



America's Blood Centers

It's About *Life.*

**Government's Role in Assuring the Safety and Adequacy of
the National Blood Supply:
Supporting Community-based Blood Centers**

**Louis M. Katz MD: President, America's Blood Centers
Presentation to the Advisory Committee on Blood Safety and
Availability
27 January 2004.**

The US Blood Collection System

- ▲ 47% ABC: Locally controlled not-for-profit, individually FDA licensed collection centers
- ▲ 45% ARC: Nationally controlled not-for-profit organization with a single FDA license
- ▲ 6% Hospital based donor centers: generally registered, most not FDA licensed
- ▲ 1% Armed Forces Blood Program
- ▲ 1% Other

The US Blood Collection System

- ▲ ARC and the community-based ABC centers were formed to meet local needs
 - ▲ About 7% of RBCs from ABC centers with effective collection strategies are shared with other centers
- ▲ Hospital-based programs were established to meet hospital's individual needs
 - ▲ Most are not self-sufficient
 - ▲ Most cannot export across state lines
- ▲ The military meets most of its own "routine" needs

Where Have all the Donors Gone?

- ▲ Surrogate testing for NANB Hepatitis
- ▲ Deferrals for malaria, medications
- ▲ vCJD Deferrals
- ▲ Implementation of cGMP – “When in doubt, defer”
- ▲ HCV/HIV testing
- ▲ WNV Deferrals
- ▲ Closure of access to military sites during conflict

Blood Shortages Are Increasing

- ▲ US blood center supply
 - ▲ Before September 11, 3-5 days
 - ▲ Today, 2-3 Days
- ▲ FDA deferrals are increasing
 - ▲ For example, vCJD affected 8-10% of willing, frequent donors; continuously additive
- ▲ Blood demand increases as US population ages
- ▲ Sub-optimal utilization patterns

Meeting Today's Challenges

- ▲ Why don't most hospitals feel the effect?
 - ▲ We work harder to assure supply
 - ▲ Blood center inventories have been shifted to hospitals

- ▲ Successful collections depend upon investment of more resources (\$\$) in:
 - ▲ Recruitment
 - ▲ Personnel, mobile and fixed collection units, paid and pro bono advertising

ABC Donor Recruitment Initiatives

 *My Blood, Your Blood*

 MDI (Member Donor Initiative)

 Ad Council campaign (with ARC & AABB)

 National Blood Drives

 E-Donation

Initiatives Focused on the Blood Supply

- ▲ ABC Stoplight, 1st national public realtime supply monitor
- ▲ Resource Sharing
 - ▲ BCA, direct center contracts, AABB National Blood Exchange supplemented by:
 - ▲ ABC efforts to support shortage areas (e.g.: New York, Memphis, Richmond)
 - ▲ Internet system for members to post surpluses and order blood
 - ▲ “Blast e-mail” to all 76 members about emergency blood needs



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America's Blood Centers

Important Information
About West Nile Virus
& the Blood Supply

1-888-USBLOOD

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★ How to Give Blood

- Join Our National Blood Donor Registry
- "The ABC's of Blood"
- How Blood Saves Lives
- FAQ

▪ How to Get Involved

- Meet Other Blood Donors
- National Blood Drives
- How to Hold a Corporate Blood Drive
- Information for Students

▪ Who We Are

- About America's Blood Centers
- Our Members
- The Foundation for America's Blood Centers

▪ What We Do

- Medical Issues in the Blood Industry
- Government Affairs
- America's Blood Centers Publications
- America's Blood Centers Partners

September 11, 2001

What's New

Newsroom



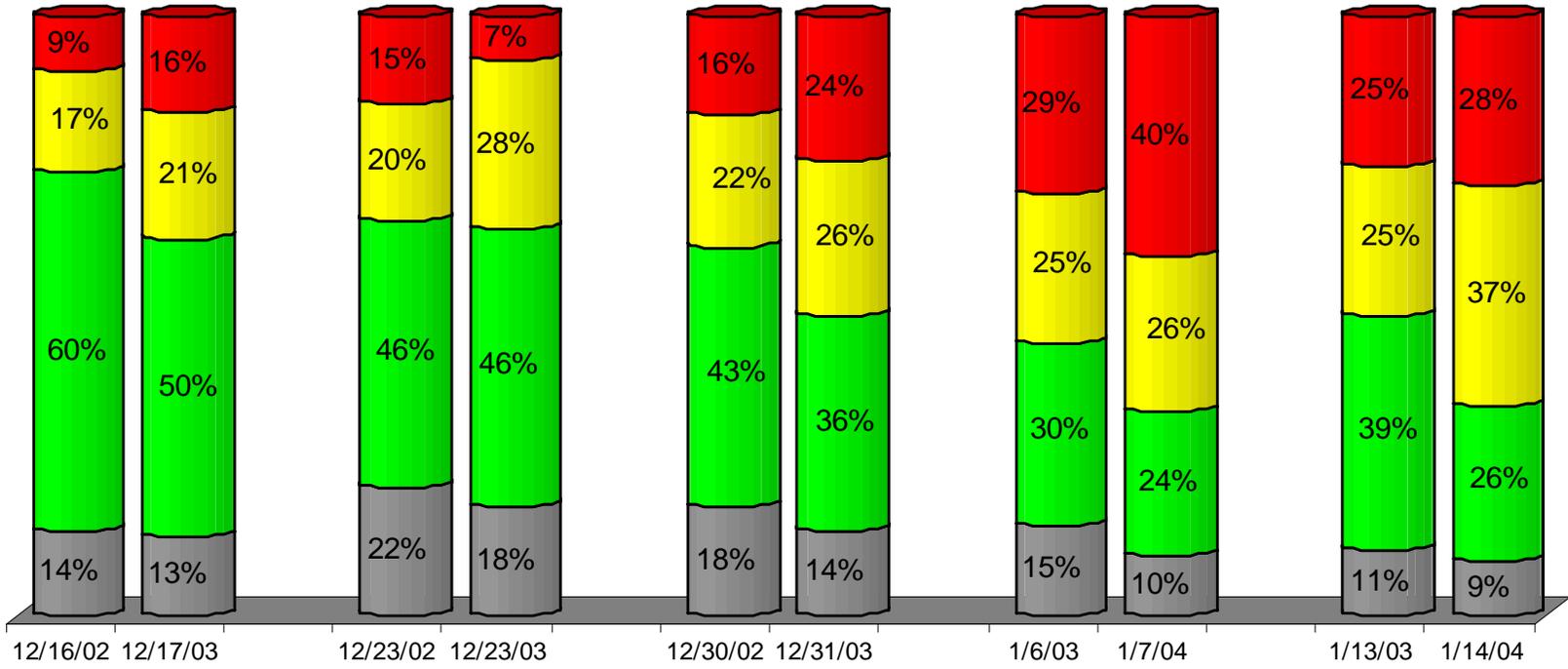
Check
Blood
Supply

Click to
Find Your Local
Blood Center



Despite Historic Success, Supply is not Keeping Pace with Demand

ABC's Red Blood Cell Supply: Percent of Supply



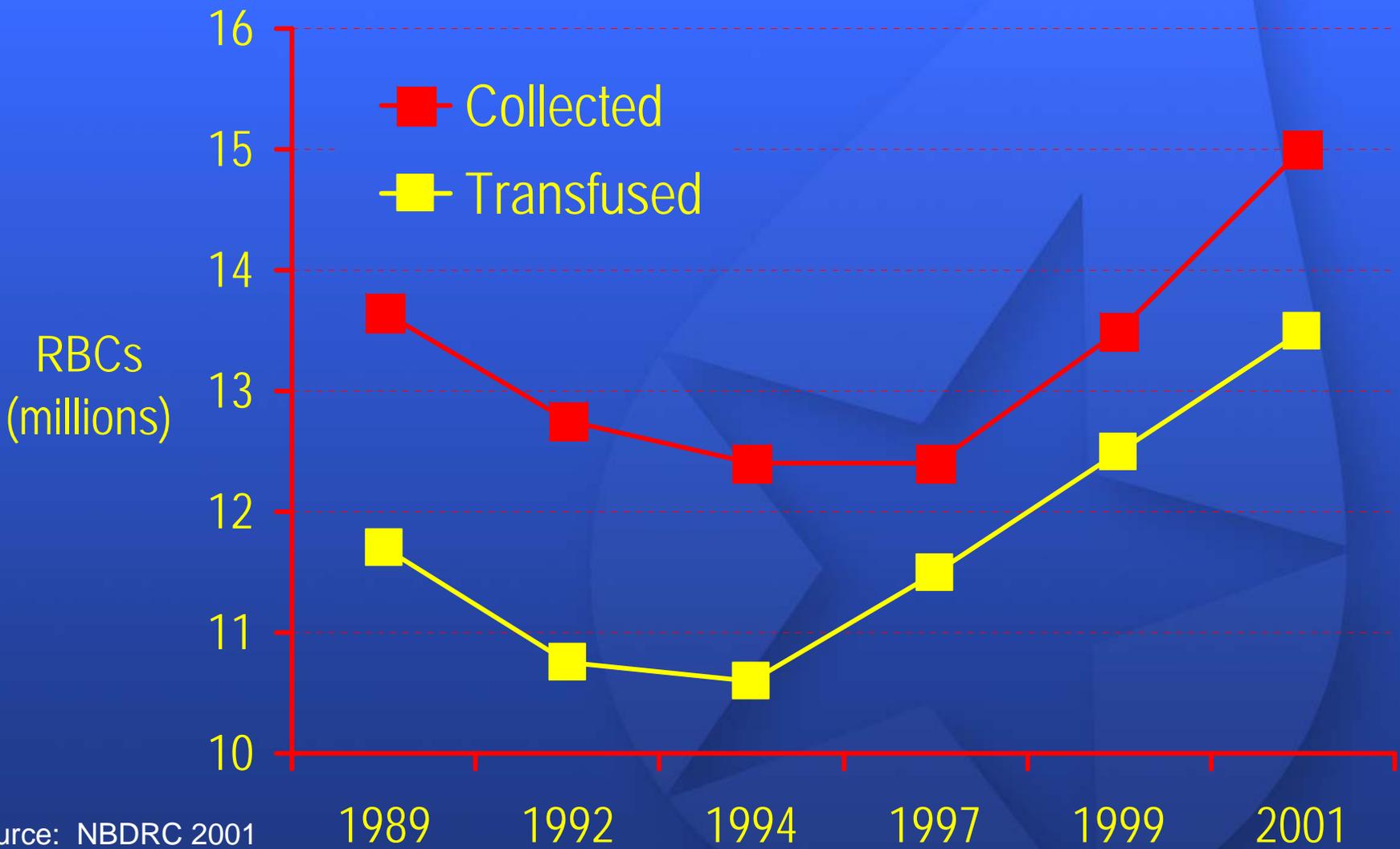
■ No Response ■ Green: 3 or More Days Supply ■ Yellow: 2 Days Supply ■ Red: 1 Day Supply or Less

The order of the bars is (from top to bottom), red, yellow, green, and no response

Some Centers Have Been Unable to Offset Increased Demand & New Deferrals

- ▲ Large number of tertiary care centers
 - ▲ Increased use, disadvantageous case mix
- ▲ Located in areas with
 - ▲ Complex economic and demographics
 - ▲ Competition for altruism
 - ▲ Rural vs. urban sense of community & priorities
- ▲ Disproportionate local impacts of new restrictions
 - ▲ NYBC and vCJD: 25% immediate loss
 - ▲ Centers dependent on military/former military donors

Can we Meet Increased Demand in the Current System?



Source: NBDRC 2001

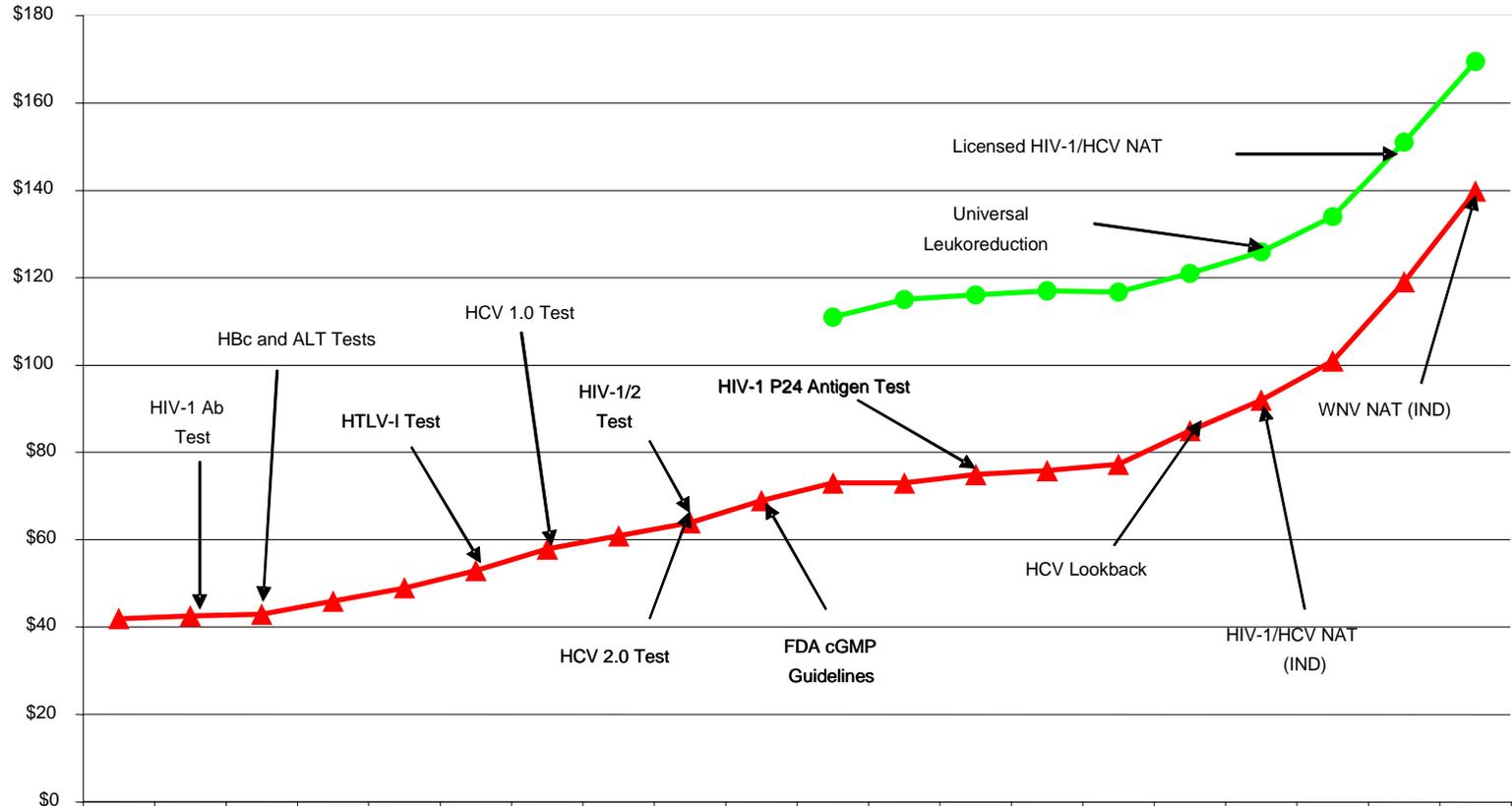
Why Don't We Charge More?

- ▲ Reimbursement by CMS is slow to reflect mandated increases in cost for safety
 - ▲ Last year (despite WNV NAT and vCJD related expenses and no increases for leukoreduction or HCV/HIC NAT), CMS proposed cutting reimbursement for blood
 - ▲ Regulatory costs mandated by FDA are not considered by CMS
- ▲ Non-CMS payers use CMS as benchmark
- ▲ Enormous pressure from hospitals to restrain increases in component cost result

The Cost of Safety

- ▲ Blood collection organizations have absorbed multiple additional costs associated with producing a safer product.
 - ▲ Unrecovered costs of safety measures reduce operating margins. Money spent for compliance is shifted from:
 - ▲ Capital investment
 - ▲ Innovative donor recruitment
- ▲ The future depends on this committee tying reimbursement to safety and availability, as its name implies
 - ▲ ACBSA must maintain pressure on CMS and the Secretary to quickly and accurately determine the cost of blood products and adjust reimbursement and we will reinvest in infra-structure and recruitment

America's Blood Centers Safety Measures and Average Red Blood Cell Service Fees 1984 - 2003



	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
▲ RBCs	\$42	43	43	46	49	53	58	61	64	69	73	73	75	76	77	85	92	101	119	140
● RBCs, LR											111	115	116	117	117	121	126	134	151	169

Despite Challenges, the System Works

- ▲ More than 4 million lives saved each year by blood transfusion
- ▲ On occasion, elective surgeries have been delayed to assure a local emergency supply (Triage)
- ▲ Local and regional shortages occur, but there has been no NATIONAL crisis (e.g., deaths or widespread organ wastage)

Does Government Have a Role in a Country without a National Blood Program?

Yes, in:

- ▲ Promoting the will to donate as a civic responsibility
- ▲ Insuring adequate reimbursement and timely adjustments
- ▲ Funding initiatives necessary for the appropriate regulation of a safe and adequate blood supply, e.g.,
 - ▲ Validate proposed donor screening questions before they appear in Regulations or Guidance Documents
 - ▲ Evaluate changes in eligibility criteria before implementation and work with private sector on strategies to offset donor losses

Government Role

- ▲ Rapidly and openly assessing new threats to blood safety and risks to donors or patients
- ▲ Supporting research on the appropriate use of blood components
 - ▲ Any decline in the blood use is an increase available supply
- ▲ Changing rules that prohibit CBER from talking to private sector before promulgating regulations or guidance (a role for “negotiated rulemaking?”)
 - ▲ Negotiations may uncover ways to improve safety with little disruption in process or supply
 - ▲ Could have improved outcomes in recent CBER actions regarding vCJD, SARS, Smallpox vaccine, WPM

Government Role in Disaster Response

- 🇺🇸 September 11 and the weeks following are a clear demonstration that adequacy is not an issue in response to disaster
- 🇺🇸 September 11 and Top Off exercises have demonstrated the need for...
 - 🇺🇸 ...logistical and transportation support to move blood, testing reagents and supplies to the appropriate location in the event of a natural or man made disaster
 - 🇺🇸 ...a system available to rapidly collect and disseminate information in a crisis

Summary

- ▲ The current system has saved tens of millions of lives in over 60 years of blood banking
- ▲ Government should...
 - ▲ Protect the safety of donors and recipients
 - ▲ Promote a culture of donation as a civic responsibility
 - ▲ Assure that reimbursement reflects the cost of safety
 - ▲ Promote innovation and research:
 - ▲ To rapidly and openly assess the risks of new threats and impact of safety initiatives
 - ▲ To promote appropriate use of blood
 - ▲ Leave the management of collection, processing and distribution to the experts



America's Blood
Centers

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Thank you