



United States Department of
Health & Human Services

Supply Status, Risk, and Guidelines for Blood Transfusion

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Outline

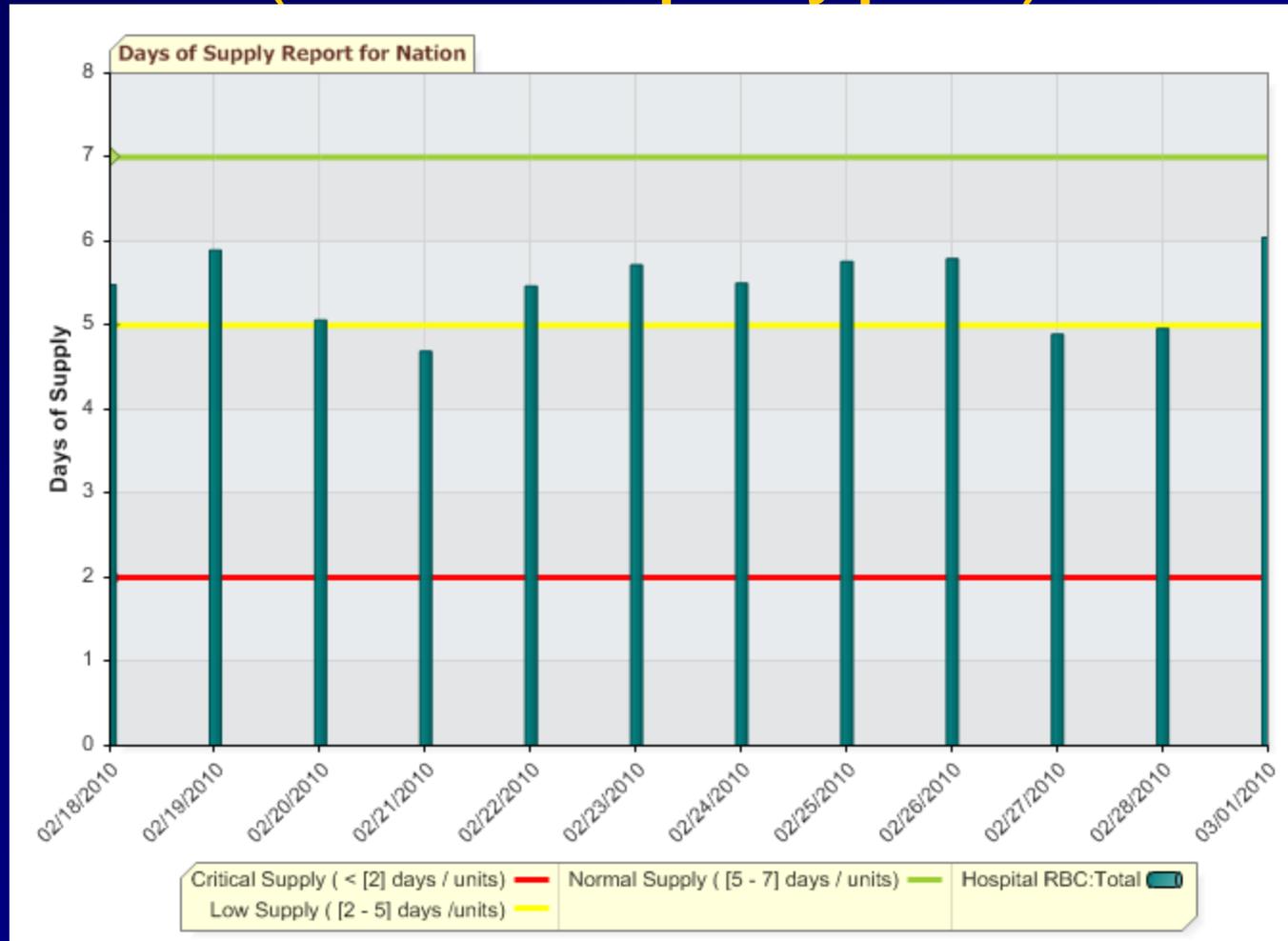
- ❑ Status of blood supply
- ❑ Current risk of blood
- ❑ Activities to monitor adverse events
- ❑ Transfusion practice patterns and guidelines

Estimated US Blood Supply

Mar 5, 2010

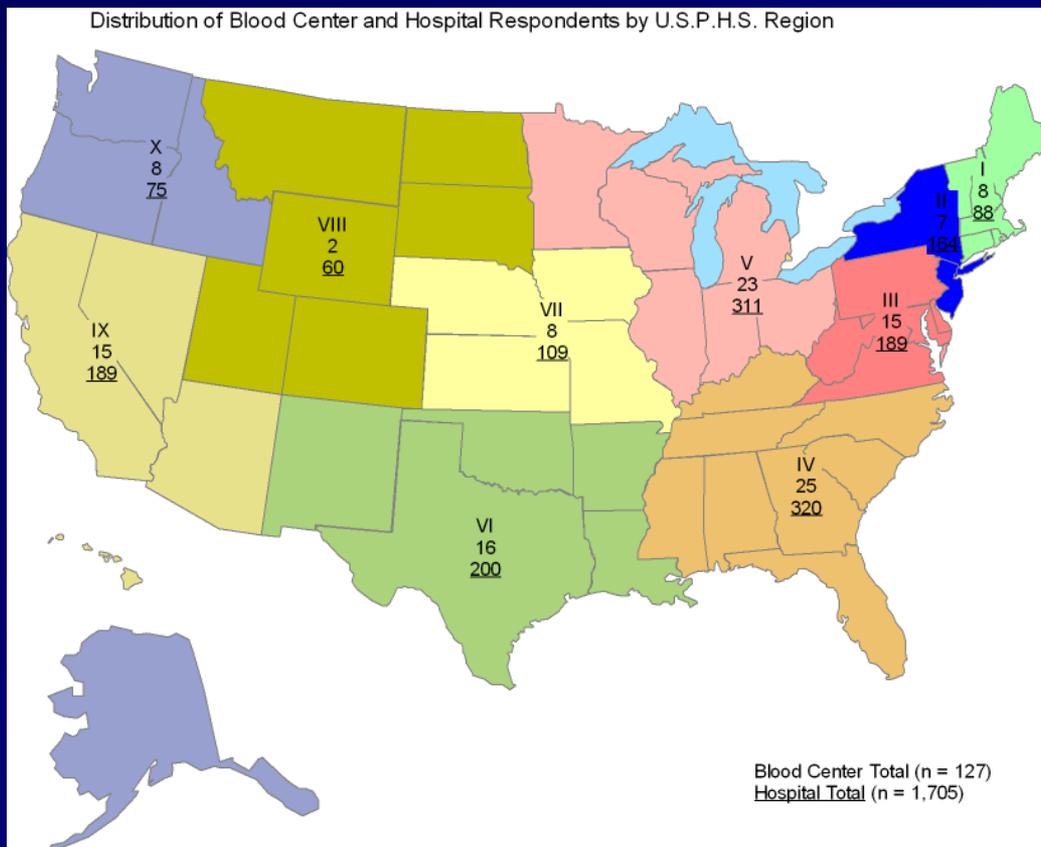
| Blood Groups/ Type | Estimated Days of Supply | Blood Distribution Inventory | Estimated Hospital Inventory: constant 6 day supply | Estimated US Blood Supply (RBC) |
|-----------------------|--------------------------------|------------------------------------|---|--|
| O+ | 8.0 | 143,025 | 107,058 | 250,082 |
| O- | 3.3 | 10,779 | 19,721 | 30,500 |
| A+ | 8.4 | 134,680 | 95,788 | 230,469 |
| A- | 6.7 | 18,847 | 16,904 | 35,751 |
| B+ | 8.9 | 37,575 | 25,356 | 62,931 |
| B- | 5.0 | 4,659 | 5,635 | 10,294 |
| AB+ | 18.4 | 25,872 | 8,452 | 34,324 |
| AB- | 9.3 | 4,344 | 2,817 | 7,162 |
| Total | | 379,782 | 281,731 | 661,513 |

BASIS Hospital Red Cell Supply (All Group/Types)



Represents approximately 95 Sentinel Hospitals reporting consistently

National Blood Collection and Utilization Survey Overview



THE 2007
NATIONAL
BLOOD COLLECTION
AND UTILIZATION
SURVEY

Report



Source: HHS NBCUS 2007

www.hhs.gov/bloodsafety

2006 Key Findings: Donors

- ❑ 12,142,000 donors presented
- ❑ 9,554,000 allogeneic donors
 - ❖ 2,726,000 first-time donors (28.5%)
 - ❖ 6,828,000 repeat donors (71.5%)
- ❑ Repeat donors provided 11,697,000 donations – **1.7 donations/donor**

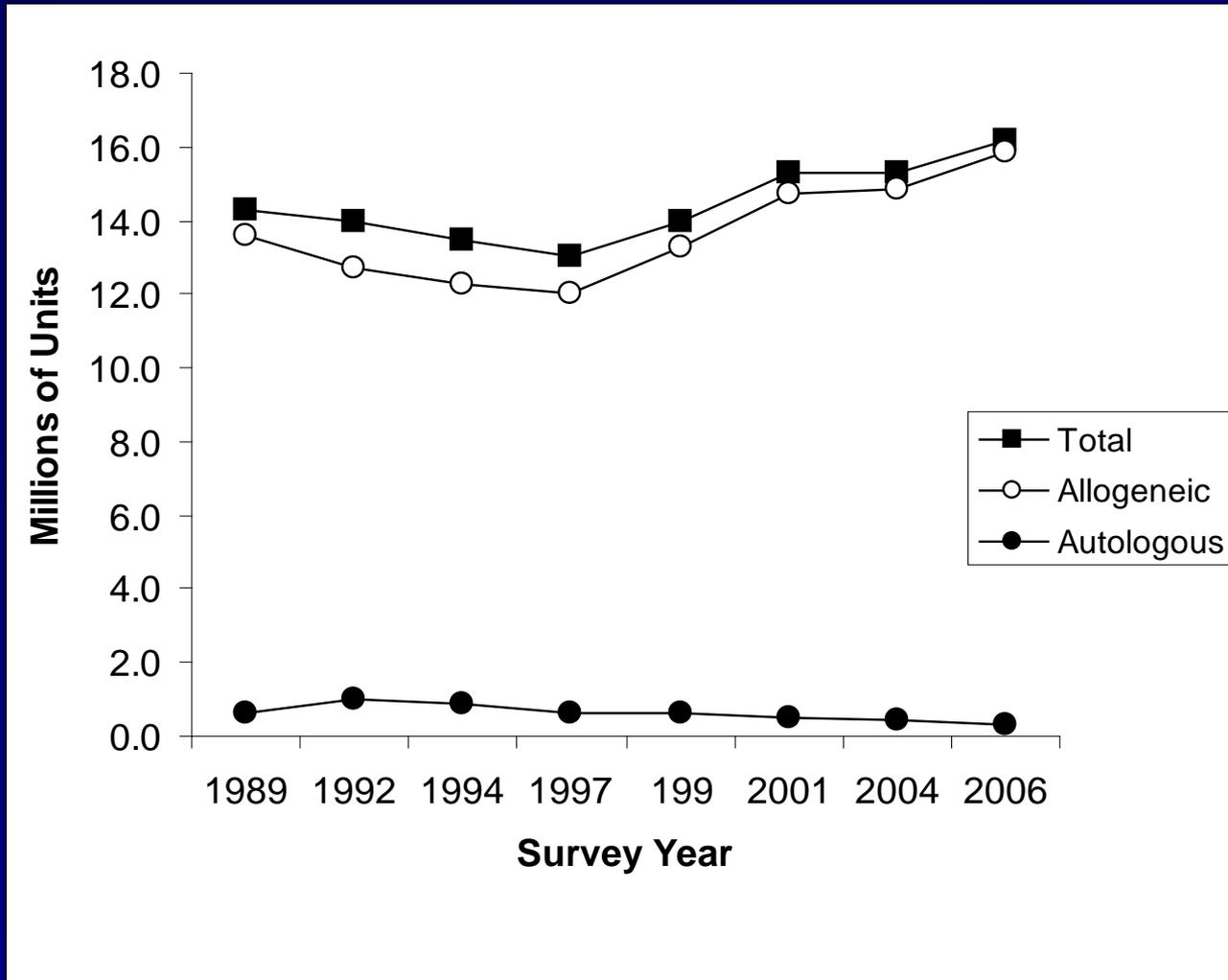
Hospital Cost of Blood

| Blood Component | Average Cost to Hospitals | HOPPS Reimbursement Rate |
|------------------------|----------------------------------|---------------------------------|
| Red Blood Cells* | \$213.94 | \$163.16 |
| Fresh Frozen Plasma** | \$59.84 (w/in 24 hours) | \$70.40 (between 8-24 hours) |
| WB derived Platelets | \$84.25 | \$51.50 |
| Apheresis platelets* | \$538.72 | \$493.12 |
| | \$53.31 | \$47.10 |

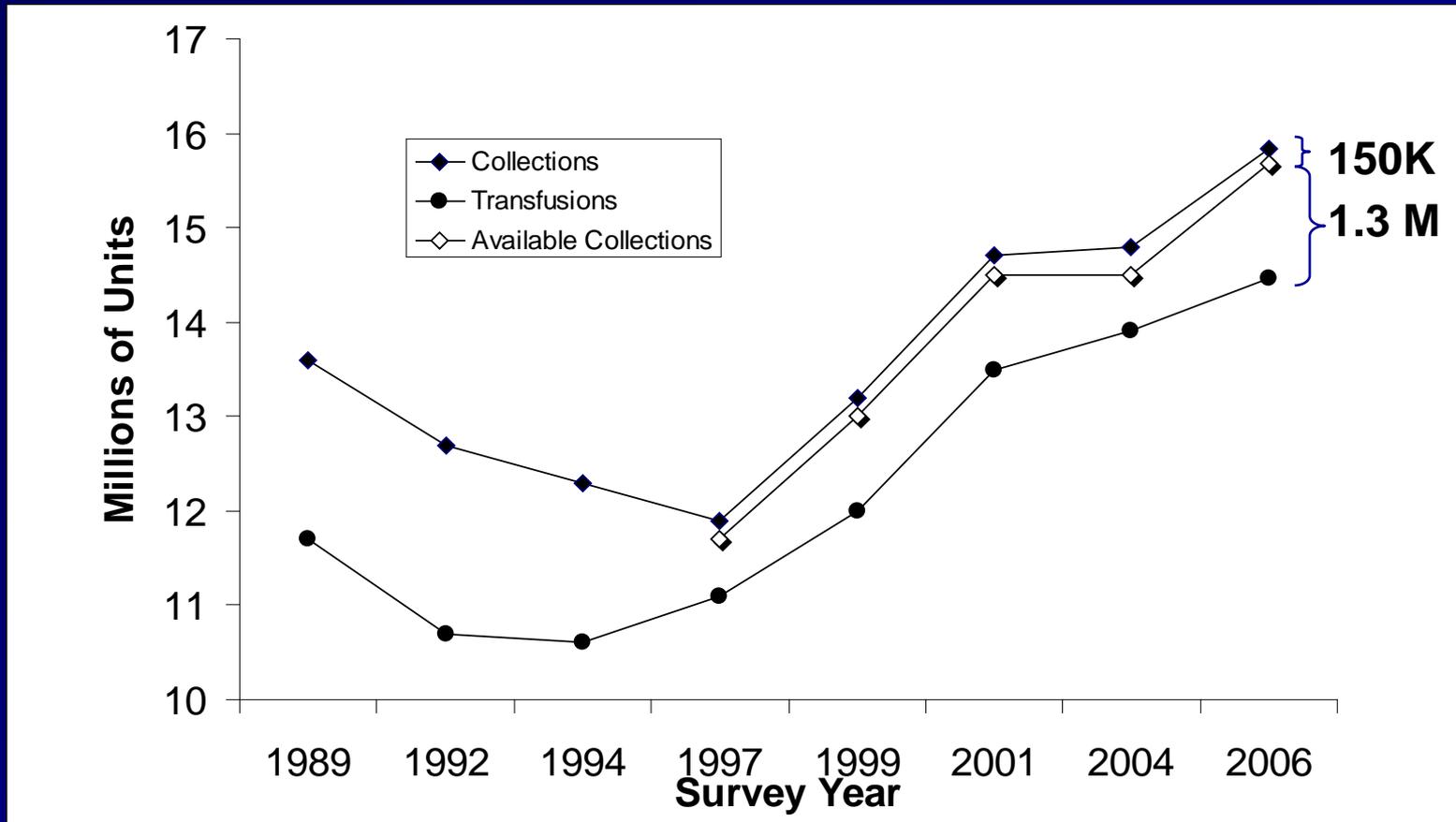
2006 Key Transfusion Findings

- 30,044,000 components transfused
 - ❖ 14,650,000 red cells
 - ❖ 10,388,000 platelet concentrate eq.
 - ❖ 4,010,000 plasma
 - ❖ 993,000 cryoprecipitate

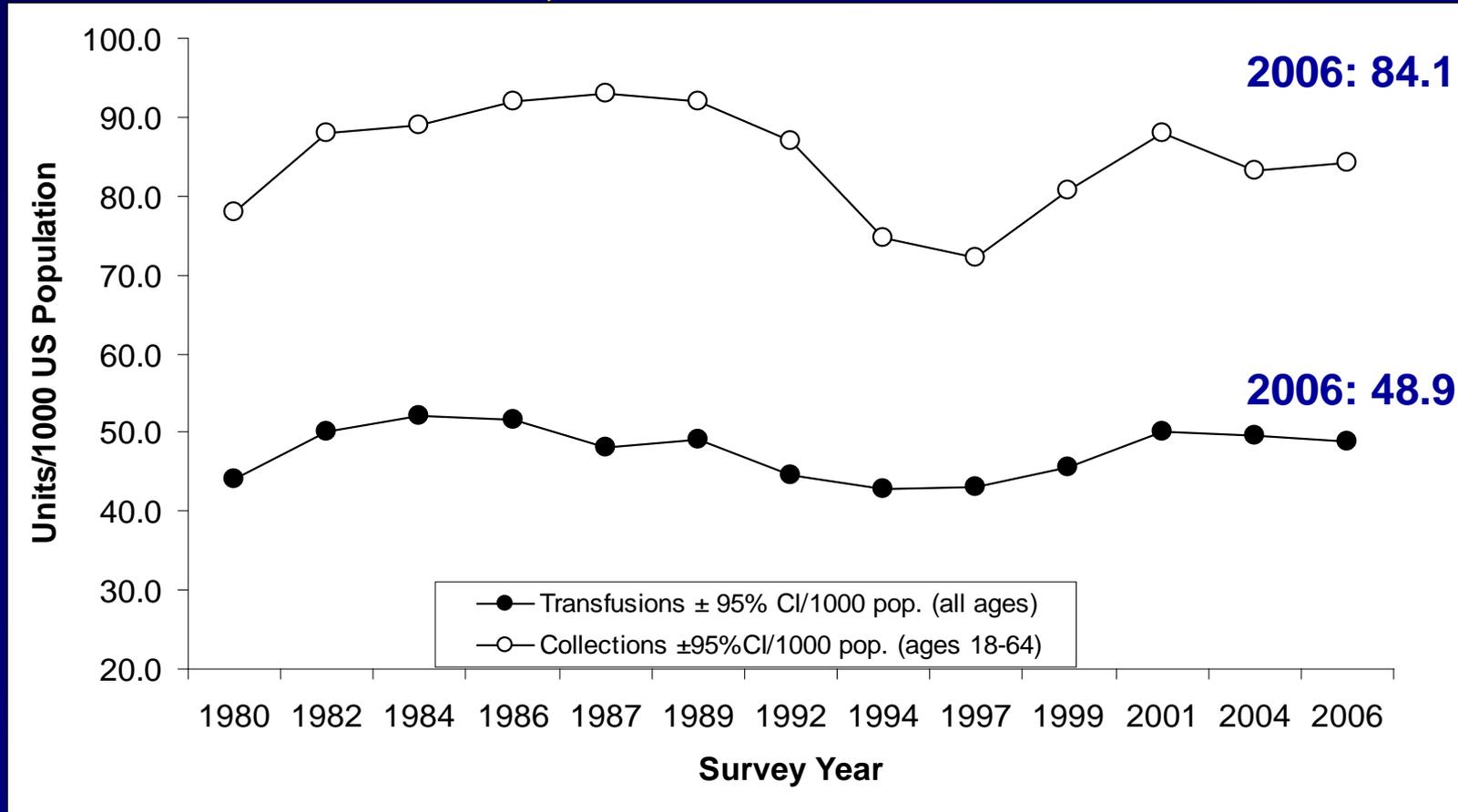
Trends in WB and RBC Collections



Trends in WB and RBC Collections and Transfusions



Trends in Estimated Rates of Blood Collection and Transfusion in the US, 1980-2006



Comparison in Developed Countries

| | US | England | Australia | Denmark | Sweden |
|----------------------------------|---------------------------------------|--|--|---------------------------------------|---------------------------------------|
| Units of RBC per 1000 Population | 48.75 (2001) 48.9 (2006) | 44.9 | 28 | 54.08 58.6 (2000-2002) | 45.3 (1996-2002) |
| Recipient Age | <41 18.8% 41-65 27.8% >65 53.3% | <40 14.4% 40-70 38.4% > 70 47.2% | <40 15.4% 40-70 36.7% > 70 47.9% | <39 9.4% 40-59 18.2% > 60 72.4% | <39 9.8% 40-59 15.1% > 60 75.2% |
| Gender | M 48.5% F 51.5% | M 50.4% F 49.6 | M 52.5% F 47.5% | M 53.2% F 46.8% | M 52.9% F 47.1% |

Characteristics of Transfusion Recipients

- Typical Blood Recipient Age Distribution
 - ❖ <41 18.8%
 - ❖ 41-65 27.8%
 - ❖ >65 53.3%
- 2006 - 6.6% decrease in transfusion recipients (compared to 2004) ~ unweighted 3 units per transfused patient
- Characteristics of Inpatient Medicare stays, ages 65 years or older
 - ❖ Male mean number of blood furnished 4.5(pints)
 - ❖ Female mean number of blood furnished 3.6 (pints)

Kamper-Jorgensen Transfusion 2009; 49:888-894

Cobain Transfusion Medicine 2007; 17, 10-15

Anderson et al, Transfusion 2007; 47: 582-592

Blood Safety

- ❑ ABO blood grouping
- ❑ Rh type
- ❑ Red cell antibody screen
- ❑ Antibodies to hepatitis B Core
- ❑ Hepatitis B Surface Antigen
- ❑ Antibodies to hepatitis C
- ❑ Antibodies to HIV-1
- ❑ Antibodies to HIV-2
- ❑ Antibodies to HTLV I/II - (human T-Lymphotropic Virus Types I and II)
- ❑ Nucleic Acid Amplification Testing (NAT) for hepatitis C
- ❑ Nucleic Acid Amplification Testing (NAT) for HIV
- ❑ Nucleic Acid Amplification Testing (NAT) for West Nile virus
- ❑ Syphilis

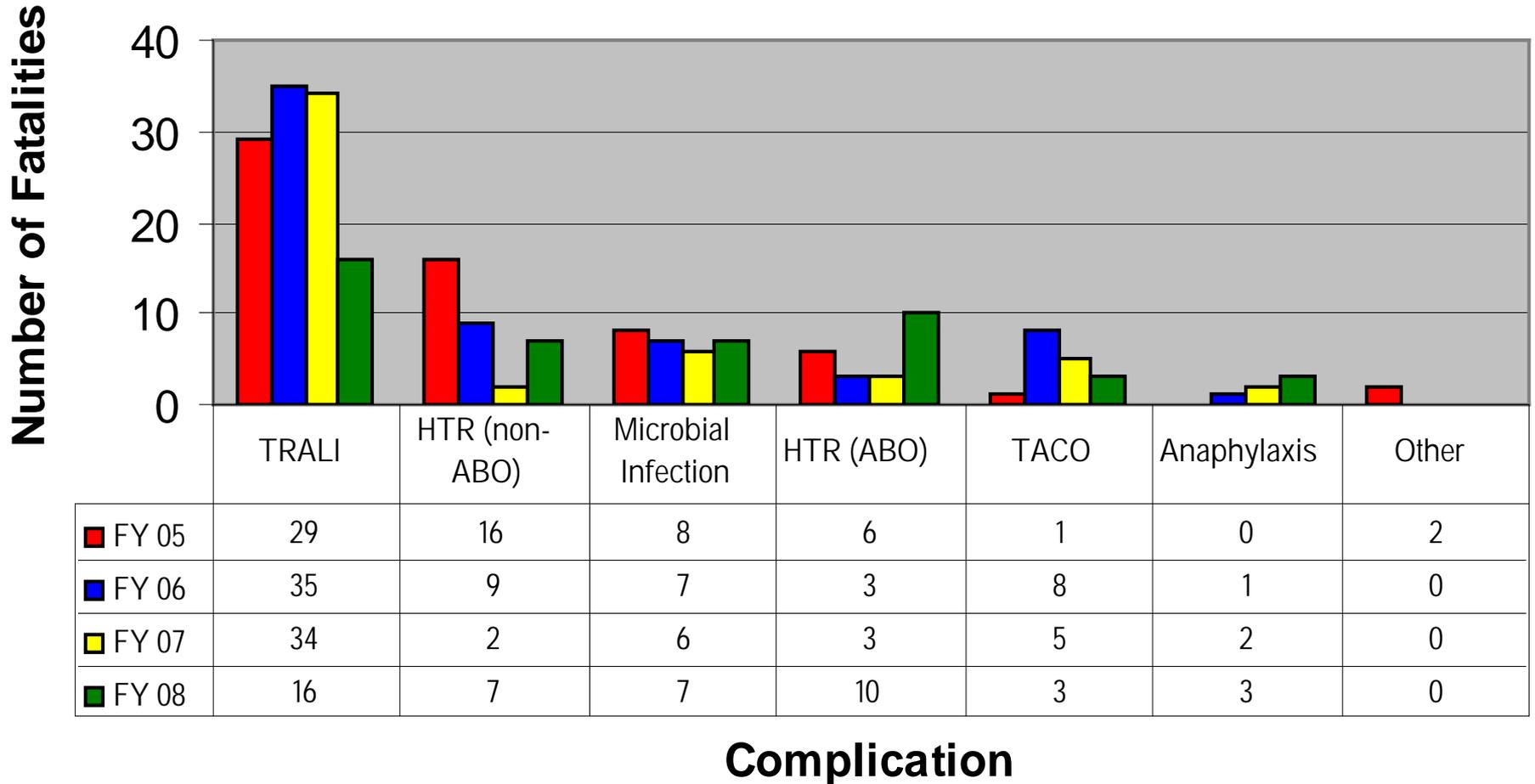
Current Risk of Infection for Test-Negative Blood Components in US

| Agent | Risk |
|--------|---|
| HIV-1 | 1 in 2,135,000 |
| HIV -2 | None (no direct or modeled measurement, fewer than 10 positive reported since 1992) |
| HCV | 1 in 1,935,000 |
| HBV | 1 in 205,000 to 488,000 |
| WNV | None |

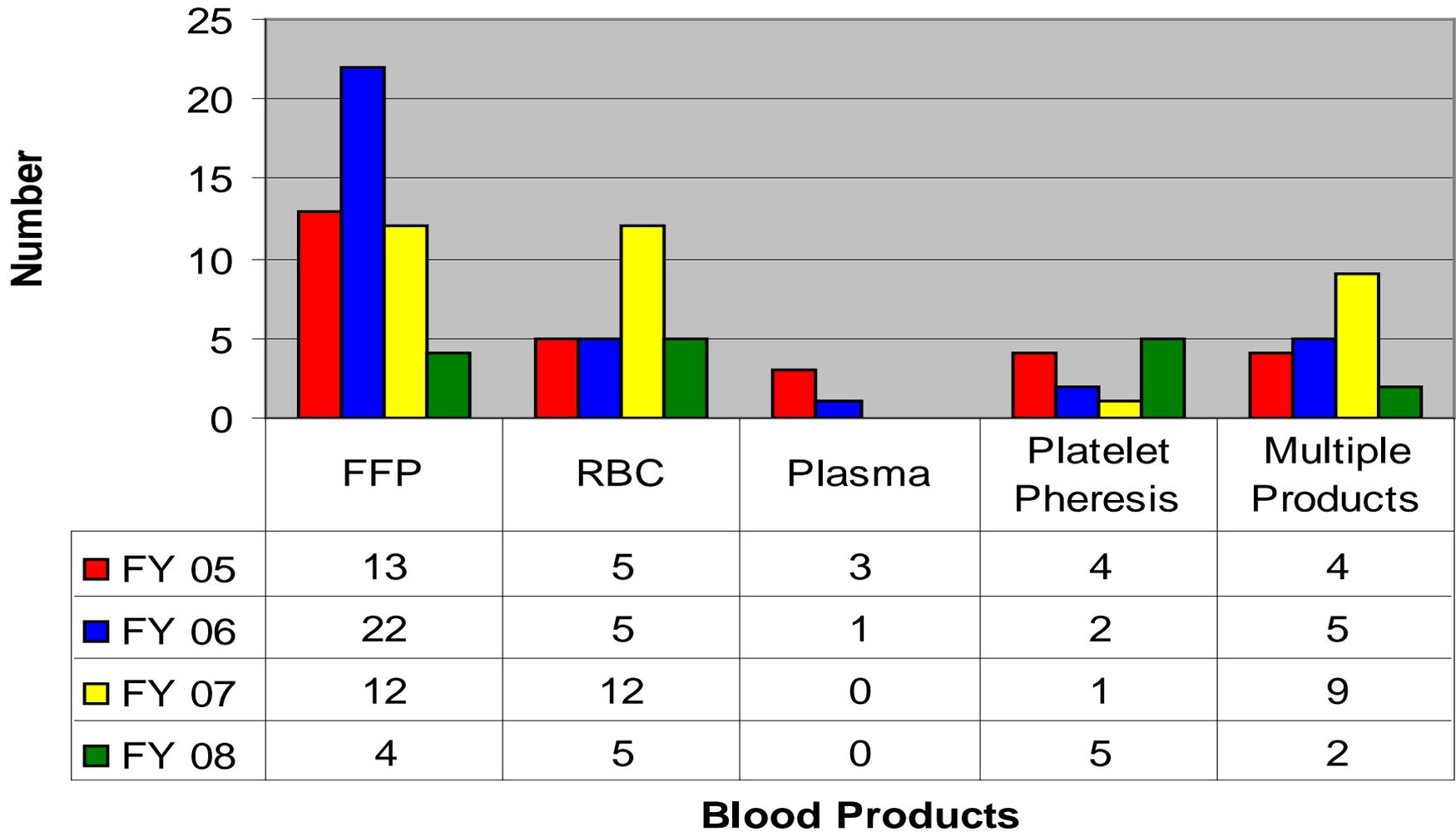
Risk Factors to Transfusion

- ❑ Transfusion Related Acute Lung Injury (TRALI)
 - ❖ Human Leukocyte Antibodies (HLA)
 - ❖ Human Neutrophil Antibodies (HNA)
- ❑ Hemolytic Transfusion Reactions (ABO and non-ABO)
- ❑ Microbial Infections
- ❑ Transfusion Associated Circulatory Overload (TACO)
- ❑ GVHD
- ❑ Anaphylaxis
- ❑ Panel Reactive Antibodies

FDA Reported Transfusion-Related Fatalities by Complication



FDA Reports of TRALI by Implicated Blood Products



Monitoring Adverse Events

- ❑ Hemovigilance (Recipient Module of CDC National Healthcare Safety Network)
- ❑ Patient Safety Organizations (AABB)
- ❑ Sentinel Initiative (FDA-CMS)
- ❑ The Joint Commission – Blood Measurement Elements

Transfusion Practice

- ❑ “Transfusion is rarely indicated when the hemoglobin level is above 10 g/dL and is always indicated in patients when the hemoglobin is below 6 g/dL.”
- ❑ “The determination of transfusion whose hemoglobin level is between 6-10 g/dL should be based on any ongoing indication of organ ischemia...”

Practice Guidelines for Blood Transfusion, American Red Cross, Second Edition 2007

Klein, HG, Anstee DJ eds. Mollison's Blood Transfusion in Clinical Medicine. 11 ed. Blackwell Publishing, 2005

Transfusion Practice

Australian Recommendations*

- ❑ “Decision to transfuse red blood cells should be based on clinical assessment of the patient and his or her response to any previous transfusion as well as the haemoglobin level.”
- ❑ Use of RBC is likely to be inappropriate when Hgb > 10 g/dL unless there is specific indications and documented
- ❑ Use of RBC may be appropriate when Hgb is in the range of 7 to 10 g/dL. Supported by the need to relieve clinical signs and symptoms and prevent morbidity and mortality.
- ❑ Use of RBC is likely appropriate when Hgb < 7 g/dL. Patients who are asymptomatic and/or where specific therapy is available, lower threshold may be acceptable.

*Clinical Practice Guidelines on the Use of Blood Components, endorsed September 2001 by National Health & Research Council and Australian Society for Blood Transfusion, Commonwealth of Australia 2002

Guidelines for the Clinical Use of Red Blood Cell Transfusions*

“Chronic anaemia is better tolerated than acute anaemia because of better oxygen delivery associated with an increase in 2,3 DPG and a shift in the oxygen dissociation curve.”

- ❑ “Reserve of oxygen-carry capacity is such that cardiac output at rest does not usually increase until the haemoglobin concentration falls below 7 g/dL”
- ❑ Risk and benefit must be considered. Clinical condition should be weighed into clinical judgment

**British Journal of Haematology* 2001; 113(1): 24-31

University of Iowa Guidelines

- ❑ No further justification for packed red cell use would be required if:
 - ❖ patients were critically ill (e.g., trauma, peri-operative) and without significant cardiac, pulmonary, renal, vascular, or neural disease and with a hemoglobin <7 g/dl.
 - ❖ patients were critically ill and with significant cardiac, pulmonary, renal, vascular, or neural disease and with a hemoglobin <9 g/dl.
 - ❖ patients were critically ill with sepsis and with a hemoglobin level of <10 g/dl.
 - ❖ patients were acutely bleeding.
 - ❖ patients had chronic anemia including myelofibrosis and with evidence of hypovolemia, poor oxygen delivery to tissues, angina, or congestive heart failure and with a hemoglobin level of <8 g/dl.
 - ❖ patients had marrow failure and the diagnosis of stem cell transplant, pre-cancer, cancer, or documented severe marrow hypoplasia and hemoglobin level of <10 g/dl.

University of Texas

Medical Branch Guidelines

- The following conditions were considered to be reasonable for packed red cell transfusion:
 - ❖ Hemorrhagic shock
 - ❖ Active bleeding with 20% blood loss, 20% increase in heart rate, and/or 20% decrease in blood pressure.
 - ❖ Symptomatic anemia --Angina or CNS symptoms and hemoglobin <10 g/dL. Other symptoms and hemoglobin <8 g/dL.
 - ❖ Asymptomatic anemia—Expected blood loss of 500 ml with a surgical procedure and hemoglobin <8 g/dL.

Comments to Consider

- ❑ Steinbrook R., N Engl J Med 356;24 June 14, 2007
 - ❖ Unfinished business includes:
 - Completing and reporting on better safety studies
 - Assessing the risk of ESA as compared to blood transfusions
 - Understanding relationship of erythropoietin doses to hemoglobin and cardiovascular risk.
- ❑ Unger, Ellis F et al, N Engl J Med 362; 3 Jan 21, 2010
 - ❖ Erythropoiesis Stimulating Agents – Time for a Reevaluation
 - Establish “through randomized control trials, the optimal hemoglobin target, dosing algorithm, and monitoring approach for patients with anemia from chronic kidney disease.”
 - Conservative hemoglobin values well below 12 g/dL should be evaluated.