

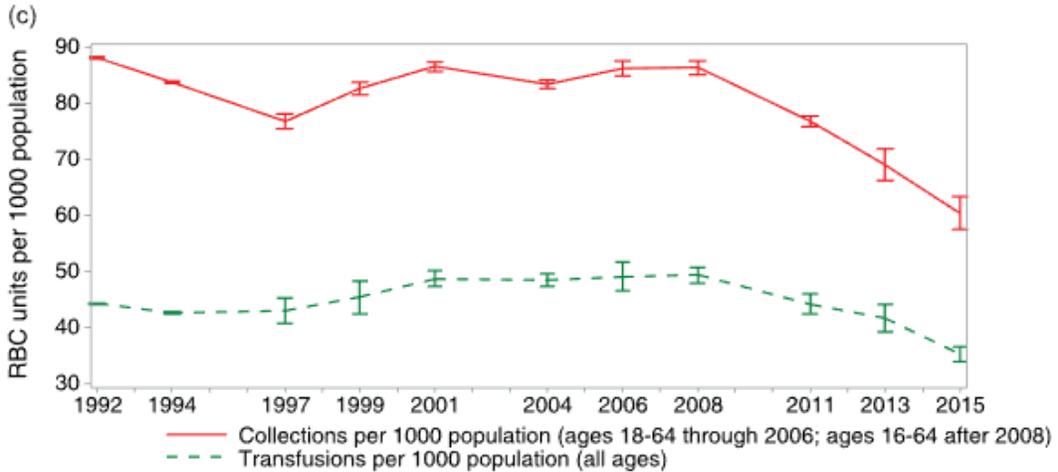
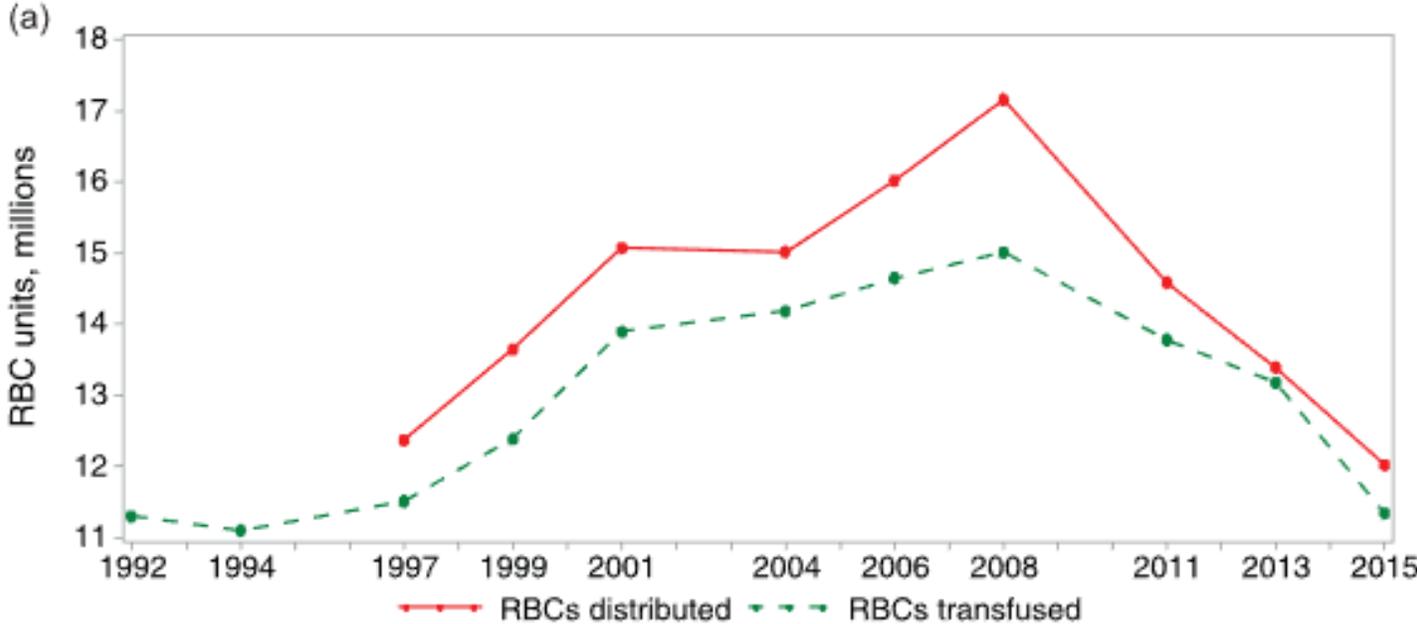


Session 3: STRATEGIC APPROACHES TO THE SECURITY OF THE SUPPLY

Towards a sustainable blood supply in the US - View of different stakeholders; including presentation from RAND

Jay E. Menitove, M.D.
September 11, 2017

Dramatic Utilization Decline—U.S.



National Blood Collection and Utilization (NCBUS)

• Ellingson KD, et al. Transfusion 2017;57: 1588-98

Utilization decline 2013-2015

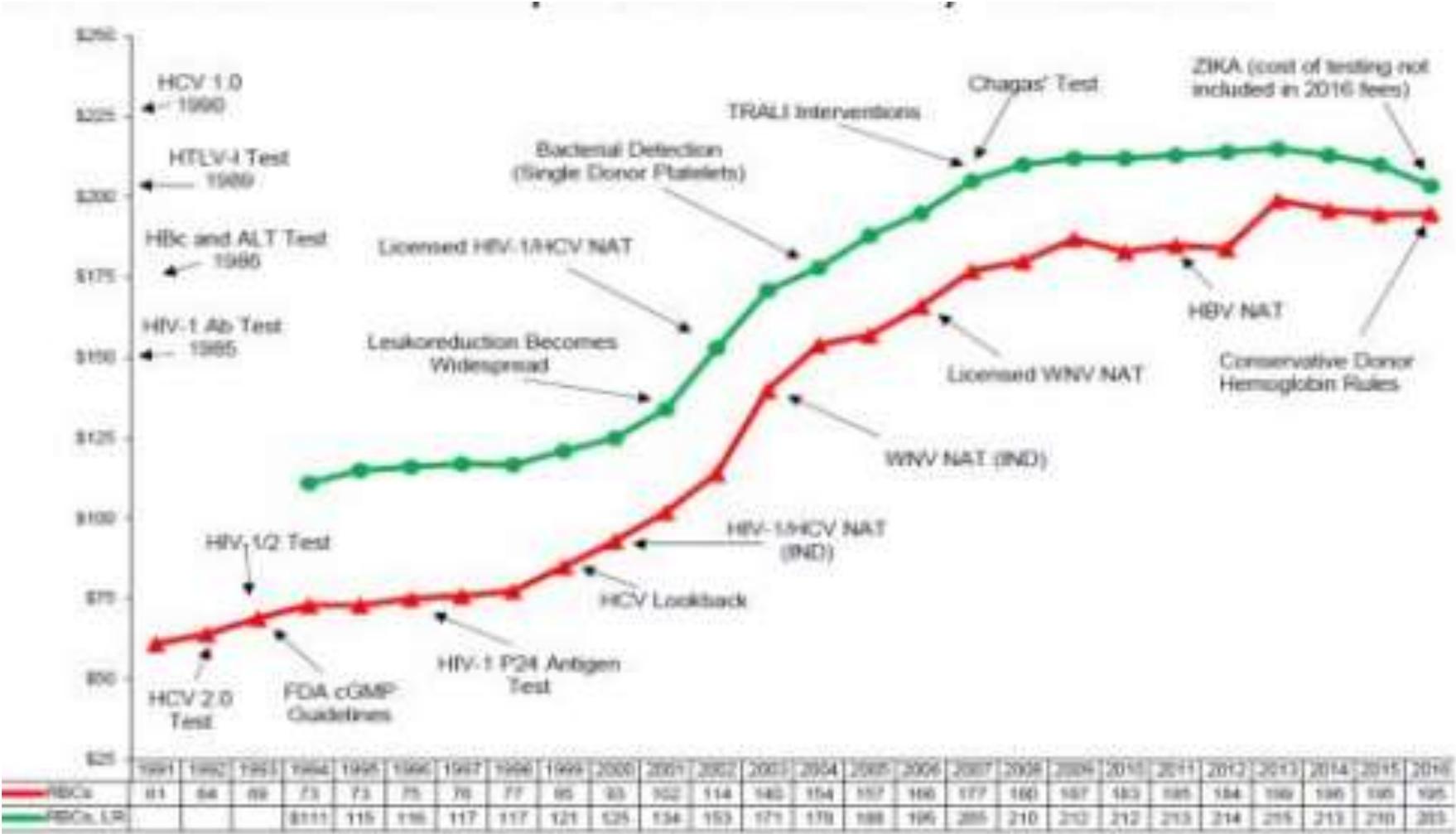
- Red cell collections decreased 11.6% and transfusions 13.9%.
- From 2008 peak: **red blood cell collections/use decreased 27.2%/16.1%**
 - 2008---- 17,286,000 units collected and 15,014,000 transfused
 - 2015 ----12,591,000 units collected and 11,349,000 transfused
- Red cell transfusions per 1000 U. S. population declined
 - 48-49 during 2001 to 2008 • 41.7 in 2013
 - 44.0 in 2011 • 35.3 in 2015.

Utilization decline 2013-2015

- Platelet usage decreased 13.1% Plasma transfusions declined 24.8%

- Another 2.2% decline between 2015 and 2016
 - Declining ~ one-half that observed during each of the two previous years
 - possibly suggesting an approaching plateau (Blood Centers of America, April 2017)

Median ABC price/safety initiatives



With permission: Katz, L America's Blood Centers

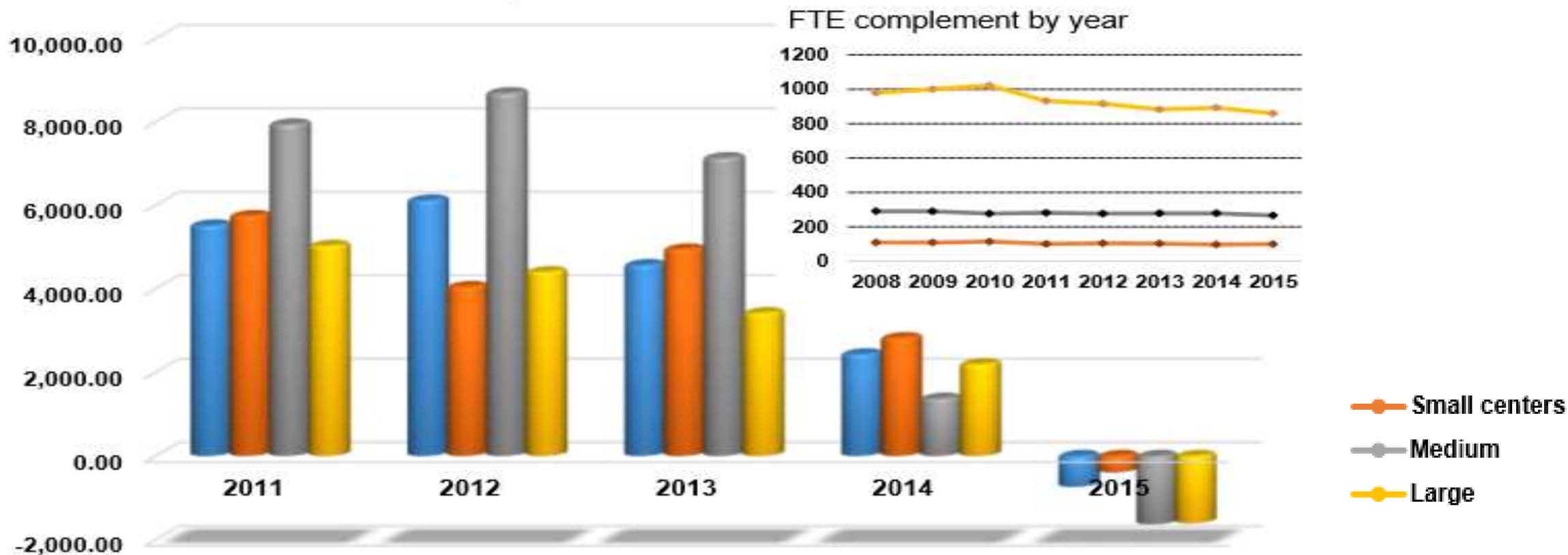
Median and mean dollar amount paid per blood product unit-United States, 2013 and 2015

Component	Amount paid, 2015 (\$)			Amount paid, 2013 (\$)			Difference, 2015-2013 (\$)	
	Median (N)	IQR	Mean	Median (N)	IQR	Mean	Median	Mean
RBCs, leukoreduced	\$211 (1630)	\$197-\$228	\$217	\$221 (843)	\$205-\$240	\$228	-10	-11*
RBCs, nonleukoreduced	\$204 (262)	\$185-\$225	\$207					
Whole blood-derived PLTs, each unit, not leukoreduced, not irradiated	\$95 (101)	\$68-\$120	\$242					
Apheresis PLTs, leukoreduced	\$524 (1668)	\$495-\$560	\$537	\$540 (812)	\$510-\$590	\$557	-16	-20*
FFP	\$54 (1062)	\$45-\$64	\$60	\$59 (499)	\$50-\$68	\$63	-5	-3
PF24	\$52 (1389)	\$45-\$60	\$63	\$58 (667)	\$48-\$65	\$60	-6	3
Cryoprecipitate, each unit	\$56 (1356)	\$45-\$80	\$115	\$54 (625)	\$45-\$69	\$101	2	13*

NCBUS

Fewer staff/reduced blood center income

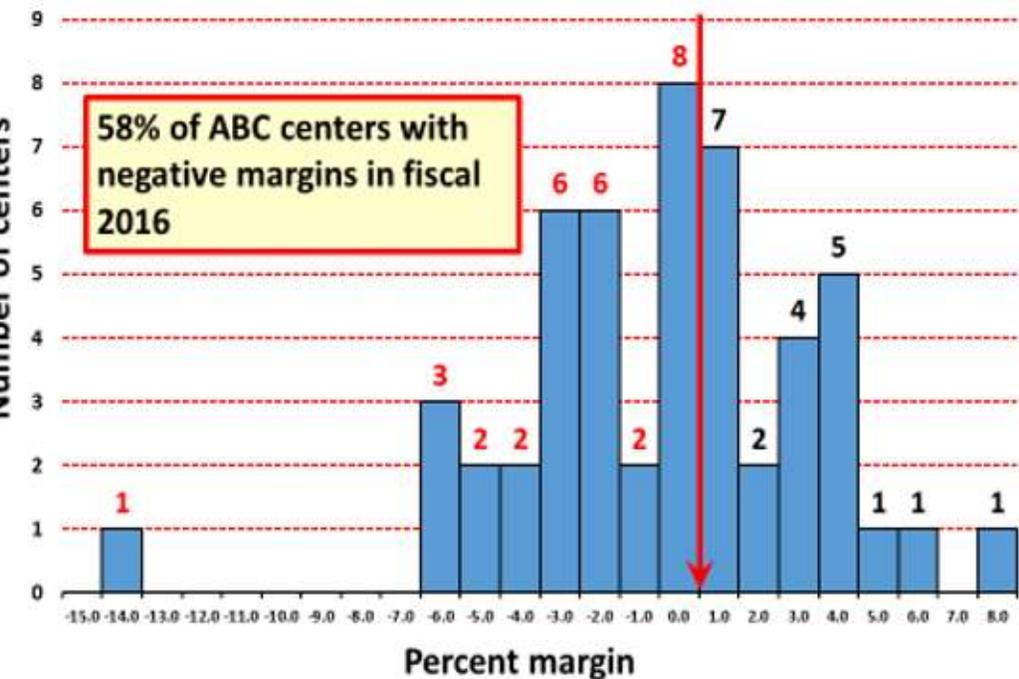
Median net income per FTE



Resultant fiscal impact

Margin (percent of total revenue):

ABC financial ratio survey: calendar 2015



In conjunction with fewer distributed products, blood center revenues declined further (2013-2015).

Median prices paid by hospitals for LR RBCs decreased by \$10 to \$211 compared to \$204 for non-LR red cells.

Apheresis platelet and plasma prices declined \$16 and \$5-6 to \$524 and \$52-54, respectively.

Presumably reflecting increased competition among blood centers for market share.

Donor Demographic Changes

	All facilities, number (95% CI)		All facilities, 2011*	Percentage of total		
	2015	2013		2015	2013	2011*
Donations by donor age (years)						
16-18	1,521 (1,406-1,636)	1,591 (1,458-1,724)	1,646	13.4	12.4	10.5
19-24	1,236 (1,165-1,308)	1,569 (1,470-1,668)	1,556	10.9	12.2	10.0
25-64	7,182 (6,737-7,627)	8,252 [†]	11,108 [†]	63.3	64.1	71.5
65 or older	1,401 (1,297-1,504)	1,457 (1,363-1,550)	1,219	12.4	11.3	7.8
Repeat allogeneic donations	7,216 (6,545-7,886)	‡	9,534	63.6		61.4
Total successful donations	11,339 (10,689-11,989)	12,869 [‡]	15,529			
Number of donors						
First-time allogeneic	2,223 (2,058-2,388)	2,530 (2,288-2,771)	2,840	32.6		30.8
Repeat allogeneic	4,589 (4,213-4,966)	‡	6,364	67.4		69.2
Total individual donors [§]	6,812 (6,343-7,282)	‡	9,203			

Donor Demographic Changes

Shift towards younger and older donors accounting for 13.4% and 12.4% of the 6,812,000 individuals donating in 2015 (compared to 9,203,000 persons in 2013).

First time donors declined to 2,223,000 from 2,840,000 in 2011.

Concern about **Fe depletion** likely leads to reduce blood donations.

The long- term consequences of these changes raise a cautionary flag about **blood supply adequacy** if transfusion needs increase as the U.S. population ages.

Sustainability of US Blood System discussed by ACBTSA 2013+

Spring, 2015

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.**

RFP: *“Toward a sustainable blood supply in the United States: an analysis of the current system and alternatives for the future.”* (cont’d.)

- Describe **market vulnerabilities** to changes in clinical technologies (e.g. less invasive surgeries), and transfusion medicine practices (especially evidence-based conservative transfusion practices).
- Quantify the **“Insurance Value of Blood”** or in other words, what are costs and benefits of **having blood available for transfusion during both routine, urgent, and public health emergency** related medical and surgical practice, whether it is actually **transfused or not**.
- Assess the **declining elasticity** of blood product availability brought about by the industry reducing capacity to **meet only current needs**, switching to a “just-in-time” business model and its impact on public health emergency response (i.e., **hospital surge capacity**).

Advisory Committee on Blood Safety & Availability

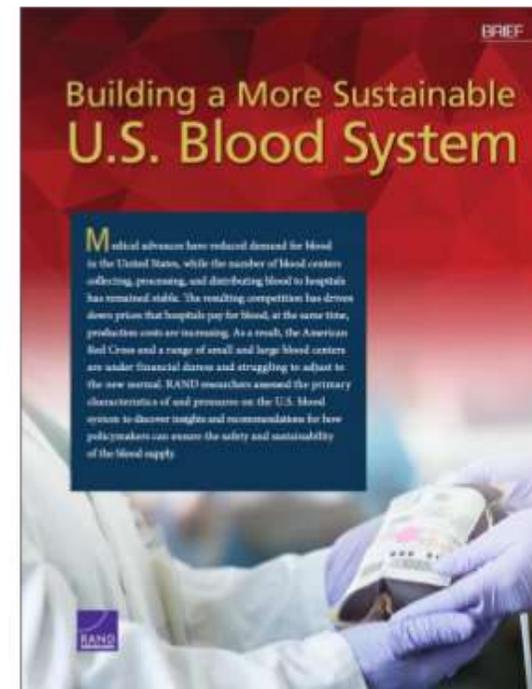
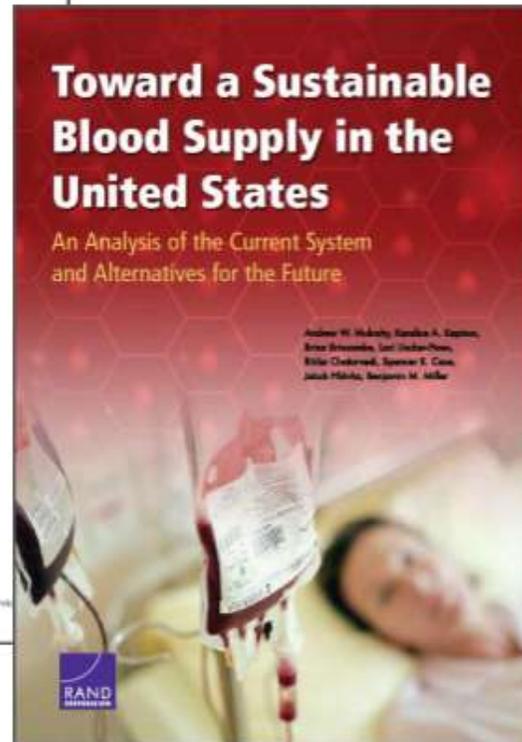
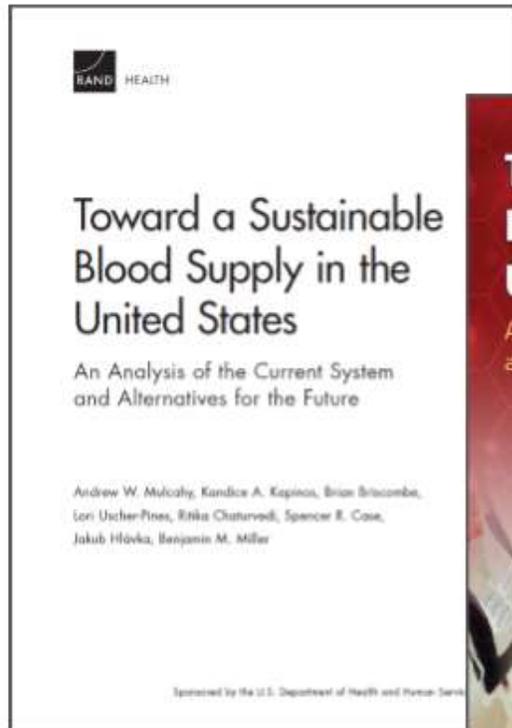
- April-July, 1993
 - Senators Edward Kennedy (D-MA) and Robert Graham (D-FL), Representative Porter J. Gross (R-FL), HHS Secretary Donna Shalala asked IOM to review events of the 1980's relating to transfusion of HIV.....
- July 13, 1995
 - IOM report issued
 - **Decision making under uncertainty**
 - Failure of leadership and inadequate institutional decision making processes in 1983-84
 - **No person or agency coordinated** all of the organizations sharing the public health responsibility for achieving a safe blood supply
 - **Bureaucratic management of potential crises**

Advisory Committee on Blood Safety & Availability

- 14 recommendations that might have moderated some of the effects of the AIDS epidemic
 - Recommendation 2
 - PHS should establish a Blood Safety Council to assess current and potential future threats to the blood supply
 - PHS Advisory Council on Blood Safety and Availability

RAND REPORT

Fall, 2016



RAND: Overarching Findings

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

Although our report focuses on challenges related to blood system sustainability, it is important to recognize the **success** of the system under the status quo.

Overall, we found that **blood was always or almost always available to hospitals.** Stakeholders—including blood centers in particular—relocate units to minimize outdating and wastage and to respond to a range of unanticipated needs.

...

RAND: Overarching Findings

Robust price competition controls blood costs.

Rather than completely replacing functioning aspects of this industry and accompanying incentive structures, **we propose a set of narrower recommendations that HHS could consider to improve blood system sustainability.**

RAND Report

Broad Policy Alternatives

Status quo
without policy
intervention

Targeted
policy
intervention

Fundamental
shift in blood
system structure
and management



RAND Recommendations

- Recommendation 1: **Collect data** on blood use and financial arrangements.
- Recommendation 2: Develop and disseminate a vision for **appropriate levels of surge capacity** and emergency response plans.
- Recommendation 3: **Pay blood centers for maintaining surge capacity.**
- Recommendation 4: Build relationships with brokers and other entities to form a blood “safety net.”

RAND Recommendations

- Recommendation 5: Build and implement a value framework for new technology.
- Recommendation 6: Pay directly for new technologies where there is no private business case for adoption.
- Recommendation 7: Implement emergency use authorization and contingency planning for key supplies and inputs.

ACBTSA Sustainability Subcommittee Membership

- **Richard Benjamin**, MD, PhD, FRCPath
- **Jim Berger**, MS MT(ASCP) SBB
- **David Green**, BS, MS
- **Rich Henry**, ML, MPH
- **Chris Hrouda**, BS, EVP/ARC
- **MG Bart Iddins**, MD, DVM, MHCM
(Air Force ex-officio, Col. Chetan Kharod,
Maj. Nicole Furguson)
- **Nancy Kane**, DBA
- **Louis Katz**, MD
- **Jay Menitove**, MD
- **Paul Ness**, MD
- **Louis Rossiter**, PhD
- **Karen Scott**, MD, MPH
- **Debbie Seem**, RN, MPH
- **Michael Stoto**, PhD
- **Zbigniew Szczepiorkowski**, MD, PhD,
FACP
- **Darrell Triulzi**, MD
- **Christine Zambricki**, DNAP, CRNA,
FAAN
- ***Martin Grable**
- * beginning May 12, 2017

Subcommittee Findings & Advice

- **Mixed-methodology and industry-wide view **masks** any facility/regional-level urgency of financial crisis**
 - Traditional Mergers & Acquisitions may *no longer be available*
 - The crisis in the blood industry is expanding and evolving
- **Traditional understandings of donor-base are no longer dependable and new circumstances risk significant blood collection shortfalls**
 - e.g., percent of population, first-time/repeat donors, diversity, competition, teen donors, hemoglobin levels, etc.
 - **Costs to recruit donors contradicts customary views of marginal costs**

Subcommittee: Recommend Moving Forward...

- Empower HHS to convene **central policy authority**
 - Potentially the **HHS-BOTSEC**
- Explore FTC Anti-Trust exemptions to allow blood centers to discuss beneficial solutions to public goods
- FDA commitment(s) on *draft guidance* moving towards *final guidance* to decrease regulatory uncertainty for industry R&D (e.g., infectious disease testing, pathogen red.)

Subcommittee: Recommend Moving Forward... (cont'd.)

- Compel ongoing data collection on **insurance value of blood**, collections, utilization, hemovigilance costs
- Explore CMS reimbursements to cover the cost of public good portions of the blood supply

Blood, Organ, and Tissue Senior Executive Council (BOTSEC)

Membership on the BOTSEC includes senior leadership or a designee from the following HHS organizational components:

- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Planning and Evaluation
- Office of the Assistant Secretary for Preparedness and Response
- Agency for Healthcare Research and Quality (AHRQ)

Blood, Organ, and Tissue Senior Executive Council (BOTSEC)

- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- National Institutes of Health (NIH)

Blood, Organ, and Tissue Senior Executive Council (BOTSEC)

The BOTSEC also includes liaison representatives from:

- Department of Defense (DoD)
- Veterans' Health Administration (VA)

The HHS Assistant Secretary for Health serves as the Council Chair, and the OASH Senior Advisor for Blood and Tissue Policy serves as the BOTSEC Executive Director

Recent Sustainability Sub-committee Activities

- Confirm and document U.S. blood system sustainability risk
 - **Stress test (per 2008-09 banking industry crisis)**
 - More than financial crisis
 - Shrinking donor pool support
 - Lack of supplies
 - Lack of innovation
 - ? System elasticity
 - **Lack of central decision making**

Recent Sustainability Sub-committee Activities

- Three Working groups established
 - Hospital
 - Blood Center
 - Manufacturers

Hospital Working Group

- **Reliability of the blood supply**
 - Shortages exist
 - **Safety of blood for patients**
 - Lack of adoption
 - Bacterial testing of platelets
 - Babesia
 - Pathogen inactivation
 - Hemovigilance programs
 - **Availability of specialized products**
- Paul Ness
 - Darrell Triulzi
 - Zbigniew “Ziggy” Szczepiorkowski

Blood Center Working Group

- Hb change
 - 1.2% loss of whole blood donors
 - 1.7% loss of apheresis donors
- Reliance on H.S. donors
 - Fe depletion concerns
- Preparedness
 - Unprecedented events
 - Dirty bomb
 - Bioterror event
- FDA mandates = unfunded \$\$
 - CMS price adjustments—not timely
 - “insurance value” —not compensated
- Lou Katz
- Dave Green
- Chris Hrouda
- Nancy Kane
- Nicole Ferguson

Manufacturers Working Group

- RAND did not analyze long term effect of industry investment for **innovation**
 - Revenues generated by WB and apheresis **collections**
 - BC efficiencies erode manufacturers sales
 - e.g. split rates increases
 - Industry consolidation into large diversified companies
 - **Less investment in TM**
 - **Investor ROI important for sustainability**
 - Similar to donor generosity
- Lou Rossiter
 - Richard Benjamin

BOTSEC/Sustainability Sub-committee

- Joint conference calls
 - Monthly
 - Convergence of government and TM sector
 - Data collection
 - Pertinent recommendations !!!???

Modelling

- WGs identify **stress test** issues for modelling
- Biomedical Advanced Research and Development Authority (**BARDA**)
 - Office of the Assistant Secretary for Preparedness and Response
- First phase
 - **Modelling criticality of system parameters for ? change**
 - **Mostly financial**
 - Blood collection data
 - Impact of declining blood collections

Caveats

- Blood utilization decline
 - resulting blood center **consolidation** into fewer, but larger organizations
- ACBTSA cautioned, at its November 9-10, 2015 about
 - “adverse effects of an unconstrained competitive environment in blood collection with avoidance of potentially adverse outcomes for public health
 - **monopoly or oligopoly behaviors in the absence of suitable controls”**

Caveats

- Are current customer service issues facing the **airlines industry** a harbinger for the blood system?
- **Customers benefitted for many years from fierce competition and lower prices.**
 - Prior to deregulation, the airline industry served simultaneously large and small markets,
 - Following de-regulation, it migrated into an **abusive cartel**.
- Patients differ from passengers, more than pecuniary interests avail.

Kuttner R. New York Times April 17, 2017

Menitove JE. Transfusion 2017;57:1585-7