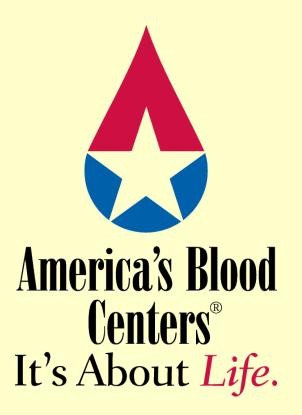
What's the value of blood?



Blood Centers of California Sacramento CA March 2016

Louis M. Katz MD
Chief Medical Officer, America's Blood Centers, Washington DC

The value of blood?

 Clinical value – there is no controversy that blood saves lives

Celso: 40 units (and plasma)

• LMK: 37 RBCs

- "Insurance value" absent capacity, things don't happen without it– whether used or not
 - Grandma's hip replacement
 - Junior's leukemia chemotherapy
 - "Dirty bomb" response
 - San Diego suspends collections for Zika

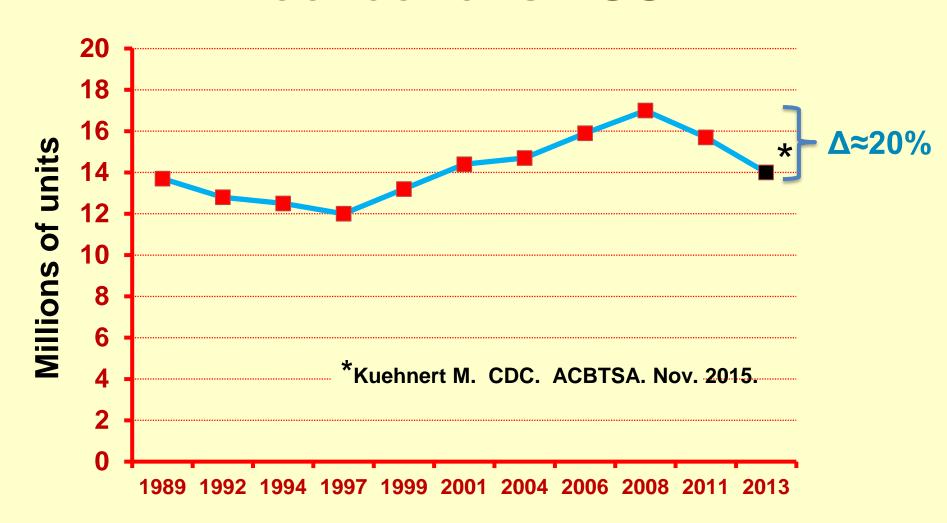
The contribution of blood to hospital revenue in the United States

Christine Brown Mahoney¹
Louis M Katz²
James L MacPherson³
Jerome Haarmann³

Region	East	Midwest	South	West
Number of facilities	633	1322	1656	812
% Medicare patients with DRGs that use blood	16.9	13.7	14.6	16.8
% revenue associated with these patients	26.8	19.7	21.4	24.3

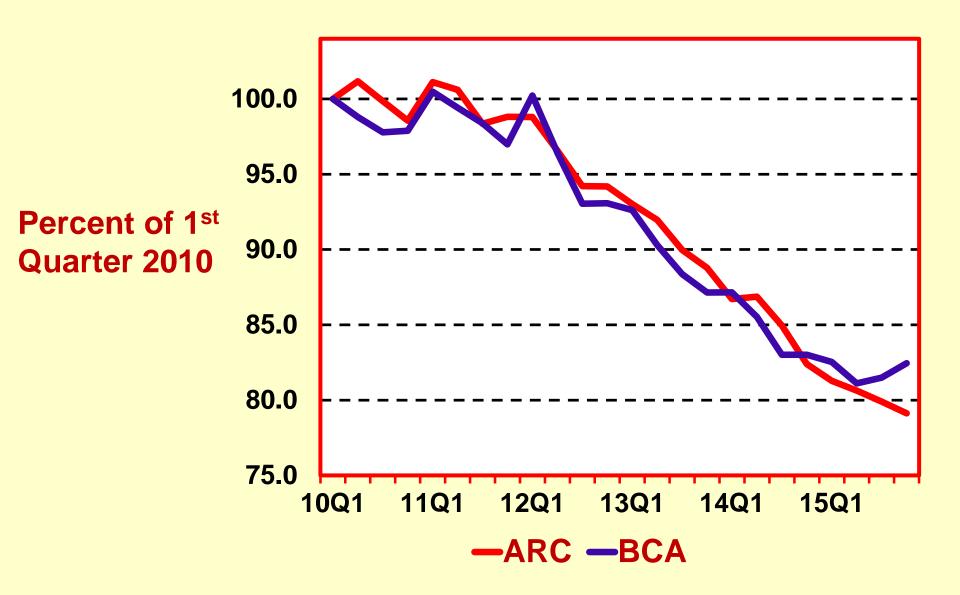
Health Affairs. Submitted 2003

Allogeneic whole blood and red cell collections: US

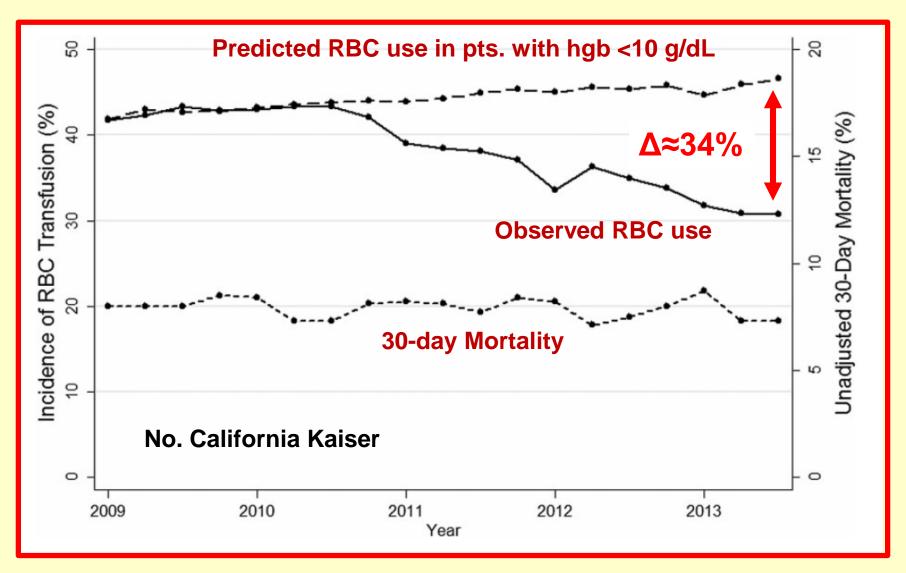


Source: HHHS, National Blood Collection and Utilization Surveys

2010-2015 US Blood Centers RBC Distributions

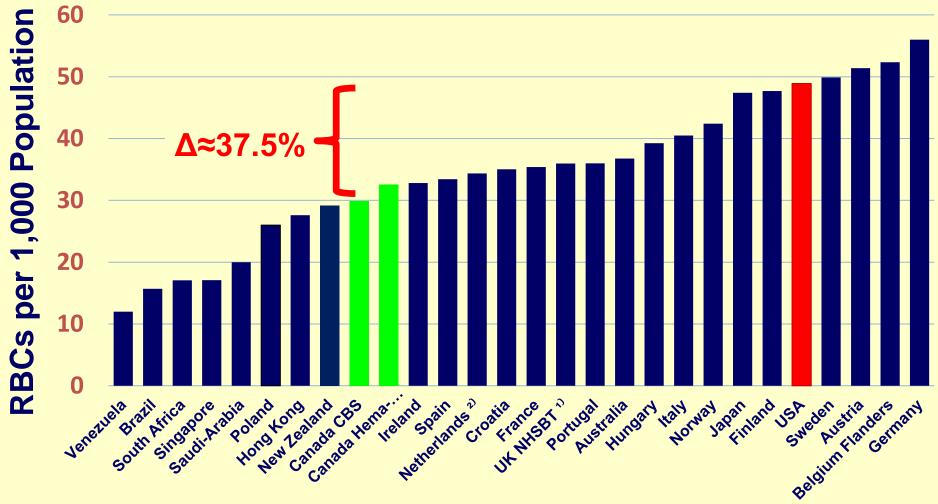


What we are doing: RBC use



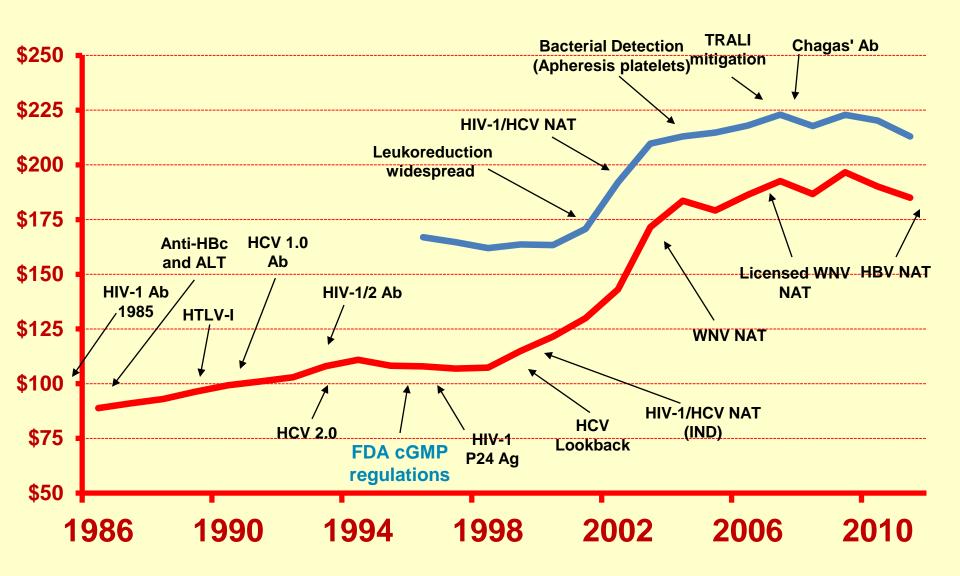
Roubinian et al. Transfusion. 2014

Variation in practice: global RBC transfusion rates: 2008-09



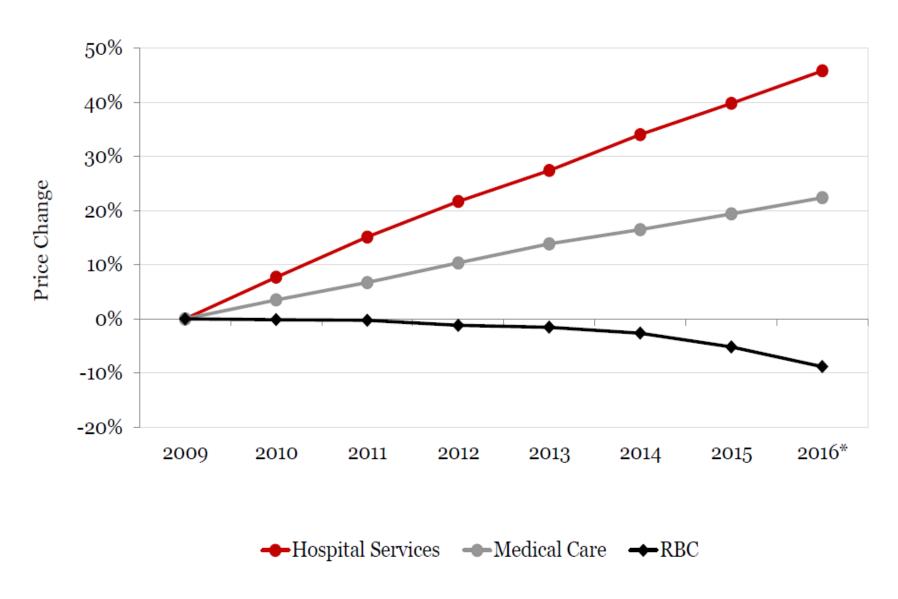
Adapted from Devine D et al: International Forum: Inventory Management. *Vox Sanguinis.* 2009.

Price v. safety RBC and LR-RBC: ABC



^{*}Median, America's Blood Centers, ABC Newsletter.

Consumer Price Index Trends



Hrouda C. ACTBSA. Nov. 2015

So, where are we?

- Declining use of the core products
 - Shed excess capacity (shed disaster capacity?)
 - Diversification (not within reach of all)
 - Fixed costs do not change
- Regulatory requirements/realities
 - Extensive licensure requirements, long approval cycles (vendor caution re: new products)
 - FDA can't consider cost, CMS "doesn't", hospitals are unsympathetic
 - Zero-risk? How safe is safe enough and who decides?
- Increasing price pressure from hospitals and systems
 - Lean operations (fewer jobs, less innovation)
 - Competition, mergers and acquisitions
 - DRG and other prospective payment systems

Now what?

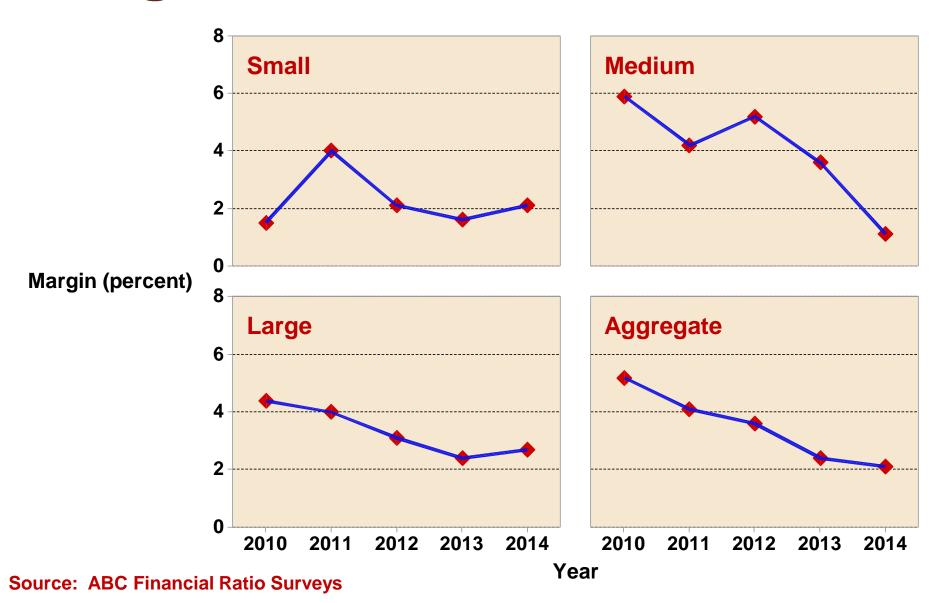
At some risk of preaching to the choir!

- Declining use of RBCs
- Adequate supply (sorta)
- †Safety/quality/regulatory burden
- Increasing price competition for hospital/system business

Commoditization of blood

No Δ fixed costs=declining margins

Margins at ABC centers 2010-14



725 15th Street NW Suite 700, Washington, DC 20005 Tel: 202-393-5725 Fax: 202-393-1282

1-888-USBLOOD | www.AmericasBlood.org

Friday, January 24, 2014

To: Dave Green, Pat McEvoy, James Aubuchon, Brian Custer, and Rob Purvis

From: L. Katz and C. Zamoricki

Re: The value of blood.

What is the value of blood? ABC staff and others are interested in answering this direct question. We would like your opinion on some basic questions before we commit to moving forward with development of a paper for publication.

Few argue that to the hemorrhaging patient or the thrombocytopenic leukemic, blood and components are not life saving. In less dramatic clinical situations, the answer is more ambiguous and many debate their worth. In addition to the usefulness of blood in the foregoing situations, there is a third circumstance in which blood is important that is not well studied. This is what we call the "insurance value of blood".

This refers to the clinical and economic benefit realized by the availability of blood, as opposed to its administration. Consider the orthopedic surgeon who will not drop the knife for a hip arthroplasty without type and cross-matched blood available in the OR refrigerator. Or the oncologist who delays chemotherapy for a high-grade lymphoma without the assurance that blood and platelets are on hand. Trauma programs are developing protocols for balanced transfusion of RBCs, platelets and plasma that in most institutions are rarely activated, but require prospectively agreed upon par levels of O negative RBCs and AB plasma, often far in excess of actual clinical use.

The ABC plan

- Commission an <u>independent</u> study to describe...
 - The "value" of blood
 - Clinical
 - Insurance
 - Disaster preparedness
 - The inventory and infrastructure required to maintain that value
 - The current system of collection, distribution and reimbursement for blood
 - The gap between that value and reimbursement
 - If a serious gap is confirmed what alternative models that should be considered

24 Sept. 2014

To: Value of blood group

From: Louie Katz and Christine Zambricki

Re: Value of blood project

We have been interviewing "think tanks" since the spring about this potential project. The interviewees include:

- 1. The Altarum Institute
- 2. The Lewin Group
- 3. The Rand Corporation
- The U of Michigan Center for Value-based Insurance Design
- Avalere Health LLC

We have asked for an independent analysis of the gap between the "value of blood" in the largest sense, and current reimbursement. We expect at least three completed proposals from this group, and want to prepare you for a discussion in the next several weeks (likely after AABB).

The analysis is to include an explicit valuation of components transfused, inventory required to be available regardless of whether it is used, and the value of the infrastructure and capacity that must be maintained in the blood community independent of the volume of transfusion. That valuation is to be contrasted to the current reimbursement levels and process. It will suggest alternative models in a white paper suitable for publication in a peer-reviewed health economics journal. This will be used as the foundation of a long-term advocacy initiative in support of the chosen reimbursement strategy(s). All the companies have been enthusiastic about the

OOPS—sticker shock!!



"I'm from the government, and I'm here to help you"

- AABB/ARC briefed, supportive, unwilling/able to commit the level of needed resources
- Our vendors (via AdvaMed) contacts
 - Issues with independence
 - No money anyway
- In light of Nov. 2013 ACBTSA hearings, HHS approached by CZ and LMK via committee staff (Jim Berger and Rich Henry in January 2015)
 - Competitive set aside funds available
 - RFP to appropriate contractors
 - Oversight by an ACTBSA subcommittee

ACTBSA: Subcommittee on Sustainability of the US Blood Supply

- Established Spring 2015
 - Broad makeup: centers, docs, hospitals etc.
- Response to \$\$\$ constrained blood community
 - Decline in RBC use
 - Increasing competition
 - Negative margins
- Overarching charge
 - Document state of not-for-profit blood community
 - Describe current system and evaluate sustainability
 - Propose changes and timelines to sustain safe, available, state-of-the-art blood supply

The Subcommittee

- Jim Berger: OASH. Sen advisor on blood and tissue policy
- Rich Henry: OASH. Advisor on blood and tissue policy
- Jay Menitove: ACTBSA Chair
- Bart Iddins: Commander, USAF 59th Medical Wing
- Chris Hrouda: ARC CEO
- Nancy Kane: Harvard Public Health. Prof. of Management
- Louie Katz: ABC CMO
- Debbie Seem: OASH. Tissue policy advisor

- Miriam Markowitz: AABB CEO
- Richard Benjamin: CMO Cerus
- Ronald Peterson: President.
 Johns Hopkins Hospital and Health System
- Louis Rossiter: College of William and Mary. Prof. Public Policy
- Michael Stoto: Georgetown
 University. Prof. of Health
 Systems Admin. and Pop. Health
- Ziggy Szcepiorkowski:

 Dartmouth-Hitchcock. Chief of
 Clinical Pathology
- Christine Zambricki: ABC CEO

ACTBSA November 2015

 Multiple stakeholders described the current environment from their perspectives: presentations @

http://www.hhs.gov/ash/bloodsafety/advisorycom mittee/pastmeetings/pastmeetings.html#nov15

- Open discussion
- Recommendations to the Sec. of HHS



划王义毛泽东思想万岁!

ACTBSA: Subcommittee on Sustainability of the US Blood Supply

Objectives for sustainability study I:

- 1. Describe/quantify business models in blood community and their sustainability
- 2. Quantify "insurance values of blood" including disasters and public health emergencies
- 3. Describe/quantify the impact on the blood community of changes in healthcare: reimbursement, consolidation into healthcare systems and other market forces that affect sustainability of the blood system
- 4. Describe relationship of hospital/healthcare system revenue-over-expenses and reimbursement schemes to current pricing for blood and components to offer incremental improvements in safety and availability

ACTBSA: Subcommittee on Sustainability of the US Blood Supply

Objectives for sustainability study II:

- 5. Describe impact of changes in clinical technologies and transfusion practices on sustainability of the blood system
- 6. Assess the declining elasticity of blood product availability brought about by the community reducing capacity to meet only current needs, switching to just-in-time business model and its impacts on public health emergencies
- 7. If appropriate based on evidence accrued, suggest alternative models for sustaining the blood supply

1)Initiative Title	2)Total Annual Budget
Evaluation to illuminate market factors deterring the U.S.	
Blood industry from adopting new and emerging public	
health safety technologies in the era of health care reform	\$320,000

3) Proposal Information

Submitting office: OASH/OHAIDP

Collaborating offices: FDA/OBRR, CDC/BOOTS, NIH/NHLBI, private sector: American Red Cross,

America's Blood Centers, AABB

Point of Contact: Richard Henry <u>ricahrd.henry@hhs.gov</u> 240-453-8804

"During (ACTBSA) deliberations, industry leadership...responded to the ASH's charge warning this...situation is a perfect economic storm of cost cutting and cost incurring events with significant potential for adverse consequences for health care in the United States, with the *very real likelihood the U.S. blood industry will simply be unable...to adopt emerging public health science and safety measures that are in place within similarly developed nations...."*

"This...project shall provide the HHS/ACBTSA subcommittee with...funding to evaluate these...circumstances, providing...illumination of market structures...to the HHS/ACBTSA for consideration of the ASH's charge and for Secretarial recommendations to facilitate the adoption of blood safety and availability measures."

The Study

Towards a sustainable blood supply in the United States: an analysis of the current system and alternatives for the future

- Contracted to RAND Corporation
 - RAND to accept technical and scientific advice from the Subcommittee relating to scope of the objectives
 - Subcommittee, via Project Officer, Rich Henry (HHS): provide oversight of deliverables and timeline in manner not disrupting the integrity of independent research from RAND

Study & develop a report that...

- ...Describes the current US blood system, including suppliers of blood, users of blood, and transaction prices;
- Outlines opportunities and challenges under the status quo system;
- Describes the potential impacts of changes in health care delivery, payment, technology, and clinical practice on blood supply and prices;
- Discusses innovative approaches to more completely capture the full value of blood and blood products from different stakeholder perspectives; and
- Synthesizes across all components to develop and describe alternative blood supply and pricing models.

(Some) possible models

- Mega centers: 5-8 large programs
- Railroad model: 5-8 large processors/labs partnering with ≈100 local programs
- Dairy coop model: local programs own mega processing and distribution hubs
- Public utility model: direct payment to collectors with oversight councils
- Medical model: integrate into health systems and receive revenue for service instead of product-based
- EU et al models: a national blood supply

Next steps

- RAND at ABC in Jacksonville
 - Presentation during Leadership Forum
 - 2 focus groups with 4 ABC members each to understand the current environment from the standpoint of blood centers
- Study completion 12-18 months
- Subcommittee to review findings
- Committee will make and broadly communicate recommendations that it believes are necessary to create a safe and sustainable blood supply into the future



Bottom line: You can't make omelets without breaking eggs

Ikatz@americasblood.org