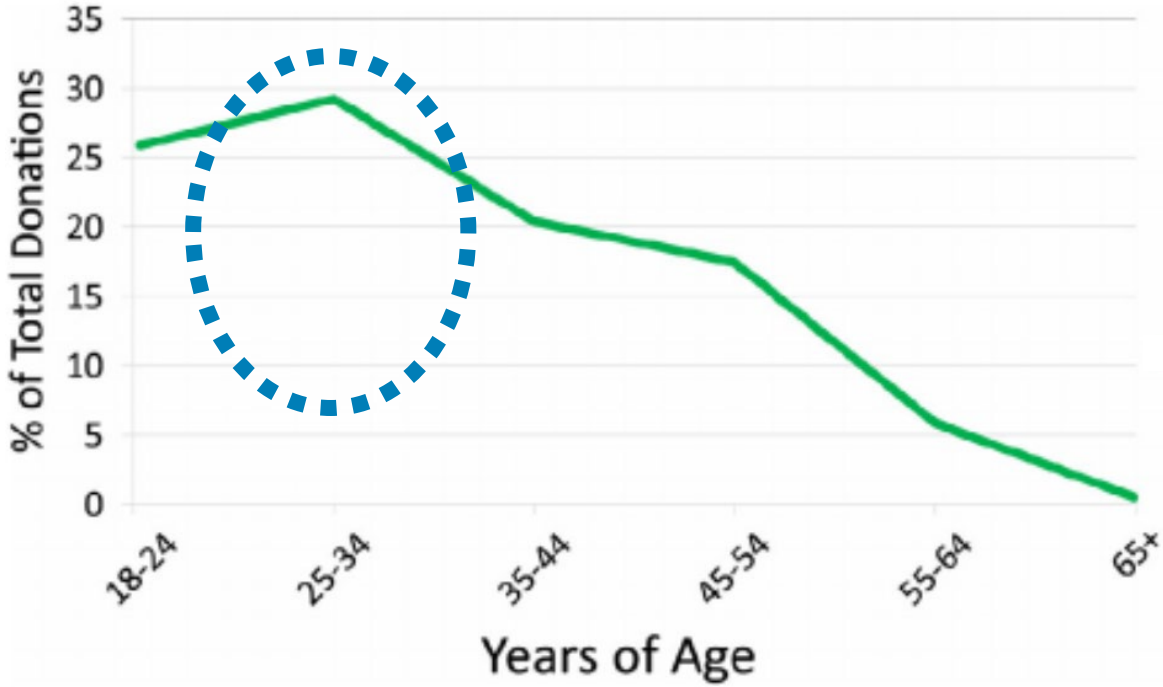
A Generational Age Gap That Can Be Solved For

Volunteer Platelet Donors, 2017



Source: Transfusion 2018 Vol. 58 Supplement S2 (p 251A)

Paid Plasma Donors, 2012



Source: Transfusion 2017 Vol. 57 Supplement 53 (p 110A)

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Secure Transfusion Solutions (STS)

- Model
  - Compensated donors with pathogen reduction and additional safety measures
  - Augment supply by diversifying donor pool
    - Female donors
    - Younger donors
  - Collaborate with not-for-profit suppliers to augment supply
  - Pedigreed donor pool with high split rate to improve efficiency/reduce cost

STS Process Surpasses FDA Regulations and AABB Standards

- Careful selection of donor center location
  - Driven by epidemiological data, avoiding high-risk regions
- Selective donor screening – initial donor meeting
  - Establish candidacy using key predictors of Split Rate
  - **Initial infectious disease screening with no collection as initial visit**
  - Screened twice with a 21-day period before initial collection*
- 100% use of pathogen inactivation
  - Use of Trima (plasma) and Amicus (PAS) collection platforms

*Time lag subject to change pending new technological developments that could shorten relevant NAT screening window periods

Window Periods with NAT Testing

The window period is time between potential exposure to infection and the point when the test will give an accurate result.

Table 1. Estimates of window period length for different testing methods*

Pathogen	Standard serology	Enhanced serology (fourth generation or combined antibody-antigen tests)	Nucleic acid testing
HIV	17–22 days (5–8)	~7–16 days (9,10)	5–6 days (5,6)
HCV	~70 days (5,8,11)	~40–50 days (12–14)	3–5 days (5,11)
HBV	35–44 days (15,16)	Not applicable	20–22 days (8,15)

Humar A, et al. American Journal of Transplantation 2010; 10: 889-899.

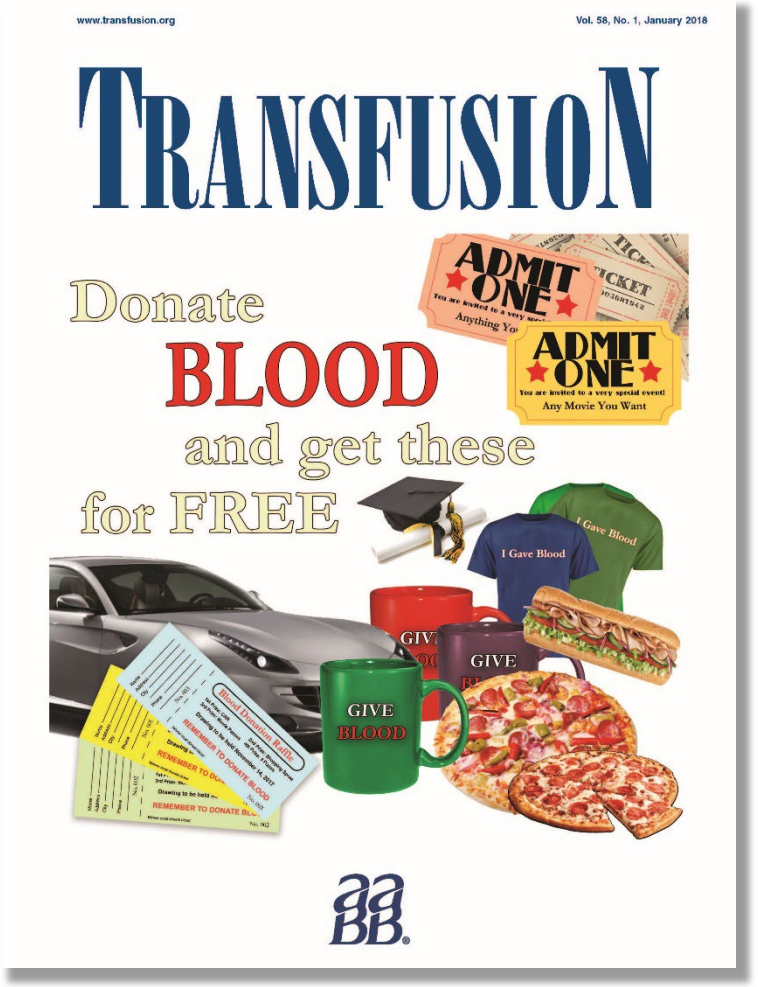
Compensated Donors Already Exist

Not-for-profit suppliers provide

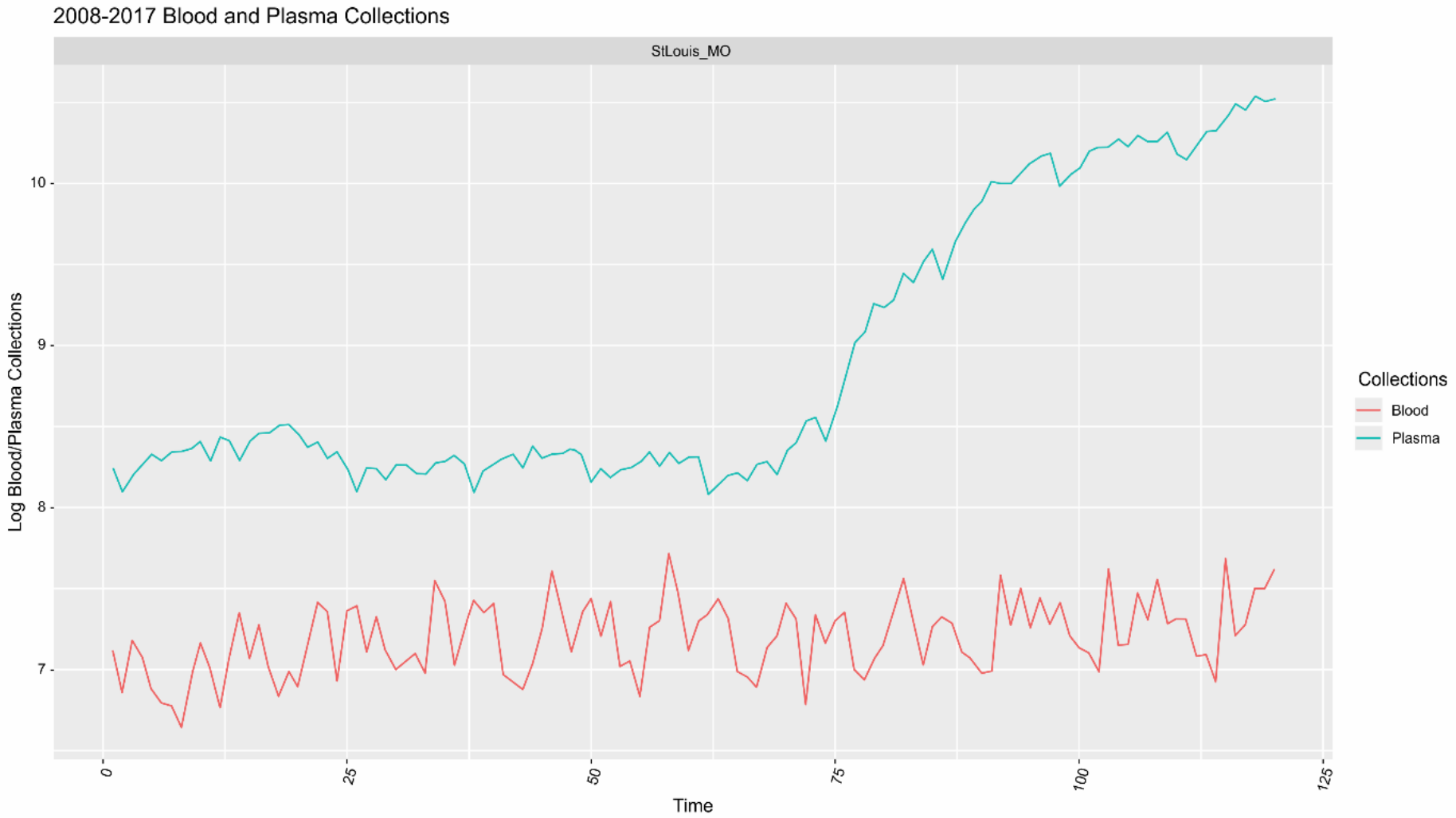
- Gift cards of monetary value $20-45 dollars
- T-shirts
- Movie tickets
- Tickets to sporting events

Some of these suppliers do not use PRT for the platelets collected with these incentives that

- Have monetary value
- Can be transferred to other people



Paid Plasma Does Not "Crowd Out" Volunteer Donations



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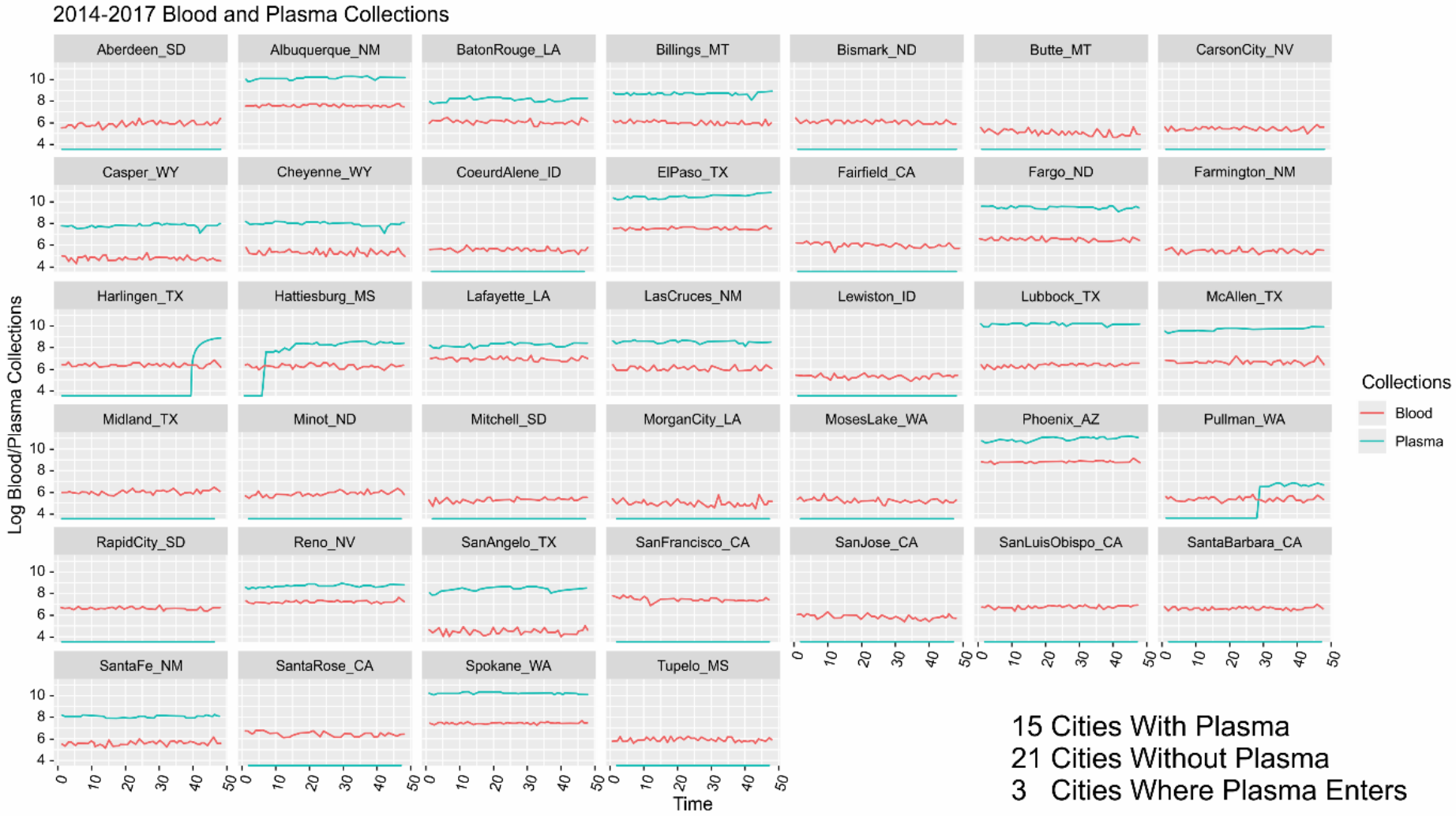
Paid Plasma Does Not "Crowd Out" Volunteer Donations



15 Cities With Plasma
21 Cities Without Plasma
3 Cities Where Plasma Enters

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STS Collection Facilities – Trusting Heart Blood Centers Inspire Confidence and Donor Retention

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trusting heart
blood center

Cost Savings

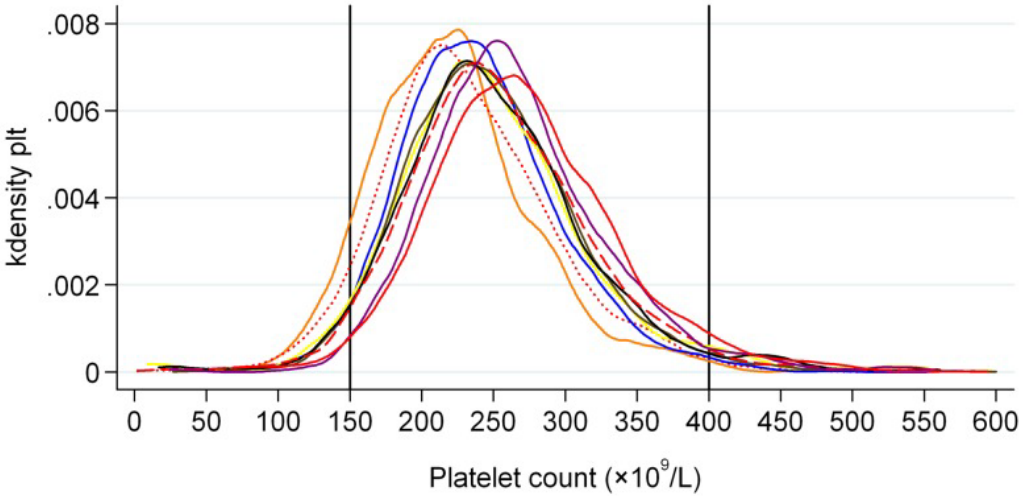
- STS offers competitive prices by leveraging pedigreed donor pool with high split rate

Split rates are the key to unlocking operating leverage in platelet collection

- Up to three units, or therapeutic doses, may be recovered from one collection

- Key determinants of number units yielded from a single collection
  - Donor height/weight
  - Platelet count
  - Currently investigating other factors

- Pre-FDA guidance the average split rate for non-profit blood centers ~1.8-2.1; post-guidance this will likely decrease due to PR guardbands



Source: PLOS ONE, January 2013, Volume 8, Issue 1, e54289

Sachias BS, et al. Blood Adv. 2017; 1:1142-1147.

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STS optimizes split rate using donor compensation

- STS' unique donor compensation model allows for the opportunity to selec
  - Select
    count
  - Incent
  - Untap
  - Young
- Collecti
  and don
  - PR-SDP split rate continues to improve
  - Average donor age is 41 years-old and F>M

Operational efficiencies with compensated donor model

⬇

Lowers per platelet unit production costs

⬇

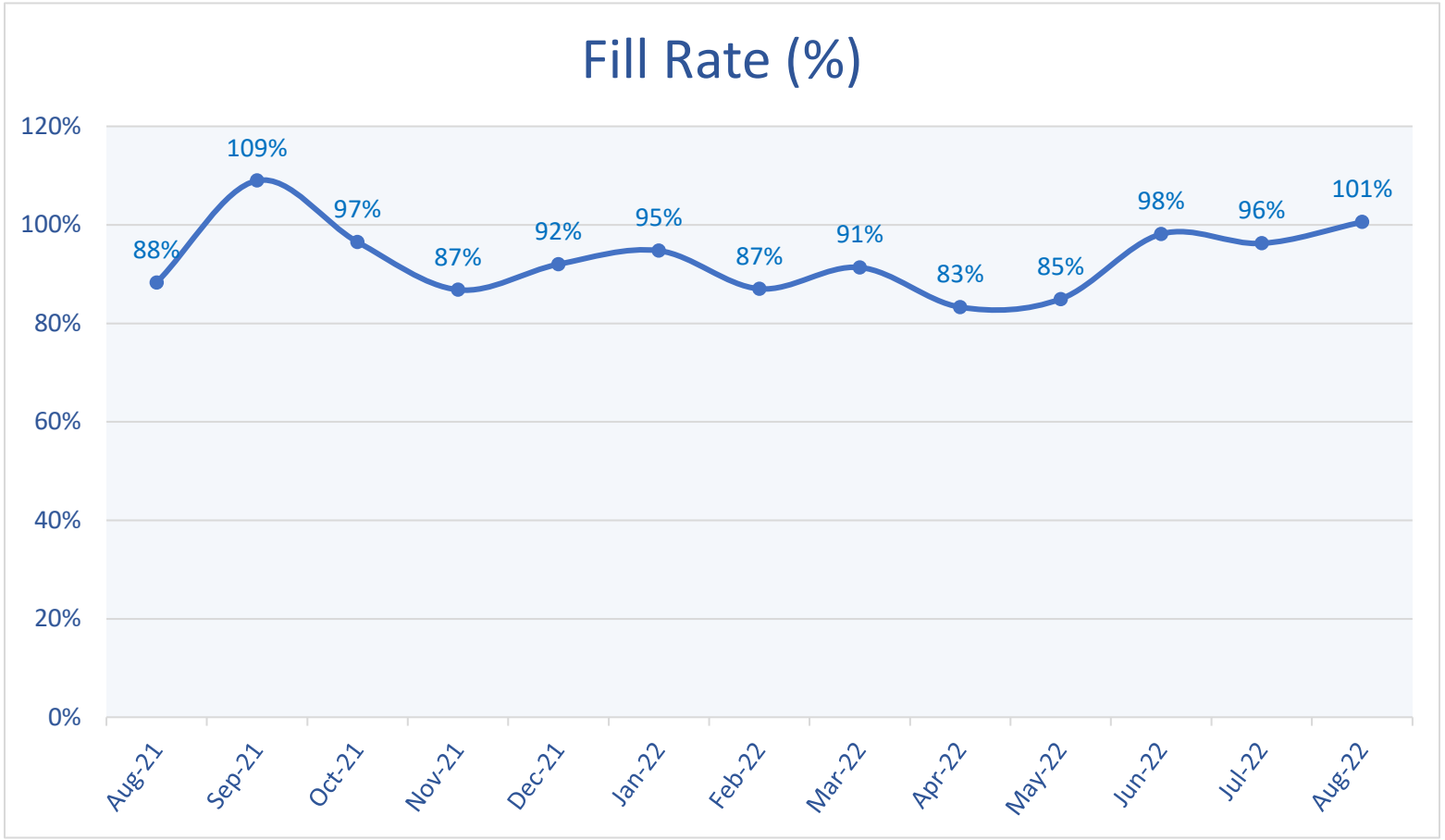
Savings passed on to customers

Performance Metrics to Date

Early Data from Trusting Heart Blood Center – Edina, MN

STS Customer Fill Rate (Aug 2021 – August 2022)

Average fill rate: **93%**



STS Split Rate Trends

Surge Capacity for Holiday Shortages

Compensated donor model allows STS to increase supply when non-profits struggle during the holidays

Labor Day weekend 2021 experience

- Increased collections to >150% of baseline collections

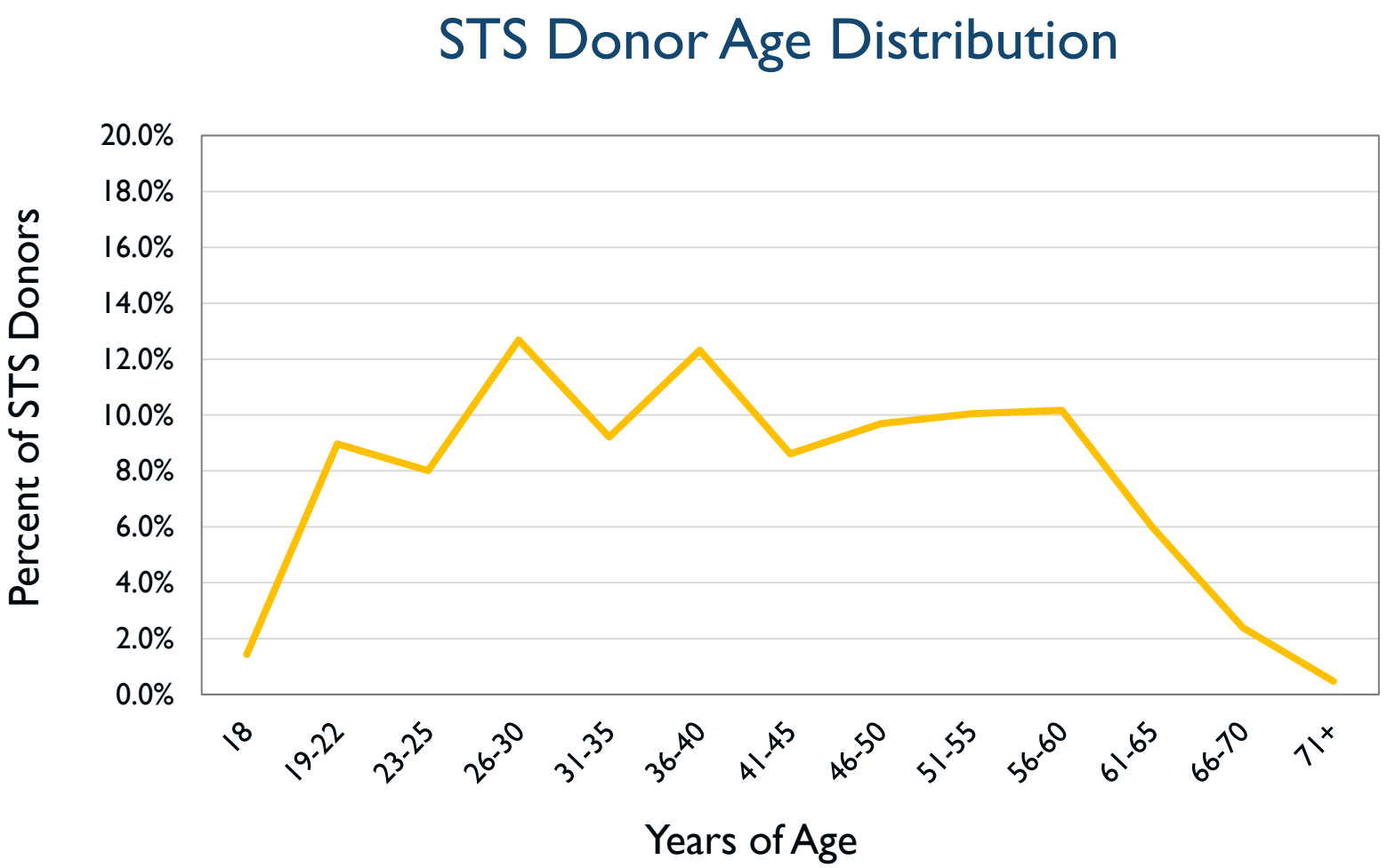
Thanksgiving week 2021 experience

- Increased collection ~200% of baseline collections

Christmas 2021/New Year 2022 experience

- Increased collection ~150% of baseline collections

STS Donor Age & Gender Trends



mean donor age:

41

male / female mix:

47% / 53%

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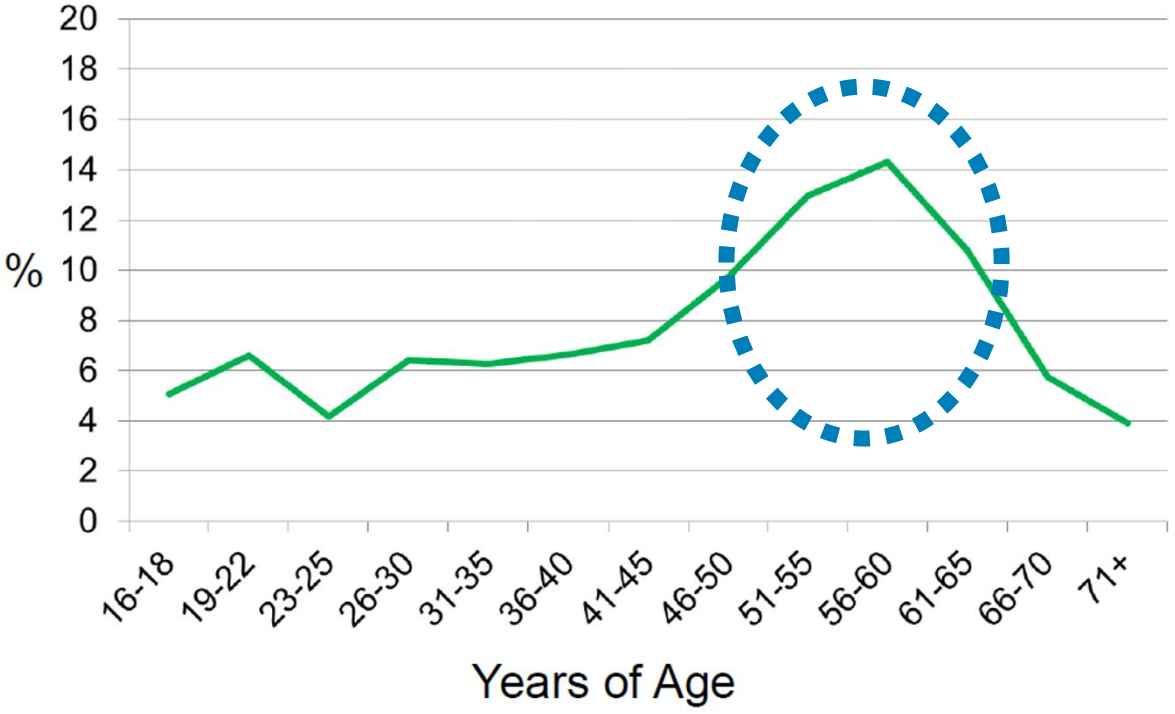
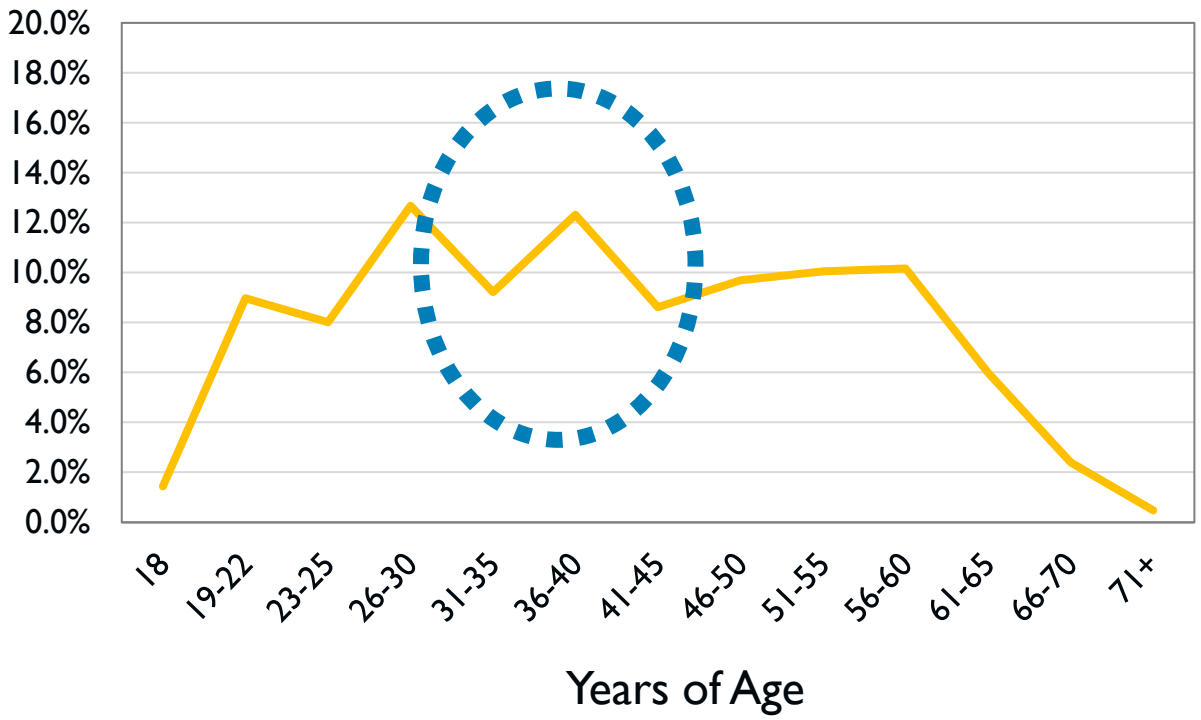
STS Donor Age versus Volunteer Blood Industry

Volunteer Platelet Donors, 2017



STS Donors, 2022



Source: Transfusion 2018 Vol. 58 Supplement S2 (p 251A)

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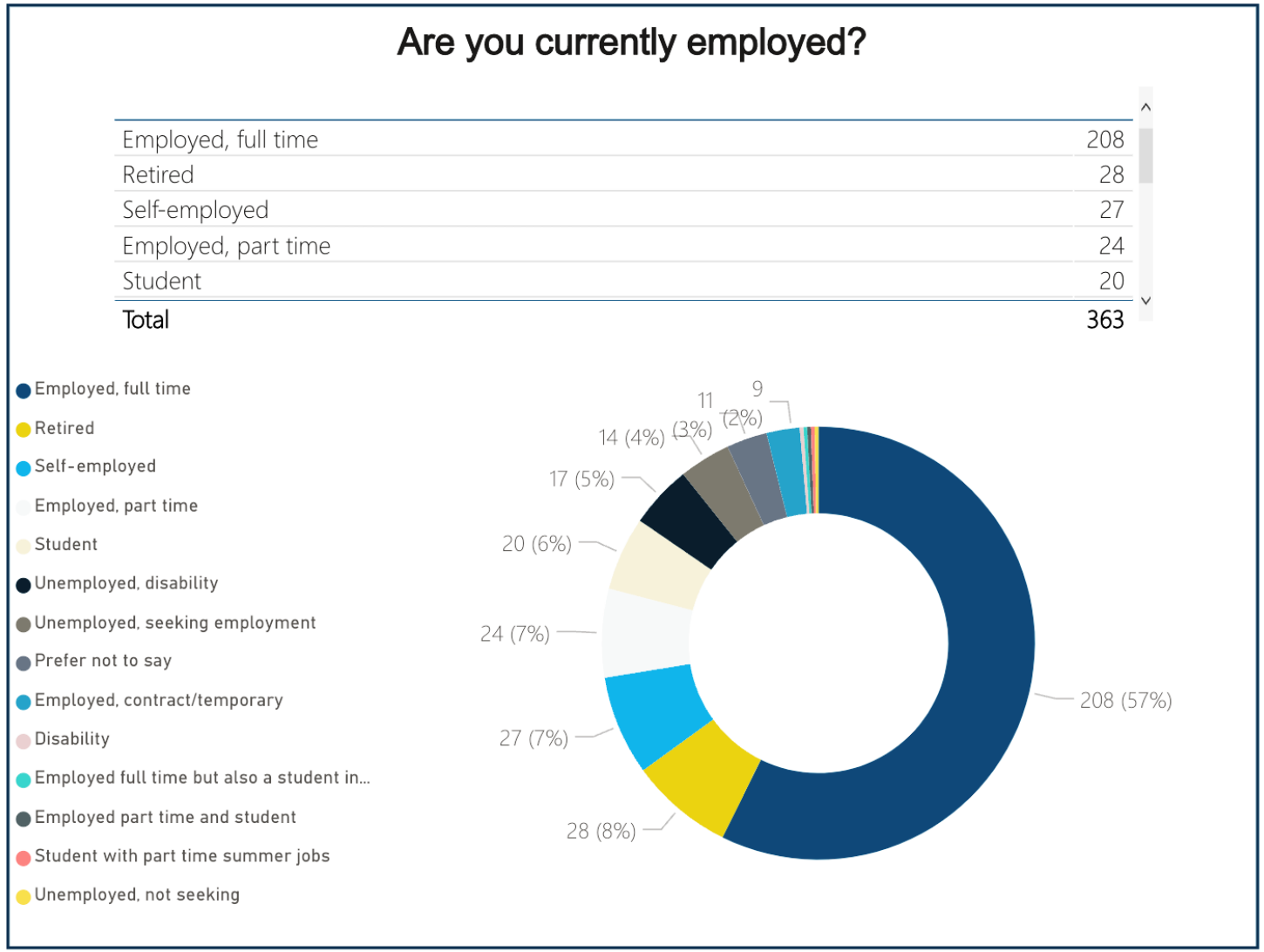
More than 95% Employed/Students/Disability



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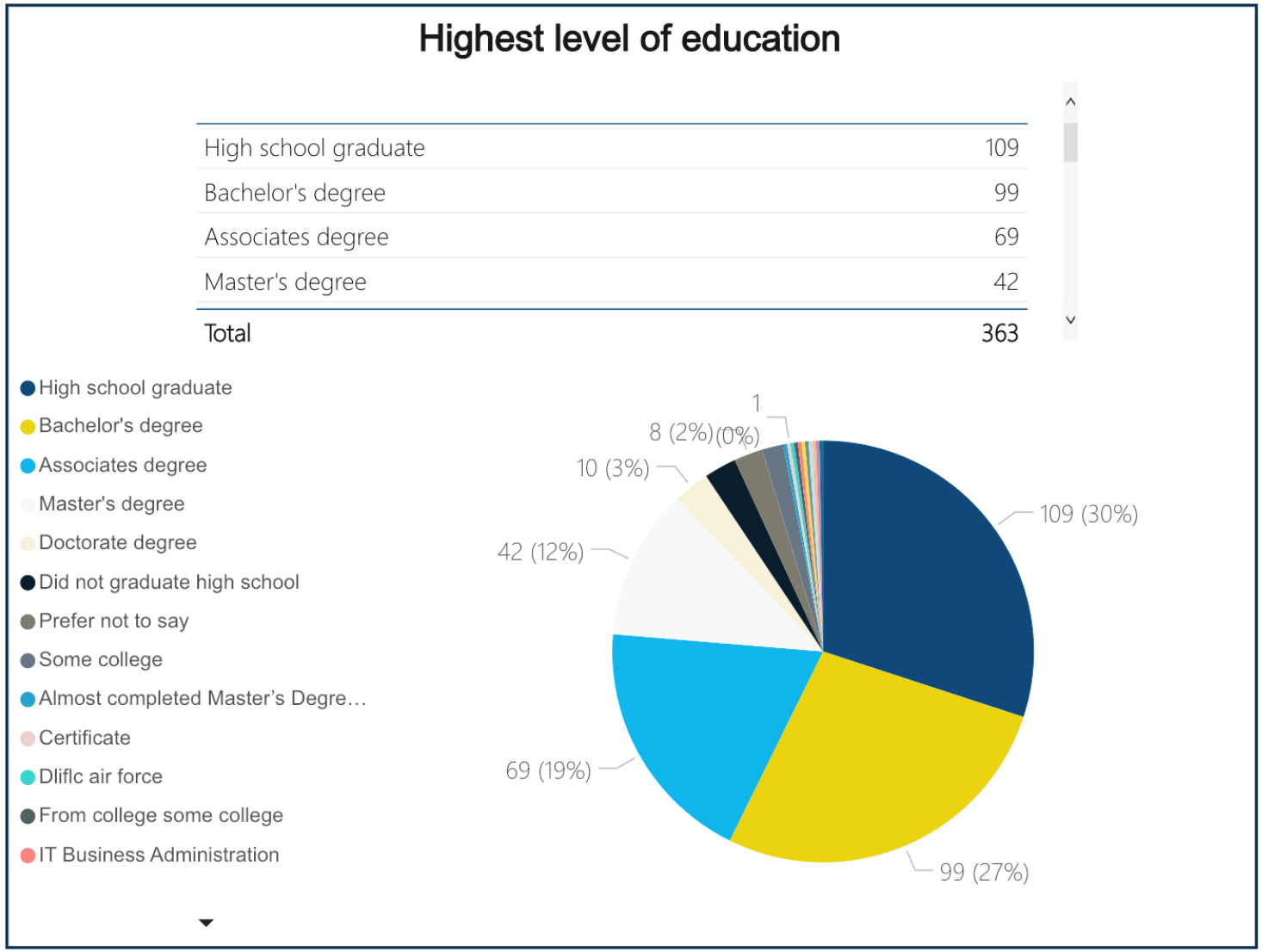
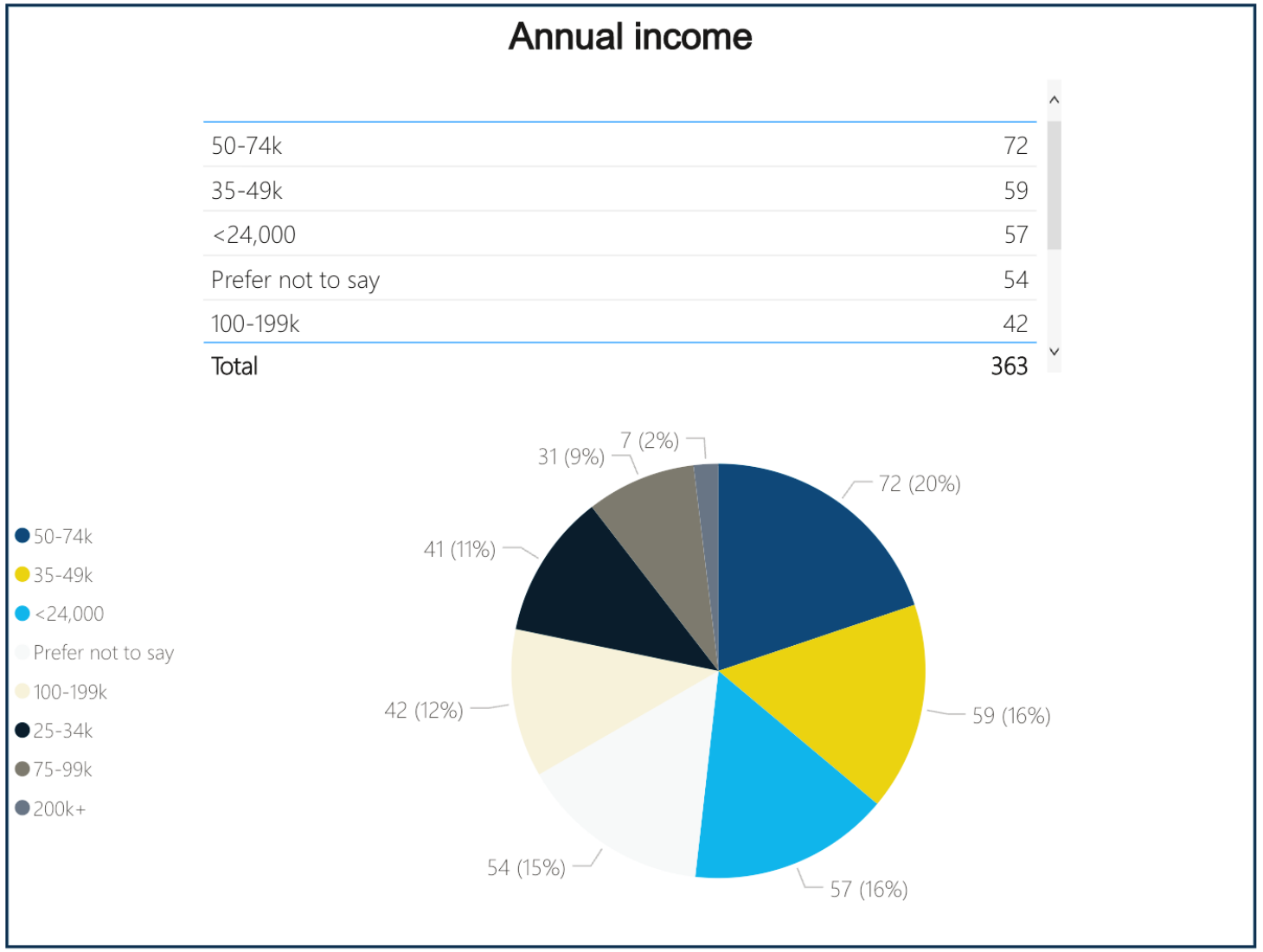
More than 60% Have College Degree



Income Evenly Distributed Among Donors



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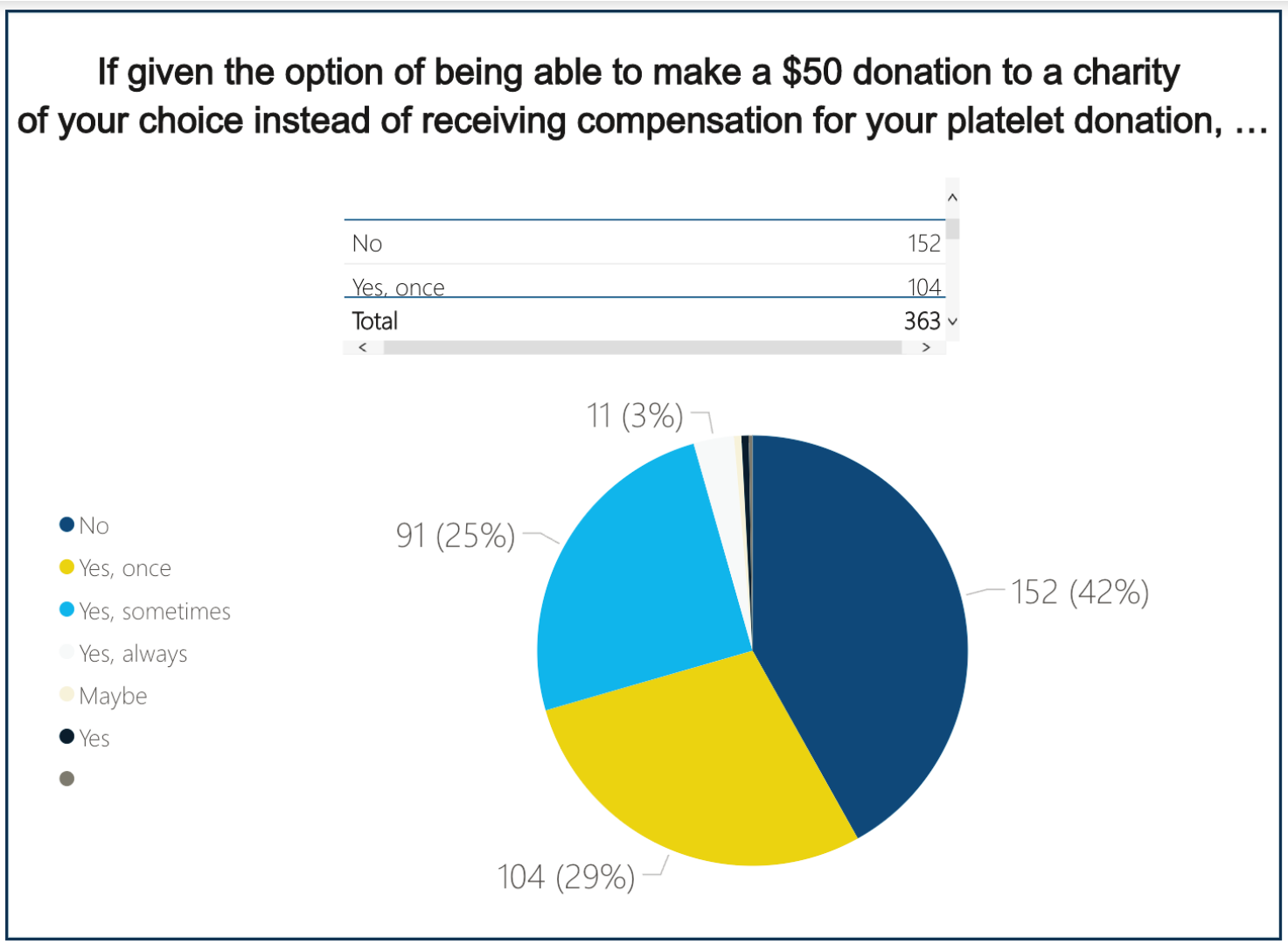
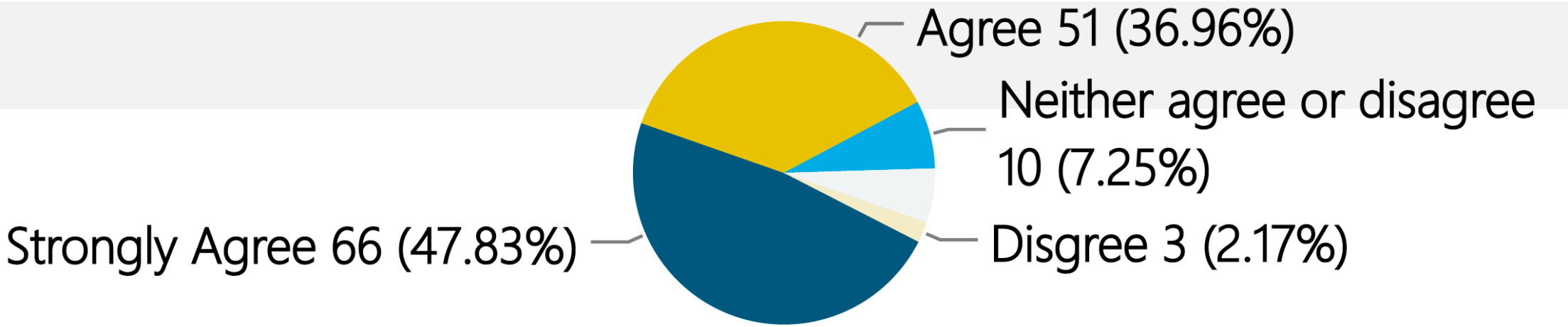
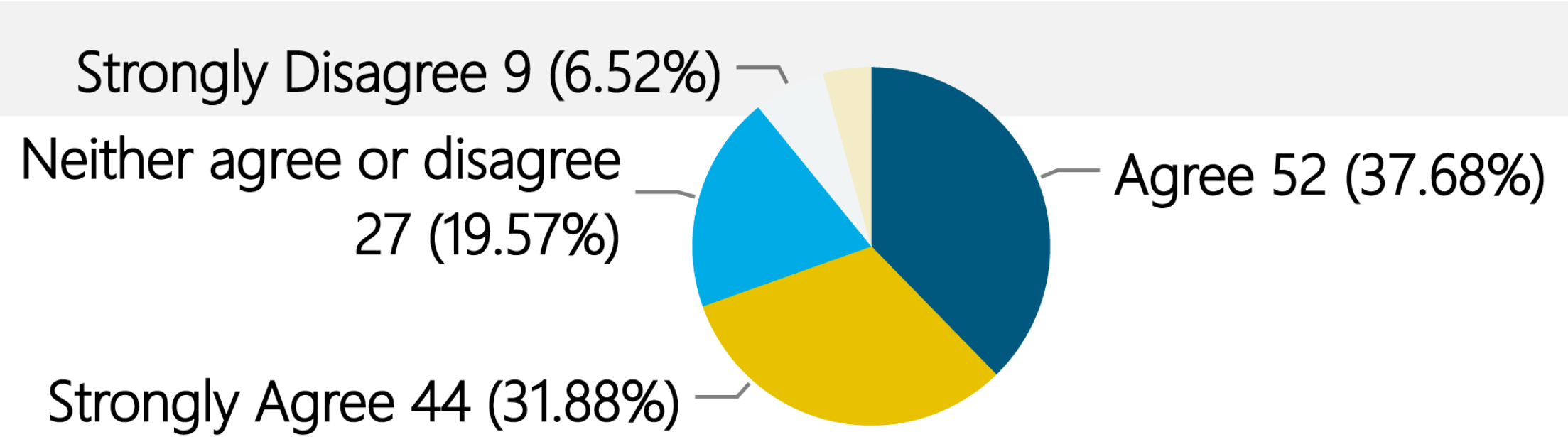
57% Would Donate Compensation to Charity



Is Your Motivation to Donate from Altruism/Goodwill/Kindness? (N=364)



Is your Motivation to Donate the Monetary Incentive? (N=364)

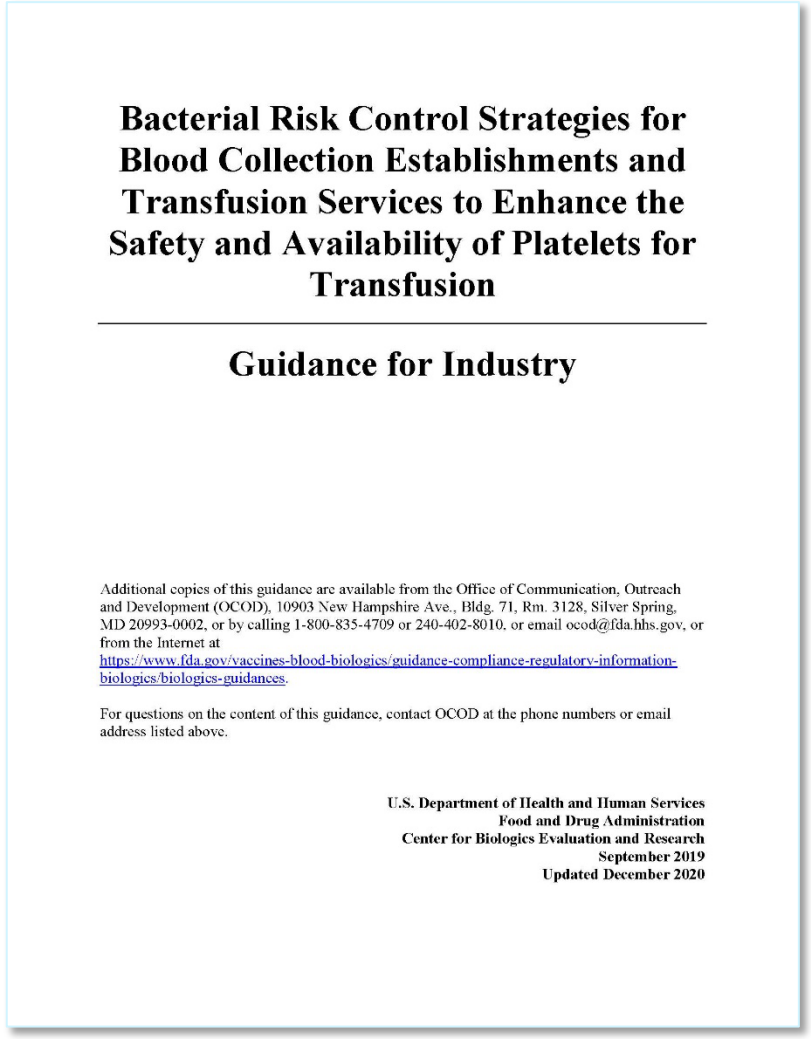


Summary

- Platelet demand will increase, and we need alternative safe models to increase supply
- Compensation with PRT is viable method to safely increase supply
- Model is successful and growing
- Donors are younger, well educated, employed, and motivated by both altruism and compensation
- Altruism and monetary incentives can coexist (not mutually exclusive)

Questions?

New final FDA regulations mandate more stringent testing which further stress the supply chain



Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion

Guidance for Industry

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
September 2019
Updated December 2020

Pathways for hospitals to become compliant

- One step solution
  - Pathogen reduction (highest standard of safety; off-the - shelf solution; simplest and most straight forward path for high volume centers)
  - Large volume culture testing (not highest safety standard)
- Two step solution
  - Sampling plus point of issuance testing (complex and requires hospital to hire/train incremental staff)

Regulations effective October 1, 2021:
Hospitals must now comply with one of the FDA's proposed strategies to mitigate bacterial risk with platelet transfusion

SECURE TRANSFUSION SOLUTIONS

Received: 6 March 2020 | Revised: 10 April 2020 | Accepted: 10 April 2020
DOI: 10.1111/trf.15851

BRIEF REPORT

TRANSFUSION WILEY

A national survey of hospital-based transfusion services on their approaches to platelet bacterial risk mitigation in response to the FDA final guidance for industry

Wen Lu[1] | Meghan Delaney[2] | Nancy M. Dunbar[3] | Susan N. Rossmann[4] | Mark Fung[5]

TABLE 1 Survey participants' preferred risk mitigation strategy provided by FDA final guidance

Bacterial risk mitigation strategy	Transfusion services that prefer this strategy (n = 77)
Pathogen reduction for up to 5-day storage	n = 36, 47%
Large volume delayed sampling (LVDS) ≥48 hours for up to 7-day storage	n = 16, 21%

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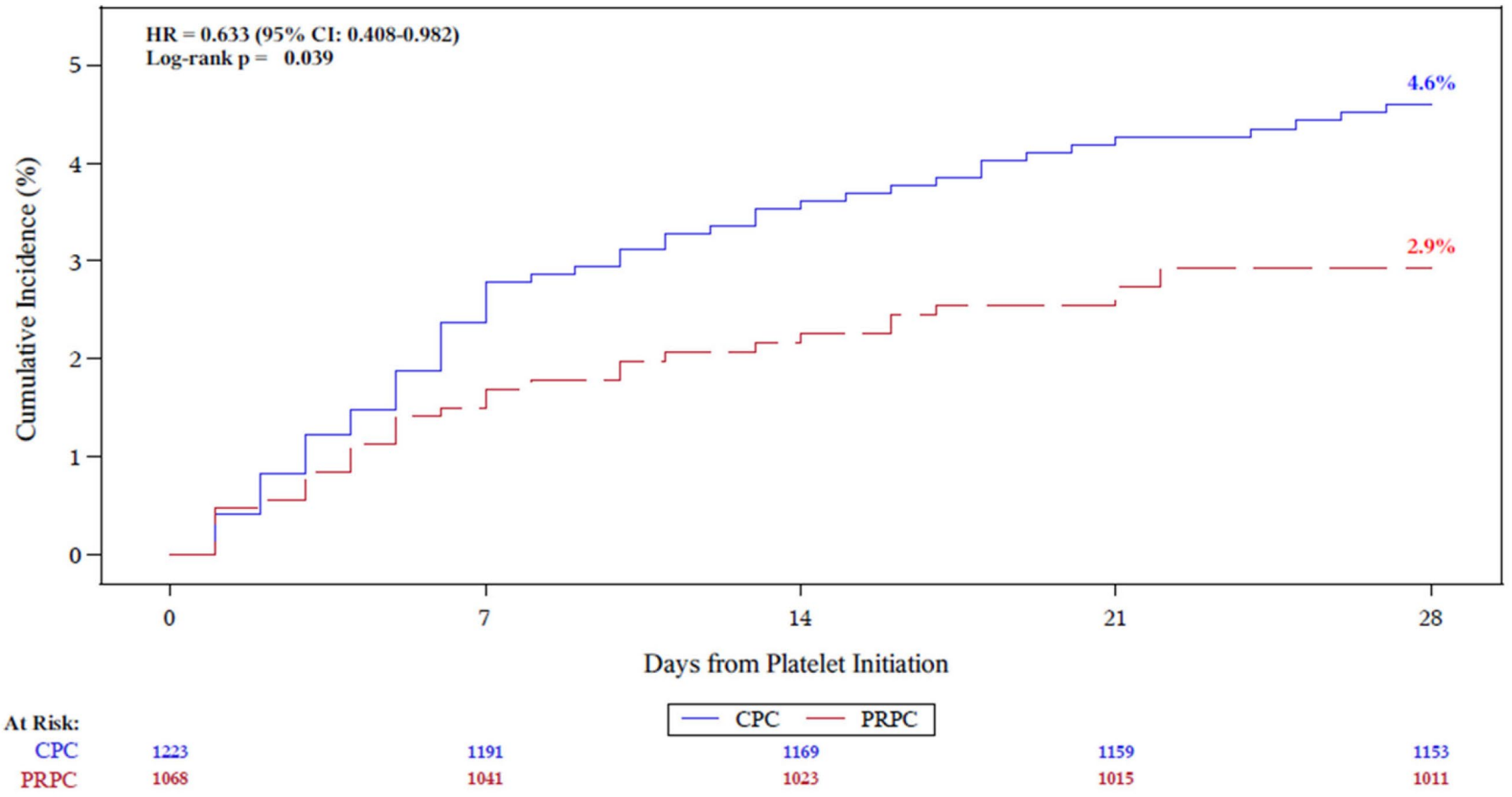
Lower Incidence of Treatment Emergent Assisted Mechanical Ventilation



PIPER Study

- Phase 4 post-market
- Open label sequential cohort design
- 2291 Heme/Onc patients
  - 5277 PRPC
  - 5491 CPC

Snyder EL, et al. Transfusion. 2022; 1-12. DOI: 10.1111/trf.16987

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No Difference in Acute Transfusion Reactions in Pediatric Patients

- International retrospective observational study involving 3839 pediatric patients ages 0-18 years old.
- Received >7930 platelet transfusions

	Control Period (N=22)	Study Period (N=19)	P-value
Overall transfusion reaction rate (Patients with reactions/Total patients in period)	22/2,134 (1.0%)	19/1,705 (1.1%)	0.803
Platelet transfusions received Median (IQR, Q1-3)	16.0 (7.0-37.0) N=22	14.0 (4.0-40.9) N=19	0.685

Delaney M, et al. AABB 2021 Virtual Annual Meeting. PL-3 AM 21-33. 18 Oct 2021.

Equivalence of PRT and Conventional Platelets

- There is no difference in clinically significant bleeding, (WHO Grade >2)
  - 5 trials, 1392 participants; RR 1.10, 95% CI 0.97 to 1.25
- There is no difference in severe bleeding, (WHO Grade >3)
  - 6 trials, 1495 participants; RR 1.24, 95% CI 0.76 to 2.02
- There is no difference in all-cause mortality at 4 to 12 weeks
  - 6 trials, 1509 participants; RR 0.81, 95% CI 0.50 to 1.29
- There is no difference in serious adverse events
  - 7 trials, 1340 participants; RR 1.09, 95% CI 0.88 to 1.35

Estcourt LJ, et al. Cochrane Database Syst Rev. 2017; 2017:CD009072.

No Difference in Mortality for Massive Transfusions with PRT Platelets

Table 3 In-hospital mortality and median time to hospital discharge (days) before (pre-IBS) and after (post-IBS) implementation of amotosalen/UVA treatment of platelet concentrates

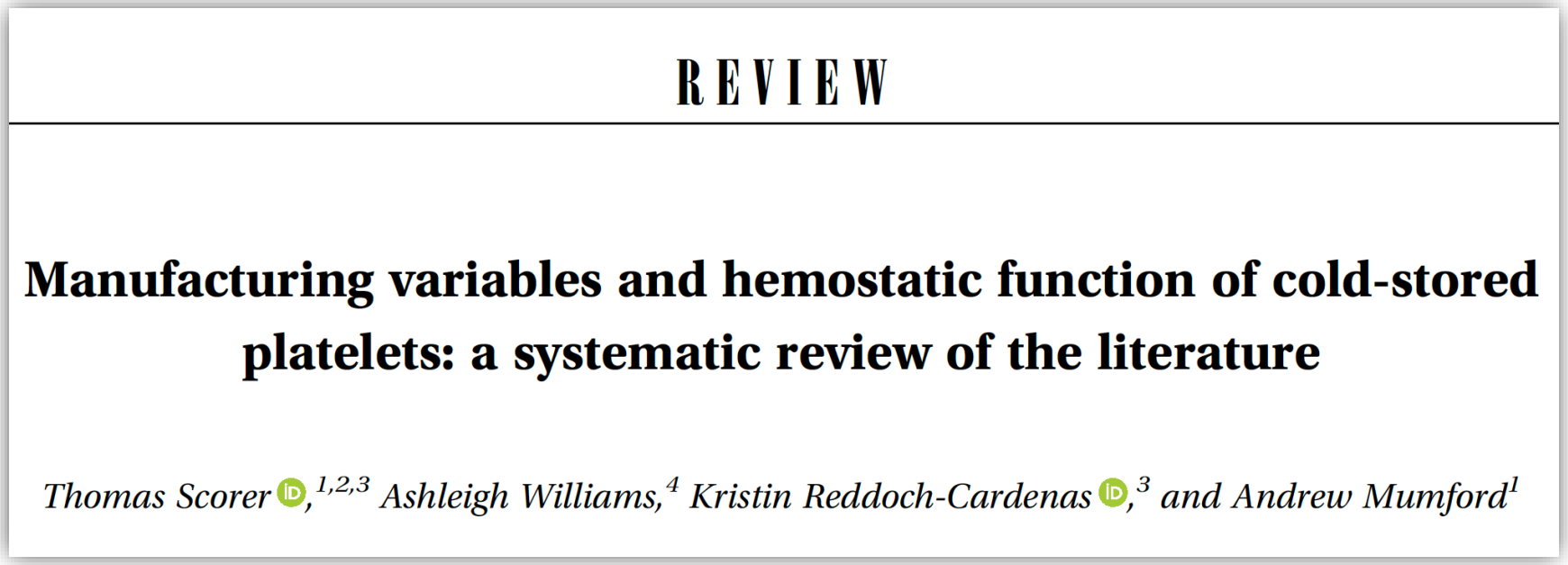
		Pre-IBS	Post IBS	*P* Value
All patients (*N* = 156/150)	In-hospital mortality (%)	43 (27·6%)	36 (24·0%)	0·51
	Median (IQR) time to discharge (days)	27 (9·0–35·0)	23 (13·0–33·0)	0·37
Liver transplant (*N* = 45/48)	In-hospital mortality (%)	1 (2·2%)	3 (6·3%)	0·62
	Median (IQR) time to discharge (days)	22·5 (17·0–34·0)	21 (16·5–28·5)	0·55
Cardiac & vascular surgery (*N* = 53/44)	In-hospital mortality (%)	20 (37·7%)	13 (29·5%)	0·52
	Median (IQR) time to discharge (days)	33 (7·0–35·0)	21 (4·5–27·5)	0·03
Trauma (*N* = 27/24)	In-hospital mortality (%)	12 (44·4%)	8 (33·3%)	0·57
	Median (IQR) time to discharge (days)	32 (1·0–34·0)	29 (11·5–33·0)	0·48
Other medical & surgical (*N* = 31/34)	In-hospital mortality (%)	10 (32·3%)	12 (35·3%)	1·00
	Median (IQR) time to discharge (days)	27 (6·0–37·0)	34 (6·0–53·0)	0·17

Nussbaumer W, *et al*. Vox Sanguinis. 2017; 112:249-256.

Cold stored platelets

Variance - Cold Stored Platelets

- STS will apply for a variance to produce cold stored platelets
  - Intercept treated, stored at 1-6 degrees C.
  - Storage duration 14 days
  - Active bleeding for any indication when conventional platelets are unavailable or their use is not practical
  - Potentially available by March 2023
- Variance obtained by
  - US Army and US Air Force
  - South TX and Carter
  - Mayo Clinic



REVIEW

Manufacturing variables and hemostatic function of cold-stored platelets: a systematic review of the literature

Thomas Scorer[1,2,3] *Ashleigh Williams,*[4] *Kristin Reddoch-Cardenas*[3] *and Andrew Mumford*[1]

- Improved hemostatic function and platelet energetics (In vitro and animal studies)
  - Up to 14 days of storage at 1-6 degrees C
  - Aggregation
  - Thrombin generation
  - Viscoelastic assays
  - Mitochondrial function
  - Platelet inhibition strong
    - Not irreversibly activated

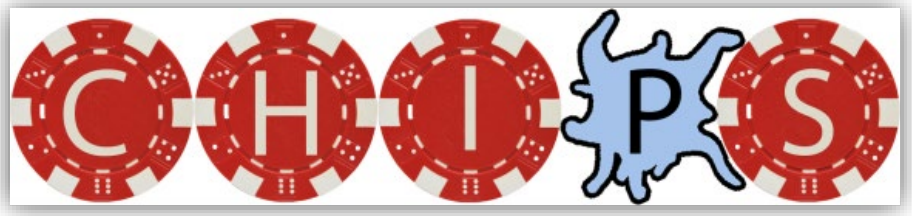
Cold stored platelets

- Improved correction bleeding time
  - RCT with whole blood derived platelets in 1973
- Pilot RCT in adult complex cardiac surgery determined feasibility
- Improved availability (if can extend storage past 7 days)
- Improved safety compared to non PRT platelets at RT

Becker et al. Transfusion. 1973;13:61-68
Strandenes et al. Anesthesiology. 2020

CHilled Platelet Study "CHIPS"

- Phase III, multicenter, randomized, double-blinded, adaptive, non-inferiority, storage-duration ranging trial in adult and pediatric patients undergoing cardiac surgery
  - Compare the transfusion of cold-stored (4C) platelets at multiple storage durations to standard room temperature stored (22C) platelets
  - Maximum of 21 days – adaptive design
- Primary outcome is 5 point bleeding score
- STS is one of the suppliers of cold platelets for the trial



Thank You for Participating in the Focus Group

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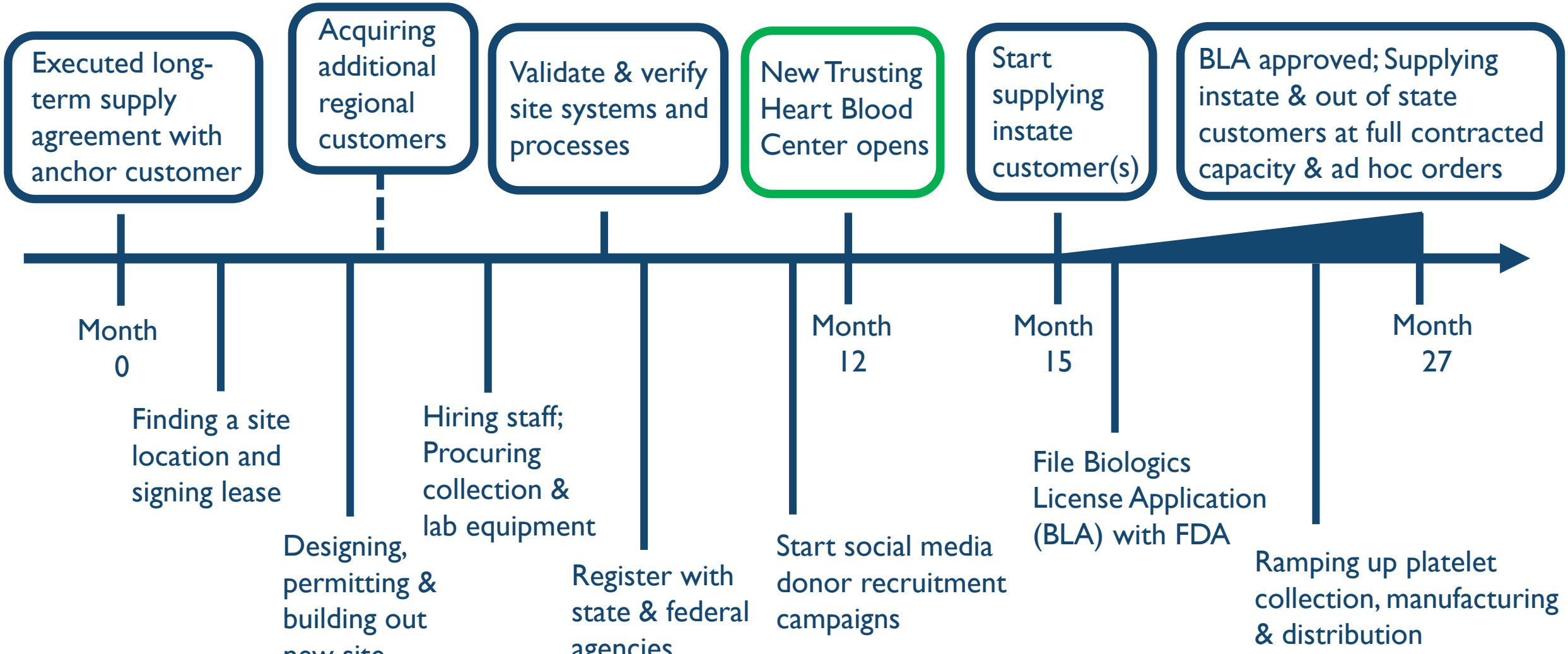
Approximate Timeline for Opening a Trusting Heart Blood Center



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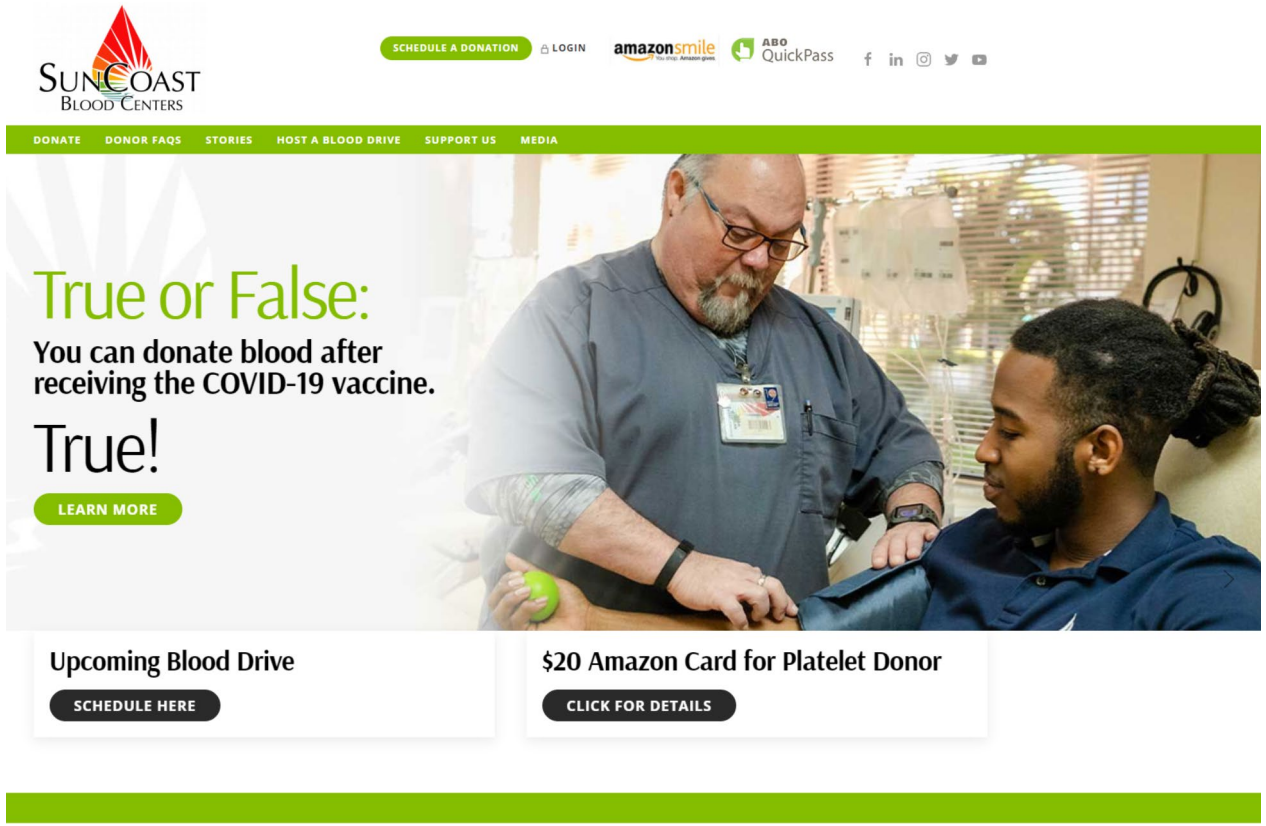
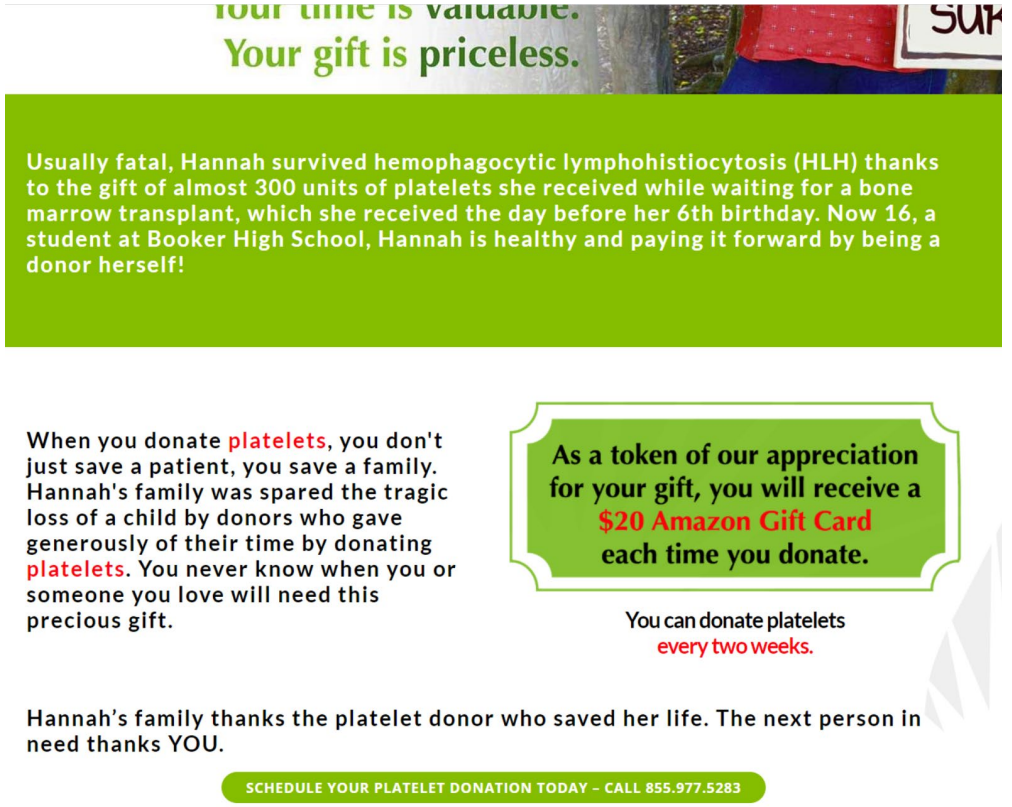
Paid Donors Already Exist





Safety & Quality

Source Plasma versus Voluntary Blood Donation

Infectious Disease Positivity Rates - Comparison

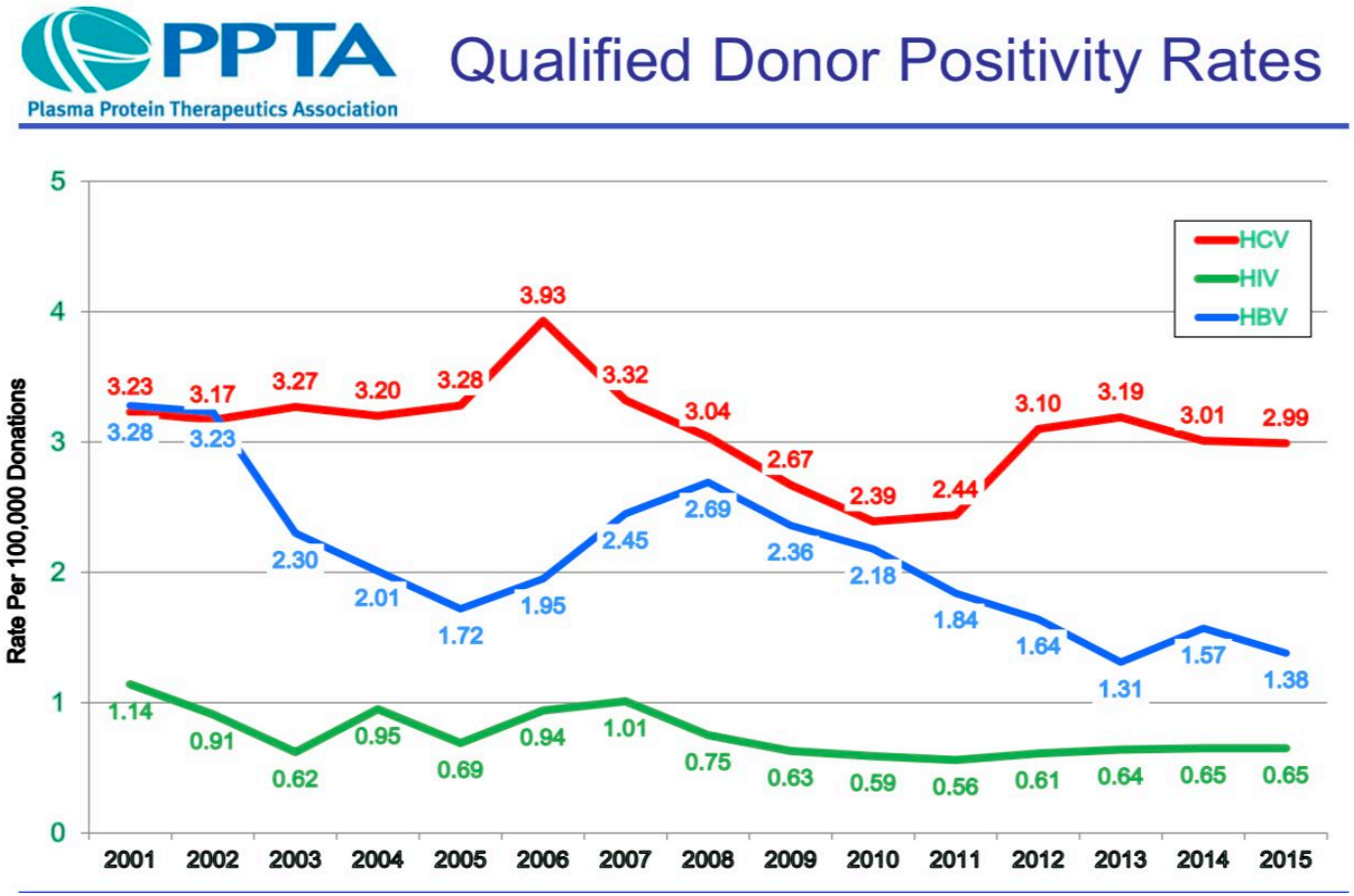
Source Plasma Industry Methodology

- "Qualified Donor" (sometimes referred to as "Pedigreed") – first two collections only released after donor passes two consecutive infectious disease screening panels

Non-Profit Industry Methodology

- Unit collected and released for transfusion on initial negative infectious disease screening panel

Qualified Donor Positivity Rates – Plasma (Paid Donors)



Source: PPTA Presentation Plasma Product Biotechnology Meeting, May '17

Qualified Donor Positivity Rates – NFP (Non-remunerated Donors)

TABLE 1. Prevalence and Incidence Rates, 2008-2015

Donation Prevalence (per 100,000 donations)					
	2008-2009	**2010-2011**	**2012-2013**	**2014-2015**	**F, R^2**
HBV	10.7	9.6	7.8	5.3	70.3, 0.97*
HCV	31.6	27.3	24.4	13.6	21.4, 0.91*
HIV	2.9	2.9	2.5	1.6	8.3, 0.81
FT Donor Prevalence (per 100,000 donors)					
	2008-2009	**2010-2011**	**2012-2013**	**2014-2015**	**F, R^2**
HBV	78.7	74.2	61.9	46.3	37.8, 0.95*
HCV	230.7	203.7	178.73	102.9	22.6, 0.92*
HIV	14.2	13.0	13.0	7.9	6.1, 0.75
Incidence (per 100,000 PY)					
	2008-2009	**2010-2011**	**2012-2013**	**2014-2015**	**F, R^2**
HBV	4.2	3.7	1.8	1.3	27.4, 0.9*
HCV	6.0	6.0	6.2	1.8	2.5, 0.6
HIV	4.2	5.2	2.6	1.7	4.5, 0.7

Source: Transfusion 2017, Volume 57, Supplement S3

Qualified Donor Positivity Rates – Comparison (per 100,000 donations)

No Meaningful Difference

Infectious Disease	Volunteer Donor Positivity Rate	Paid Donor Positivity Rate
2015		
HIV	1.7	0.7
HCV	1.8	2.9
HBV	1.3	1.4
2013		
HIV	2.6	0.6
HCV	6.2	3.2
HBV	1.8	1.3

Safety & Quality

The Mayo Experience with Compensated Platelet Donation

The Mayo Experience: 1981-2002

- Paid $50 in cash per platelet donation
- Required 7 non-compensated whole blood donations prior to being eligible for a compensated platelet donation

Mayo Clinic used paid donors (product carried the appropriate labeling) for two decades in Rochester, MN without any safety or quality adverse effects

Taswell H, Part III. Directed, paid and self donors. In: Clark GM, editor. Competition in blood services. Arlington, TX: American Association of Blood Banks, 1987; p. 137–148.

Mayo Data: Blood Donor Pool Anti-HIV Incidence*

	Paid Donors	Volunteer Donors	P Value
Number of Units	10,414	13,304	
EIA (RR)	0.36%	0.40%	0.59
Western Blot	0%	0.008%	0.38

*Previously untested donors

Taswell H, Part III. Directed, paid and self donors. In: Clark GM, editor. Competition in blood services. Arlington, TX: American Association of Blood Banks, 1987; p. 137–148.

Mayo Data: Blood Donor Pool HBsAg Incidence

	Paid Donors	Volunteer Donors	P Value
Number of Units:			
1970-1985	282,227		
1980-1985		32,828	
HBsAg Positive	0.007%	0.027%	0.0002

	Paid Donors	Volunteer Donors	P Value
Number of Units 1980-1985	94,516	32,828	
HBsAg Positive	0.004%	0.027%	0.0004

Taswell H, Part III. Directed, paid and self donors. In: Clark GM, editor. Competition in blood services. Arlington, TX: American Association of Blood Banks, 1987; p. 137–148.

Supply Chain Integrity

The key to consistently meeting the transfusion needs of your patients

Partnering with STS strengthens your platelet supply chain

- Supply chain diversity prevents and/or minimizes supply disruptions
  - Donor diversity (demographics, motivations, etc)
  - Geographic diversity (inclement weather, natural disasters, crisis)
  - Protection from seasonal disruptions and shortages (summer, holidays, etc)

- Compensated donor model allows STS to increase supply at times when non-profits struggle the most such as holidays
  - Labor Day weekend 2021 experience
    - Offered an extra bonus for current donors to donate during the holiday weekend
    - Filled all donation slots within several hours of announcing promotion
    - Increased collections to >150% of baseline collections over the weekend

Summary

- Responsibly compensated donors + PRT is a cost effective, sustainable solution to improve platelet sourcing
- The STS process of compensating donors with PRT incorporates additional safety measures that go above FDA requirements and AABB standards
- Principle of supply chain diversification applies to platelet supply
- STS works harmoniously with NFP blood centers by augmenting the platelet supply
- FDA and AABB are fully engaged and acknowledge the STS solution is legal and in full compliance with all applicable regulations and standards

STS Introduction

Secure Transfusion Services (STS) Introduction

- Builds and operates fully regulatory compliant blood collection centers focused on supplying hospitals with hard to source transfusable components; currently focusing on pathogen-reduced single donor apheresis platelets (PR-SDP)
- Goal is to improve **Customer value proposition:** Reduced cost & Increased platelet supply chain integrity by improving patient outcomes
- Increase availability of PR-SDP's in a sustainable manner, allowing hospital institutions to comply with the FDA's now effective bacterial risk mitigation guidance

Management team

Board of Directors

Laurence Cooper, MD PhD
Board Director

Cell therapy inventor and entrepreneur

Vijai Mohan
Founder and CEO, Board

Life sciences investor and entrepreneur

Carol Moore
Board Director

Senior Vice President
Regulatory Affairs
Cerus Corporation

Bud Scholl
Board Director

CEO OneBlood

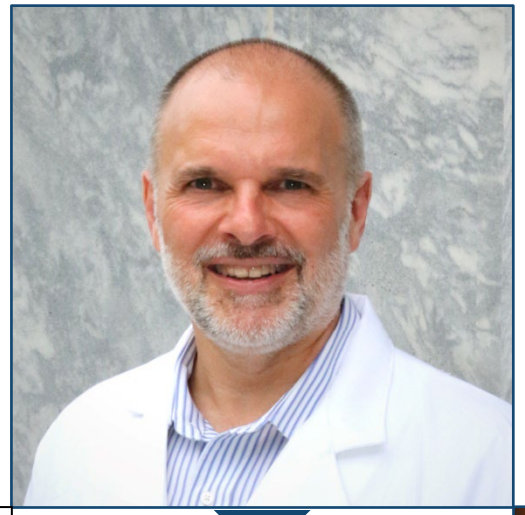
Senior advisors

Andrew Heaton, MBBS
Advisor

Former Chief Medical Officer, Novartis Diagnostics; former CEO, Blood Centers of the Pacific

William (Bill) Mercer
Advisor

Former Executive, TerumoBCT



John Roback, MD PhD
Advisor

Transfusion Director Emory University Medical Center

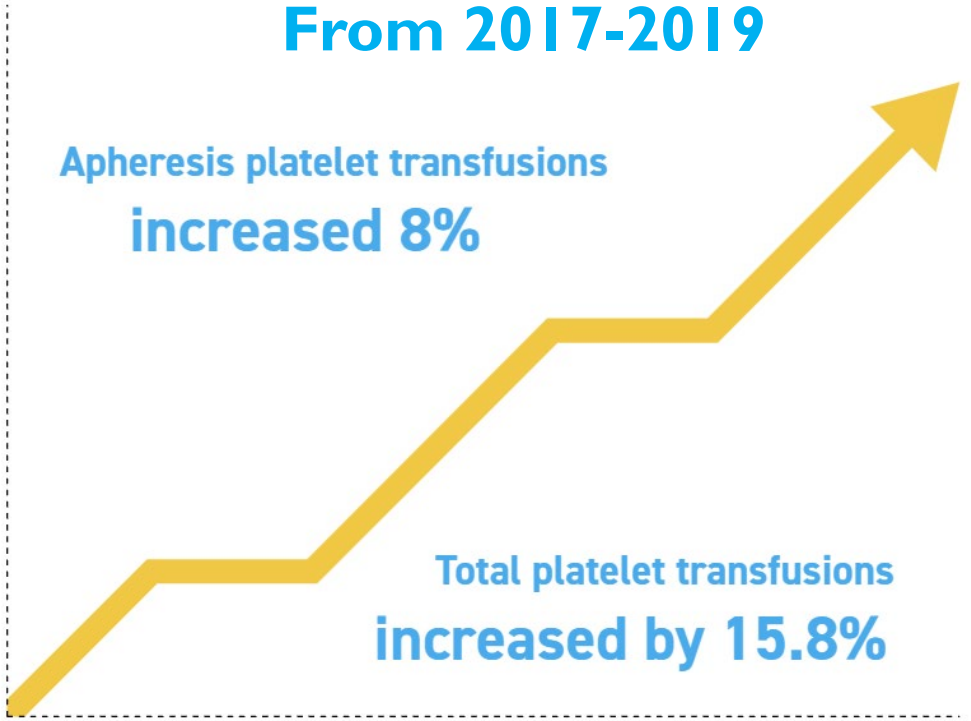
Susan Shurin, MD
Advisor

Former Deputy Director National Heart, Lung and Blood Institute

Platelet usage increases while shortages translate into real clinical impact

- Recent NBCUS Survey revealed an **8.0% increase** in apheresis platelet units transfused in the U.S. between 2017 to 2019 and a **15.8% increase** in total platelet units transfused between 2017 to 2019

- A recent survey of 481 U.S. hospitals found that **22.3%** of hospital **experience platelet supply challenges** at least once per month and **47.2%** of high transfusion volume hospitals **report supply challenges** once or more per month



- **18.7%** of U.S. hospitals report experiencing **delayed surgeries** and **31.8%** report **delayed outpatient transfusions** due to platelet supply challenges over the past 12 months

Jones, JM, et al. 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 Suppl 2:S1-S10.
Pandey S, et al. A survey of US hospitals on platelet inventory management, transfusion practice, and platelet availability. Transfusion. 2021; 61:2611-2620.

"Percent contributions to annual inventories from 31 to 50 year old donors decreased by more than half between 2001 and 2017" … "Significant aging of the apheresis donor base is such that reliance on older donors will be thwarted when, in the near future, they are more likely to be patients than they are likely to continue as apheresis donors."

Merlyn Sayers, MBBCh, PhD
Abstract Presentations from the AABB Annual Meeting, Boston MA, October 13-16, 2018.
Transfusion. 2018; 58(S2): A6-A254.

COVID-19 impact lays bare fragility of the blood system

NPR: Social distancing leads to blood shortage

NYT: Where Have All the Heart Attacks Gone?

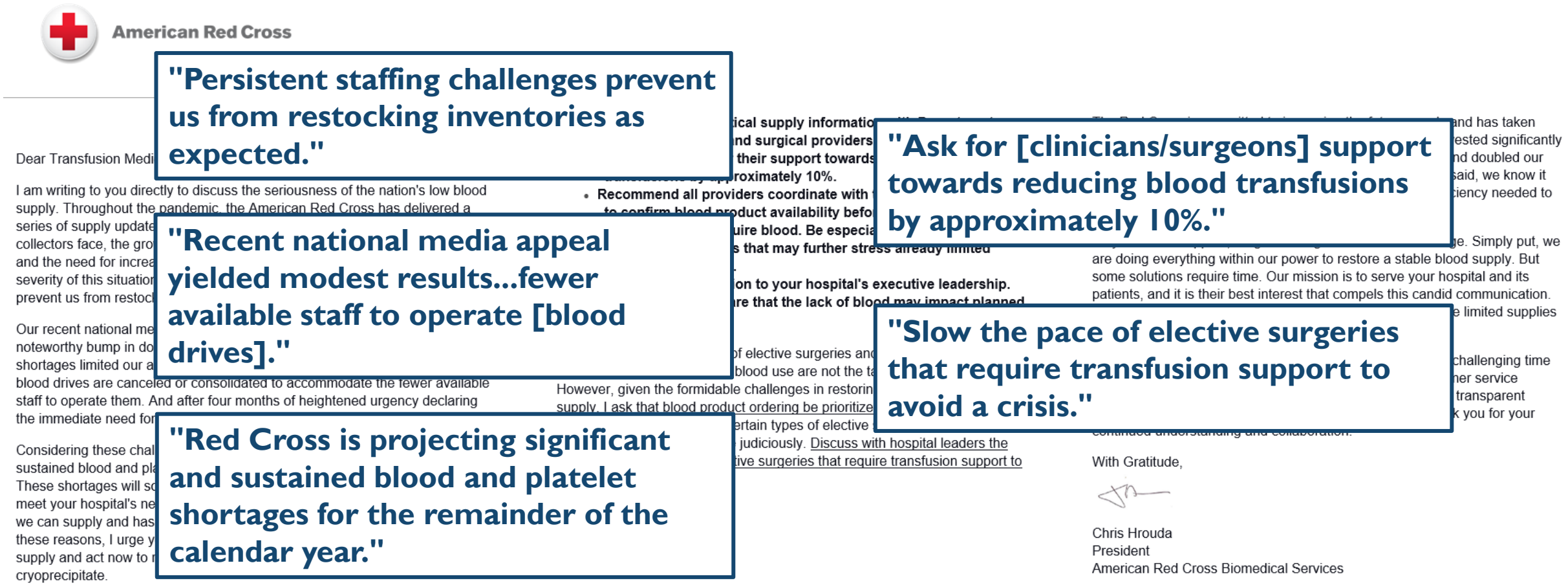
New York Times: The Coronavirus is Forcing Hospitals to Cancel Surgeries

Time: Coronavirus Fears Are Leading to Blood Drive Cancellations at 'Unprecedented' Rates

The Guardian: 'This could kill our patients': US faces blood shortage as donation sites shutter

Los Angeles Times: As people worry about gathering in public because of coronavirus, blood donations steadily dwindle

Urgent Blood Supply Update from the ARC - Oct 12, 2021



American Red Cross

"Persistent staffing challenges prevent us from restocking inventories as expected."

"Recent national media appeal yielded modest results...fewer available staff to operate [blood drives]."

"Red Cross is projecting significant and sustained blood and platelet shortages for the remainder of the calendar year."

"Ask for [clinicians/surgeons] support towards reducing blood transfusions by approximately 10%."

"Slow the pace of elective surgeries that require transfusion support to avoid a crisis."

Dear Transfusion Medi

I am writing to you directly to discuss the seriousness of the nation's low blood supply. Throughout the pandemic, the American Red Cross has delivered a series of supply update collectors face, the gro and the need for increa severity of this situatio prevent us from restoc

Our recent national me noteworthy bump in do shortages limited our a blood drives are canceled or consolidated to accommodate the fewer available staff to operate them. And after four months of heightened urgency declaring the immediate need fo

Considering these cha sustained blood and pla These shortages will s meet your hospital's ne we can supply and has these reasons, I urge y supply and act now to cryoprecipitate.

ical supply informatio
nd surgical providers
their support towards
proximately 10%.
- Recommend all providers coordinate with
to confirm blood product availability befo
uire blood. Be especia
s that may further stress already limited

on to your hospital's executive leadership.
re that the lack of blood may impact planned

f elective surgeries an
blood use are not the ta

However, given the formidable challenges in restorin
supply, I ask that blood product ordering be prioritize
ertain types of elective
judiciously. Discuss with hospital leaders the
tive surgeries that require transfusion support to

and has taken
ested significantly
nd doubled our
said, we know it
iency needed to

ge. Simply put, we are doing everything within our power to restore a stable blood supply. But some solutions require time. Our mission is to serve your hospital and its patients, and it is their best interest that compels this candid communication.
e limited supplies

challenging time
ner service
transparent
k you for your

With Gratitude,

Chris Hrouda
President
American Red Cross Biomedical Services

SECURE TRANSFUSION SOLUTIONS

Lack of Supply Chain Diversification Further Increases Risk

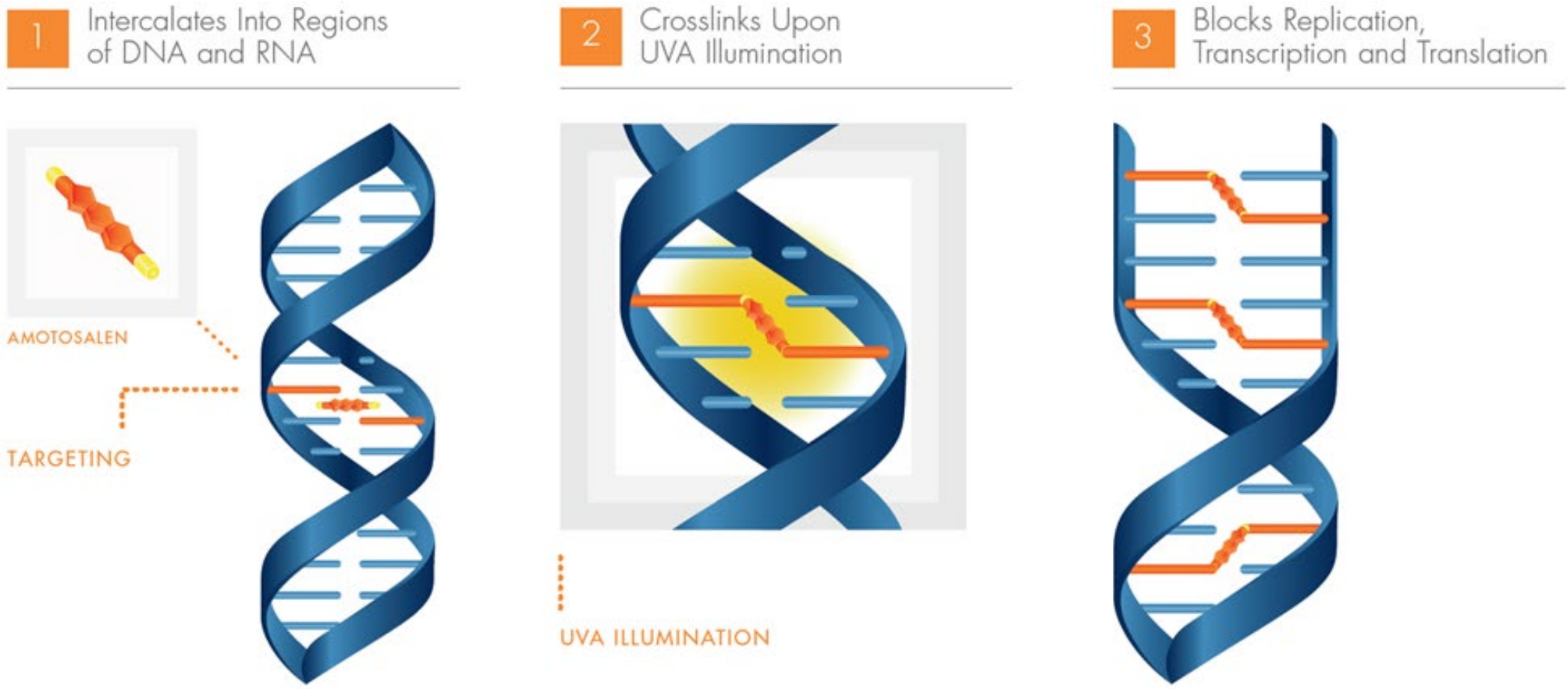
- Standard in large businesses to diversify supply chain with material that comes from different sources to de-risk not having essential material.
- Not for profit (NFP) blood collectors are all recruiting the same donor demographic
  - Having a supply from different demographics diversifies supply chain and stabilizes operations (patient care)
- The hospital systems that don't have a contracted second supplier also at increased risk of not having supply when needed
  - Especially as the demand continues to increase over time

Summary

- Population is aging
- Donors are aging without replacement with younger donors
- NFP collectors struggle with recruiting younger platelet donors
- Current platelet supply is very fragile
- Supply chain diversification reduces risk
- If the current system does not change the future risk of major platelet shortages is high

Pathogen Reduced Platelets

Cerus INTERCEPT® Pathogen Reduction



INTERCEPT Blood System for Plasma [Package Insert]. Concord, CA: Cerus Corporation; August 17, 2015.
INTERCEPT Blood System for Platelets [Package Insert]. Concord, CA: Cerus Corporation; March 15, 2016.

Broad Spectrum Inactivation with INTERCEPT® Pathogen Reduction

Viruses	Log Reduction PAS-3/Plasma
HIV-1, cell-associated	≥5.4/≥4.7
DHBV (model virus for HBV)	≥4.8/≥4.3
BVDV (model virus for HCV)	≥4.4/>3.3
HTLV-I	4.7/[b]
HTLV-II	≥5.1/[b]
West Nile Virus	≥5.7/>3.7
Chikungunya virus (CHIKV)	≥5.7/>6.5
Dengue virus (DENV)	≥4.3/3.6
Cytomegalovirus (CMV), cell-associated	≥4.9≥4.2 (PRV)
Influenza A virus	≥5.9/[b]
Bluetongue virus	4.4/[b]
Adenovirus	≥4.9/≥5.3
Zika virus	[d]/≥6.5

Protozoan Parasites	Log Reduction PAS-3/Plasma
Plasmodium falciparum	≥5.6/[d]
Babesia microti	≥4.9/[d]
Trypanosoma cruzi	≥5.3/>5.5

Bacteria	Log Reduction PAS-3/Plasma
Escherichia coli	≥6.3/>5.9
Yersinia enterocolitica	≥5.9/>6.3
Klebsiella pneumoniae	5.8/5.9
Serratia marcescens	≥6.7[c]/>7.1
Staphylococcus epidermidis	≥6.1/>6.1
Staphylococcus aureus	≥5.4/≥6.1
Streptococcus pyogenes	≥6.8[c]/>6.1
Bacillus cereus (vegetative)	≥5.5 /≥5.6
Bacillus cereus (spore forming)	3.7[c]/[b]
Clostridium perfringens (vegetative)	≥6.5/>6.0
Propionibacterium acnes	≥6.5 />6.7
Treponema pallidum	≥6.4/[a]
Borrelia burgdorferi	≥6.8/[a]

Leukocytes	Log Reduction
Human T-Cells	4

** There is no pathogen inactivation process that has been shown to eliminate all pathogens

INTERCEPT Blood System for Platelets [Package Insert]. Concord, CA: Cerus Corporation; March 15, 2016

Aubry M, et al. Inactivation of Zika virus in plasma with amotosalen and ultraviolet A illumination. Transfusion. 2016;56:33-40.

[a] = In clinical trial
[b] = Not tested
[c] = Based on culture of full platelet unit (300mL)
[d] = Study in progress

Are PRT Platelets as Effective as Conventional Platelets?

- PRT platelet transfusions had an increased risk of developing platelet refractoriness
  - 7 trials, 1525 participants; RR 2.94, 95% CI 2.08 to 4.16

- Participa[illegible]elet transfusi[illegible]
  - 6 tria[illegible]o 1.61
  - Range [illegible]

Are these the right measures & do they matter clinically?

- Participants who received PRT platelets had a lower 24-hour corrected-count increment
  - 7 trials, 1681 participants; mean difference (MD) -3.02, 95% CI -3.57 to -2.48.

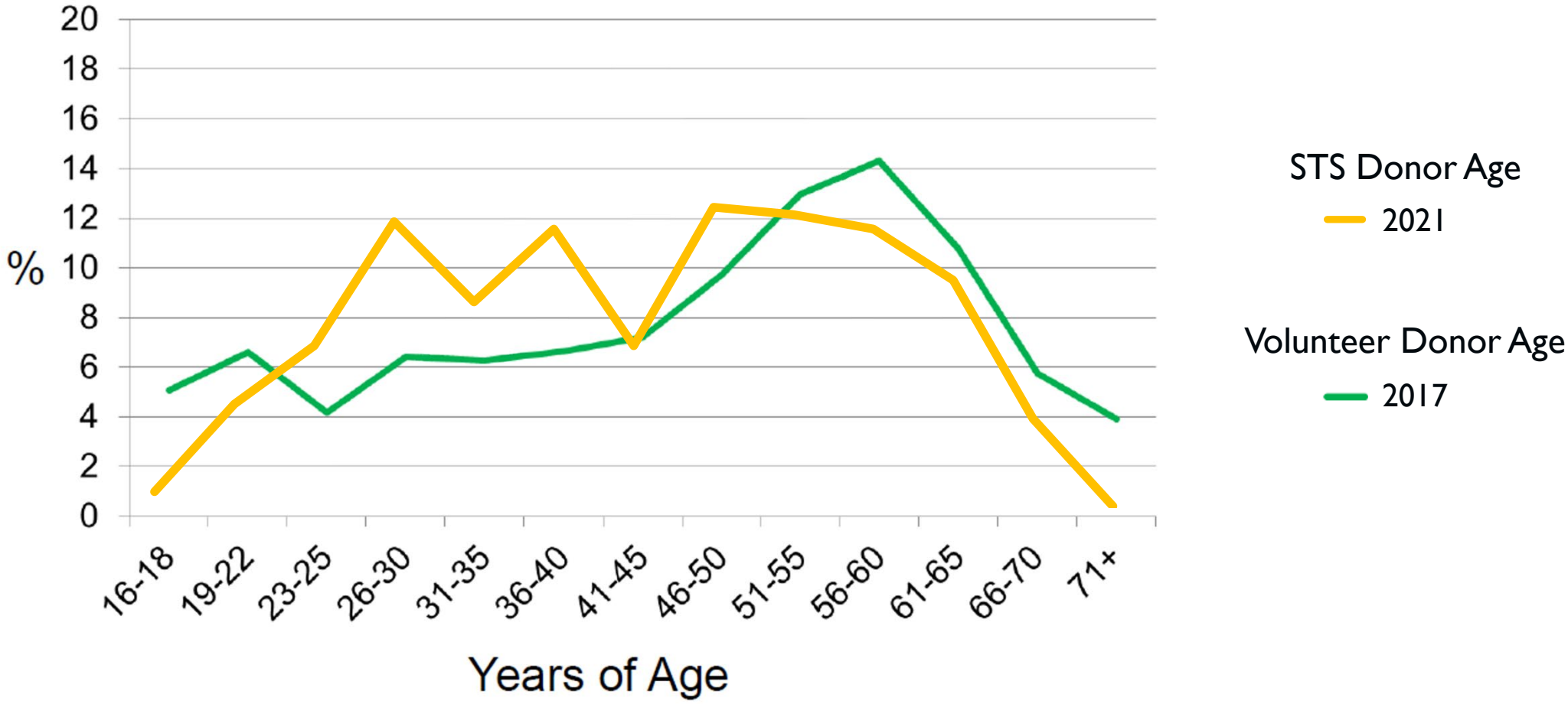
Estcourt LJ, et al. Cochrane Database Syst Rev. 2017; 2017:CD009072.

SECURE TRANSFUSION SOLUTIONS

Summary- Pathogen Reduced Platelets

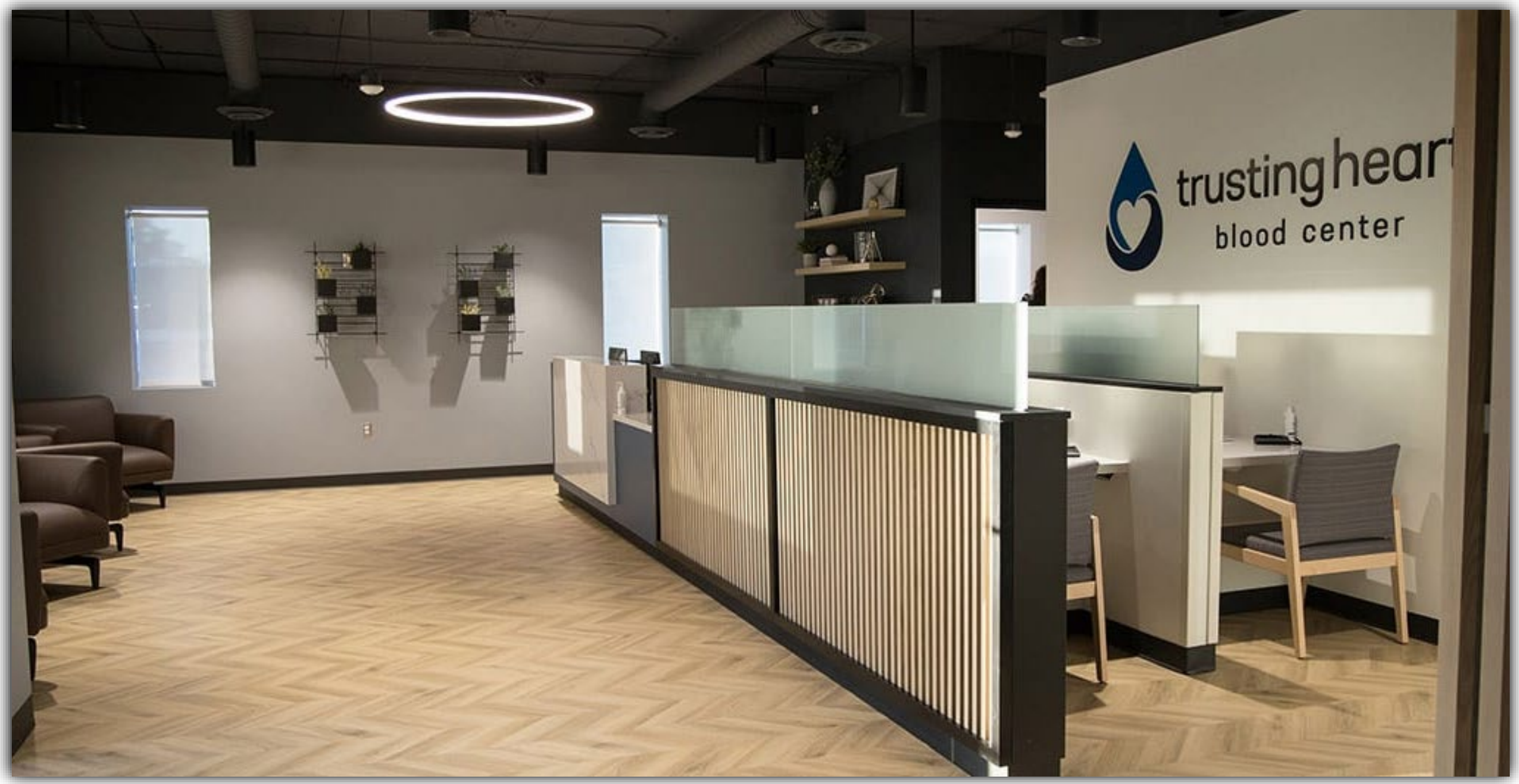
- Effective at preventing TTDs
- Effective at reducing bleeding
  - Prophylaxis
  - Massive bleeding
- Lower corrected count increment
  - Is this the right metric to use?
- Safe in adult and pediatric patients
- Most common option to meet compliance with FDA guidance on bacterial risk control strategies

STS Donor Age versus Volunteer Donor Age



Source: Transfusion 2018 Vol. 58 Supplement S2 (p 251A)


trustingheart
blood center


trustingheart
blood center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