Blood Utilization Trends

Jay E. Menitove, M.D.

October 20, 2017
Learning Objectives

• Describe the key parameters that were assessed in 2015 NBCUS

• Review at least two potential impacts of the findings of the 2015 survey to the Blood Bank Community

• Discuss the current model of the Blood Banking in the US and possible changes to this model in the future.
SOUNDING BOARD

Crisis in the Sustainability of the U.S. Blood System

Harvey G. Klein, M.D., J. Chris Hrouda, B.H.S., and Jay S. Epstein, M.D.
NEJM Sounding Board

• Nations Blood Supply
  • Public trust
  • Strategic resource

• US blood pipeline is now in danger of disruption

• Medical community treats blood as a commodity
  • With declining demand, the cost per unit increases
    • Additional safety testing further increases costs
    • Hospital consolidation shifted bargaining power to hospitals (fewer customers for BCs)
NEJM Sounding Board

- For in-patients
  - No direct link between hospital reimbursement to blood centers and hospitalized patients
  - Changes in DRG payments not passed through to blood collectors
- Some type of significant public or private intervention will probably be required to maintain adequate blood-system infrastructure
  - WG to develop models to access stressors and potential solutions
  - The blood system is not sustainable absent structural changes
  - A mechanism is needed that will pay full value
- A constructive intervention to stabilize the US blood system, although urgently needed, has yet to be envisioned
Dramatic Utilization Decline—U.S.

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)
  • Declines continue in 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount paid, 2015 ($)</th>
<th>Amount paid, 2013 ($)</th>
<th>Difference, 2015-2013 ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (N)</td>
<td>IQR</td>
<td>Mean</td>
</tr>
<tr>
<td>RBCs, leukoreduced</td>
<td>$211 (1630)</td>
<td>$197-$228</td>
<td>$217</td>
</tr>
<tr>
<td>RBCs, nonleukoreduced</td>
<td>$204 (262)</td>
<td>$185-$225</td>
<td>$207</td>
</tr>
<tr>
<td>Whole blood–derived PLTs, each unit, not leukoreduced, not irradiated</td>
<td>$95 (101)</td>
<td>$68-$420</td>
<td>$242</td>
</tr>
<tr>
<td>Apheresis PLTs, leukoreduced</td>
<td>$524 (1668)</td>
<td>$495-$560</td>
<td>$537</td>
</tr>
<tr>
<td>FFP</td>
<td>$54 (1062)</td>
<td>$45-$64</td>
<td>$60</td>
</tr>
<tr>
<td>PF24</td>
<td>$52 (1389)</td>
<td>$45-$60</td>
<td>$63</td>
</tr>
<tr>
<td>Cryoprecipitate, each unit</td>
<td>$56 (1356)</td>
<td>$45-$80</td>
<td>$115</td>
</tr>
</tbody>
</table>

NCBUS

Sapiano MRP, et al. Transfusion 2017;57:1599-1624
Fewer staff/reduced blood center income

Median net income per FTE

With permission L Katz, America’s Blood Centers
Resultant fiscal impact

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.

Financial ratio, with permission L Katz, America’s Blood Centers
## Donor Demographic Changes

<table>
<thead>
<tr>
<th>Donations by donor age (years)</th>
<th>All facilities, number (95% CI)</th>
<th>Percentage of total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2015</td>
<td>2013</td>
</tr>
<tr>
<td>16-18</td>
<td>1,521 (1,406-1,636)</td>
<td>1,591 (1,458-1,724)</td>
</tr>
<tr>
<td>19-24</td>
<td>1,236 (1,165-1,308)</td>
<td>1,569 (1,470-1,668)</td>
</tr>
<tr>
<td>25-64</td>
<td>7,182 (6,737-7,627)</td>
<td>8,252†</td>
</tr>
<tr>
<td>65 or older</td>
<td>1,401 (1,297-1,504)</td>
<td>1,457 (1,363-1,550)</td>
</tr>
<tr>
<td>Repeat allogeneic donations</td>
<td>7,216 (6,545-7,886)</td>
<td>‡</td>
</tr>
<tr>
<td>Total successful donations</td>
<td>11,339 (10,689-11,989)</td>
<td>12,869§</td>
</tr>
<tr>
<td>Number of donors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-time allogeneic</td>
<td>2,223 (2,058-2,388)</td>
<td>2,530 (2,288-2,771)</td>
</tr>
<tr>
<td>Repeat allogeneic</td>
<td>4,589 (4,213-4,966)</td>
<td>‡</td>
</tr>
<tr>
<td>Total individual donors†</td>
<td>6,812 (6,343-7,282)</td>
<td>‡</td>
</tr>
</tbody>
</table>

*NCBUS* Sapiano MRP, et al. Transfusion 2017;57:1599-1624
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.
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

ACBTSA Subcommittee on Sustainability of the Blood System

• ACBTSA is the proper entity for addressing these issues and making recommendations to the Department of Health and Human Services (discussion at ACBTSA December, 2014)

• Sub-committee on Sustainability of the U.S. Blood System
  • Document the state of the blood supply
  • The factors challenging its sustainability
  • The projected timing when change is necessary
ACBTSA Subcommittee on Sustainability of the Blood System (cont’d.)

• Approach
  • DHHS contract with a consultant
  • Sub-committee provides
    • Scope of work input
    • Study guidance
    • Consideration of the findings
    • Broad communication of findings
Sustainability of US Blood System

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**).
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.
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.
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.
• 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
IOM and Task Force Recommendations---1995

• Recommendation 1:
  • The Secretary of HHS should designate a Blood Safety Director...to be responsible for the federal government’s efforts to maintain the safety of the nation’s blood supply

  • Formation of a PHS Blood Safety Committee, chaired by the Blood Safety Director
    • FDA Commissioner
    • CDC Director
    • NIH Director
    • PHS Interagency Working Group on Blood Safety and Availability
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 (ASPE)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- 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
      • Lack of supplies
  • Lack of innovation support
  • Lack of central decision making
  • ? System elasticity
Recent Sustainability Sub-committee Activities

- Three Working groups established
  - Hospital
  - Blood Center
  - Industry Suppliers
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
Industry Suppliers Working Group

• RAND did not analyze long term effect of industry investment for innovation
  • Even existing technologies are at risk

• 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
  • Public/Government and Private/Transfusion Medicine interaction
• Data collection
• Pertinent recommendations !!!???
Modelling

- WG5s 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
Data Collection

• Inventory
  • How will supply match demand?
    • Inventory at BC’s
    • Inventory in transit
    • Hospital data
      • Fill rates
        • Standing orders
        • Ad hoc requests
  • Pricing information
    • Contractual (long term)
    • Ad hoc (spot market)
Data Collection (cont’d.)

- Sensitive information
  - Competitive issues

- Information is protected
  - Anonymous
  - Aggregated
  - Available only for analysis
  - Confidential data not available through FOIA

- Contract awarded to Blood Hub
Medicare Payment

• Discussion
  • Statutory Background
    • In-patient (IPPS)
      • Single payment/bundled
    • Out-patient (OPPS)
      • Hybrid
        • Fee-for-service/bundled
  • November 1, 2002 OPPS Final Rule
    • “…costs associated with blood safety testing are fully recognized. The safety of the nation’s blood supply continues to be among the highest priorities of the Secretary’s Council on Blood Safety and Access. Therefore, we proposed to continue to pay separately for blood and blood products.”
      • Pathogen Reduced Blood Products
        • Platelets and rapid bacterial testing
Caveats

• Blood utilization decline
  • resulting blood center consolidation into fewer, but larger organizations

• ACBTSBA 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
Questions?