

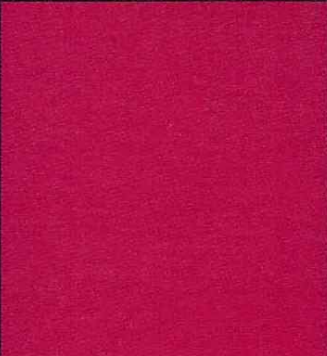


BBTS Annual Conference 2014

Analysis of Outcomes to Anticipated Regulation

Merlyn Sayers, MBBCh, PhD
Carter BloodCare, Dallas-Fort Worth, Texas
University of Texas Southwestern, Dallas, Texas

THURSDAY 25TH SEPTEMBER



Analysis of Outcomes to Anticipated Regulation

Merlyn Sayers, Carter Bloodcare, Texas, UK

What do we know about UK blood donors? Going in search of the bigger picture

Katy Davison, NHSBT, PHE, London

A year in Social Media

Jennifer Wilson, Gillian Morrison, SNBTS, Edinburgh



The Precautionary Principle

In the wake of the transfusion transmitted HIV epidemic in Canada, the Krever Commission Reported:

“Action to reduce risk should not await scientific certainty”

(The Krever Commission was established by the Canadian Government in 1993 to investigate allegations that government, the private sector and NGOs had allowed contaminated blood to be used.)

Justice Horace Krever, 1997



Carter BloodCare



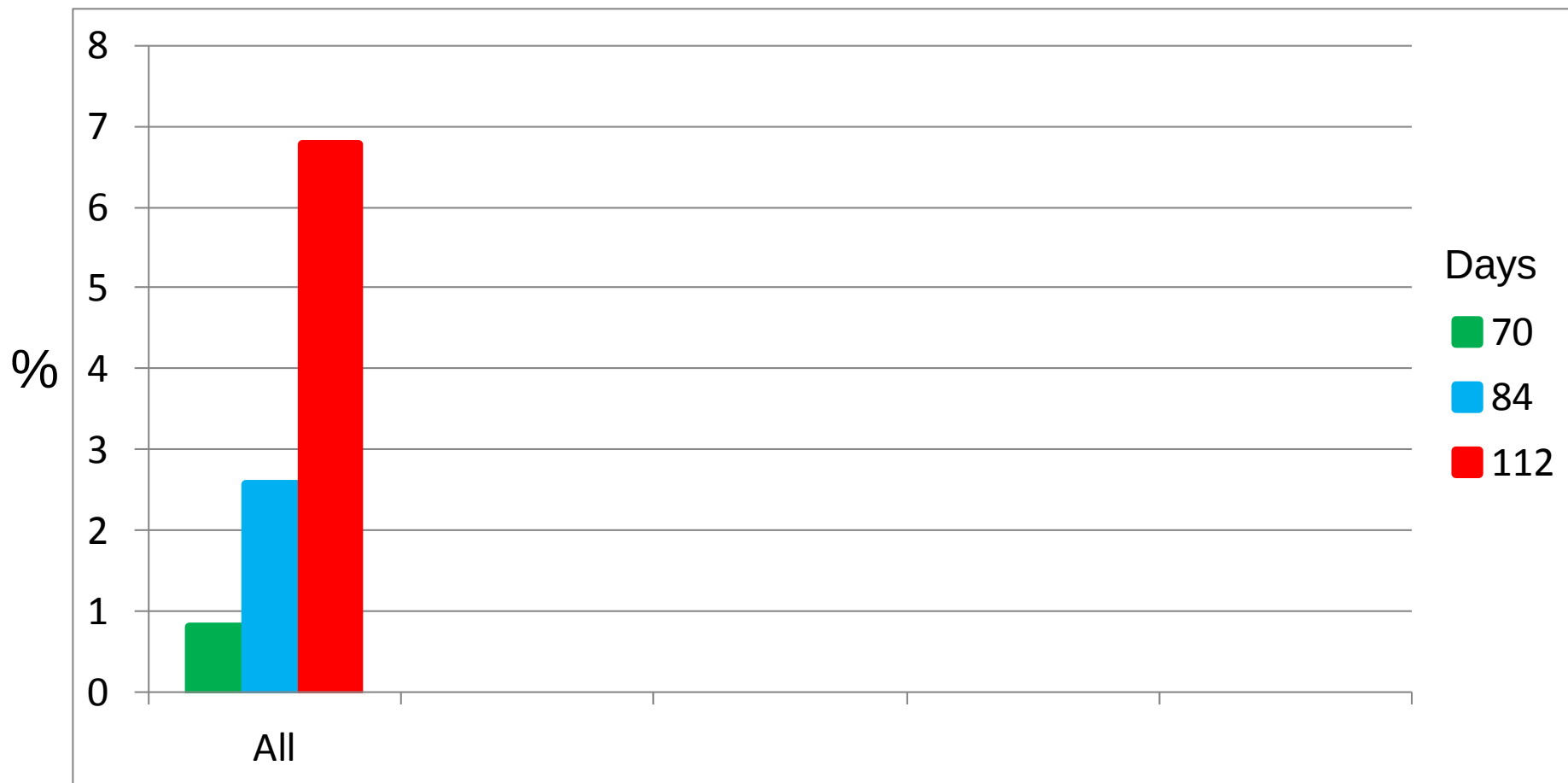
Blood Products Advisory Committee, July 27, 2010

Proposed Changes to the Hemoglobin and Donation Interval Criteria for Whole Blood Donation

Country	Minimum hemoglobin (g/dl)	Interdonation interval or frequency per year
United States	12.5	56 days
Canada	12.5	56 days
United Kingdom	12.5 for women 13.5 for men	112 days
Australia	12.0 for women 13.0 for men	84 days
Netherlands	12.5 for women 13.5 for men	Women: 18 weeks, 3x/year Men: 10 – 11 weeks, 5x/year
Hong Kong	11.5 for women 13.0 for men	Women: 3x/year Men: 4x/year



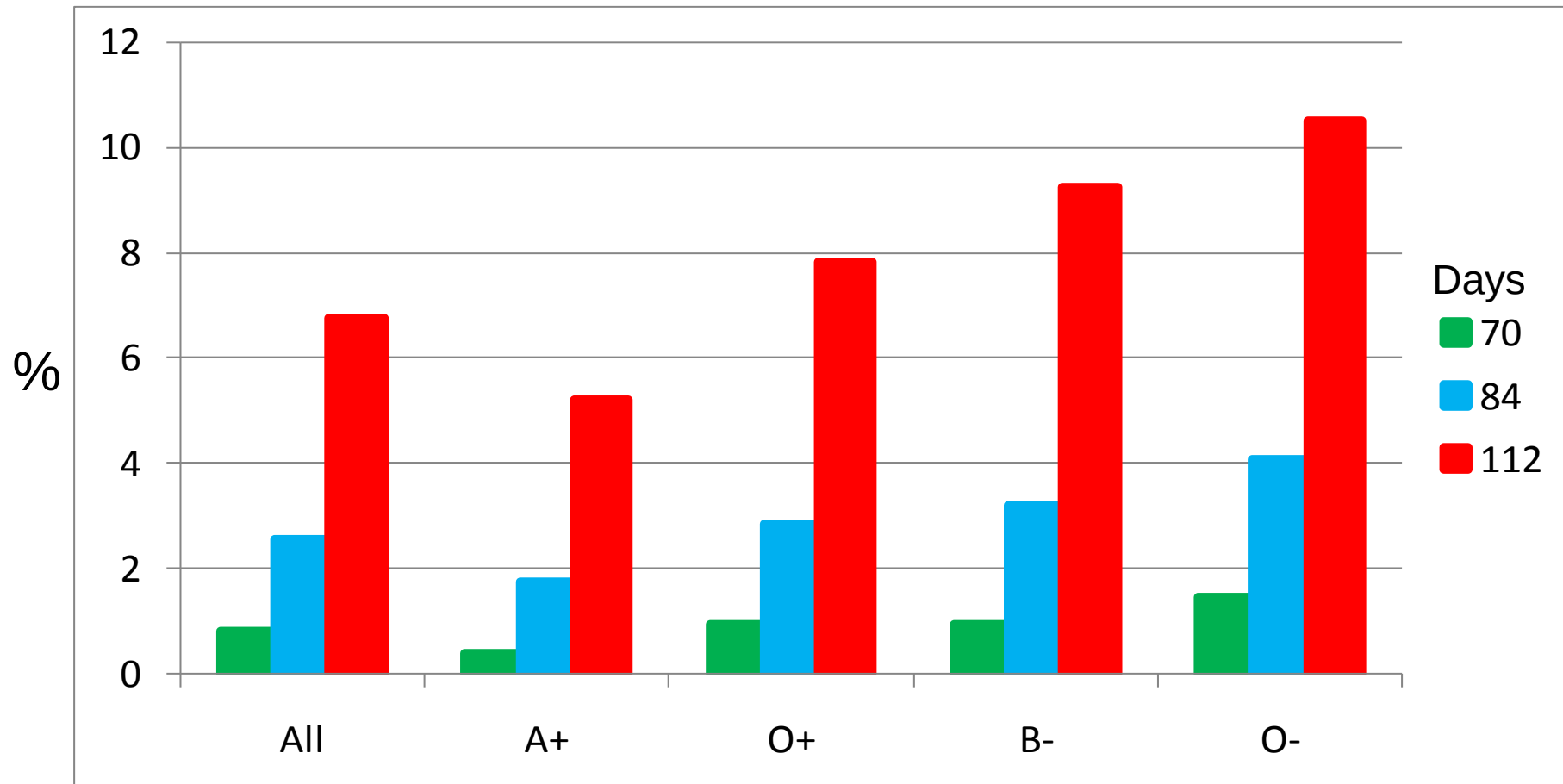
% of donors, all blood groups, who would be affected if the inter-donation interval (IDI) is increased



An IDI of 70 days would permit a maximum donation frequency of 5 times a year
An IDI of 84 days would permit a maximum donation frequency of 4 times a year
An IDI of 112 days would permit a maximum donation frequency of 3 times a year



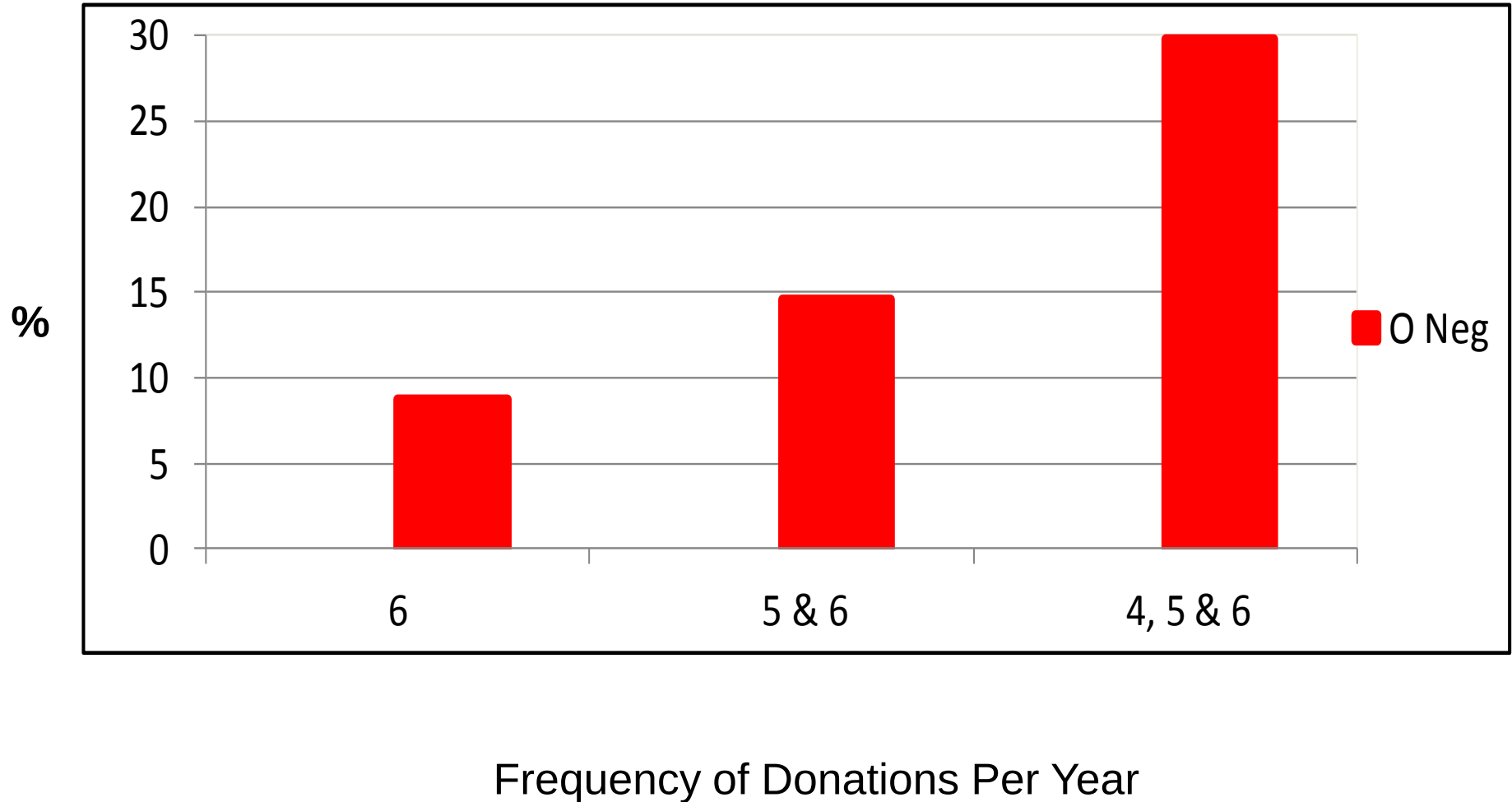
% of donors, by blood group, that would be affected if the IDI is increased



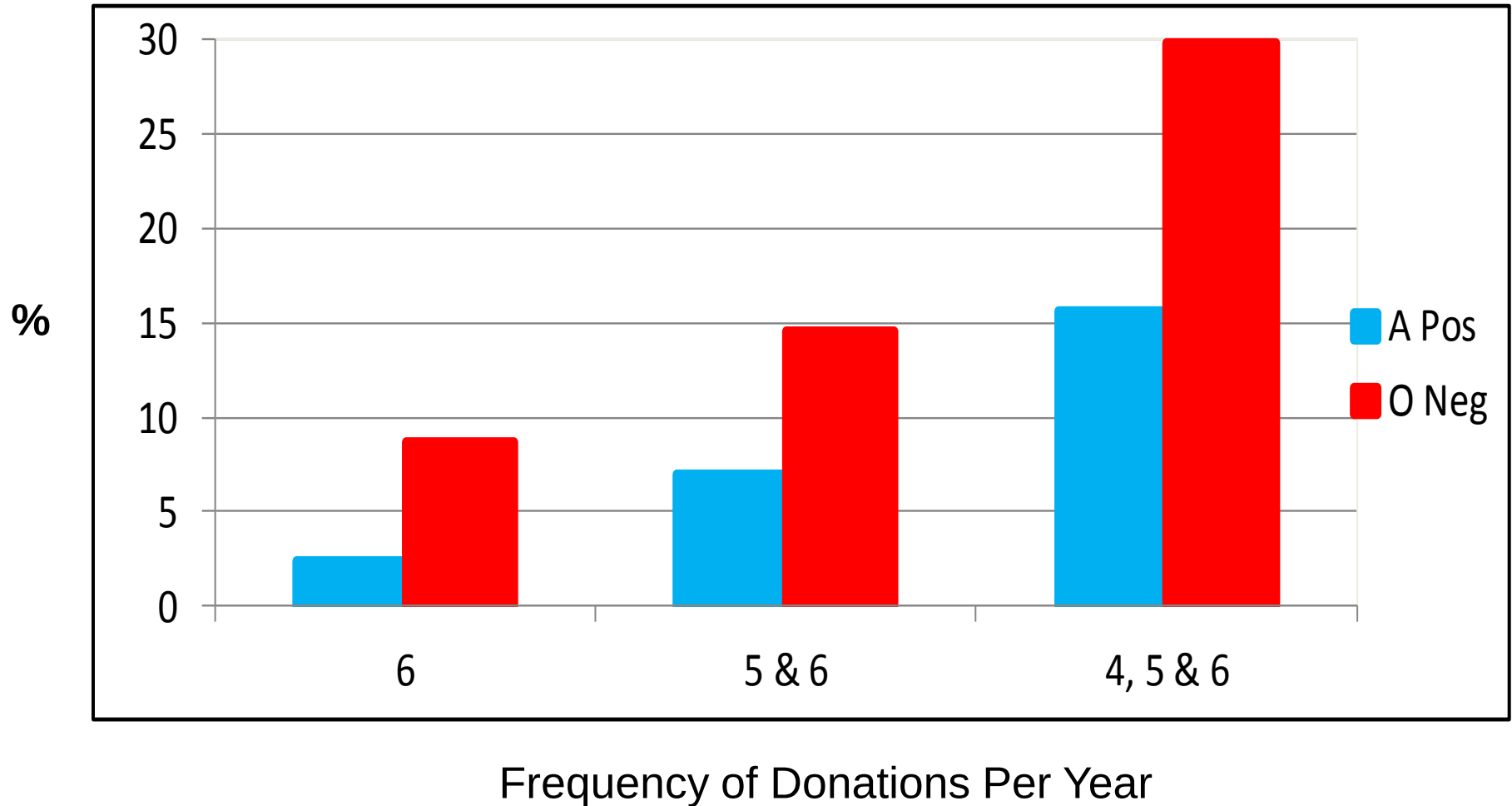
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Percentages contribution to the annual O Neg inventory, at Carter BloodCare, by frequency of donation



Percentages contribution to the annual A Pos and O Neg inventory, at Carter BloodCare, by frequency of donation



Effect of Blood Donation on Iron Stores As Evaluated by Serum Ferritin

By Clement A. Finch, James D. Cook, Robert F. Labbe, and Maria Culala

From the data obtained it would appear that male donors, while depleting their iron stores, were able to donate 2-3 U/yr without an appreciable incidence of iron deficiency. Women could donate only about half that amount, and more frequent donations were associated with a high incidence of iron deficiency and donor dropout.

Blood, Vol 50, No 3 (September), 1977

Duration of Red-Cell Storage and Complications after Cardiac Surgery

Colleen Gorman Koch, M.D., Liang Li, Ph.D., Daniel I. Sessler, M.D.,
Priscilla Figueroa, M.D., Gerald A. Hoeltge, M.D., Tomislav Mihaljevic, M.D.,
and Eugene H. Blackstone, M.D.

CONCLUSIONS

In patients undergoing cardiac surgery, transfusion of red cells that had been stored for more than 2 weeks was associated with a significantly increased risk of postoperative complications as well as reduced short-term and long-term survival.

N Engl J Med 2008; 358: 1229-1239



Blood Products Advisory Committee

Rockville, Maryland

September 21, 2012

Consultant:

“Old red cells should not be given to the critically ill patient because they are associated with a higher incidence of organ dysfunction. This is not a controversial issue . . .”

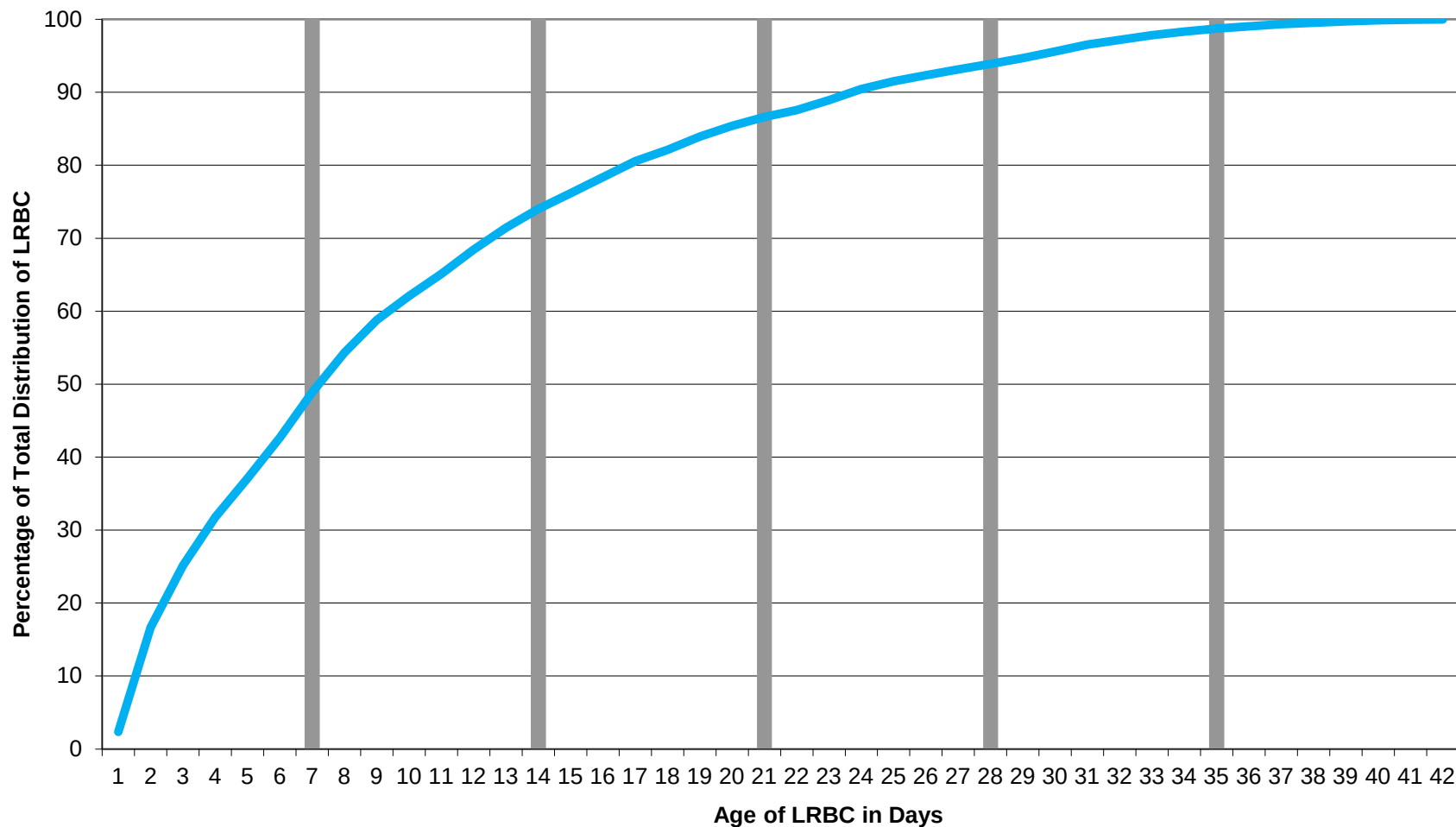
Committee Member:

“The evidence comes from observational studies. Very little comes out of blinded clinical trials.”



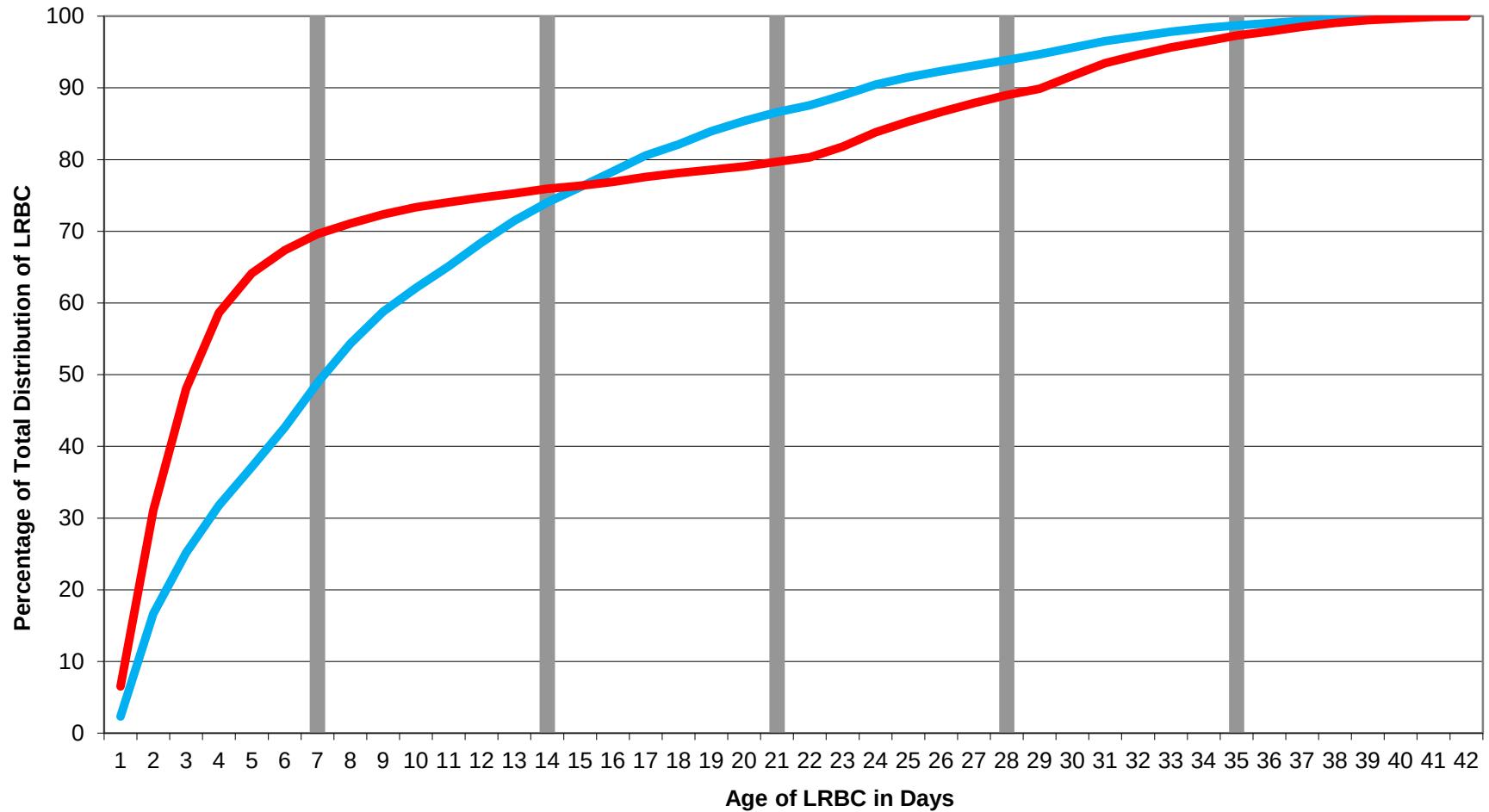
Carter BloodCare

Total Leukoreduced Red Blood Cell (LRBC) Distributions to Hospitals (260,336 Units) by Age



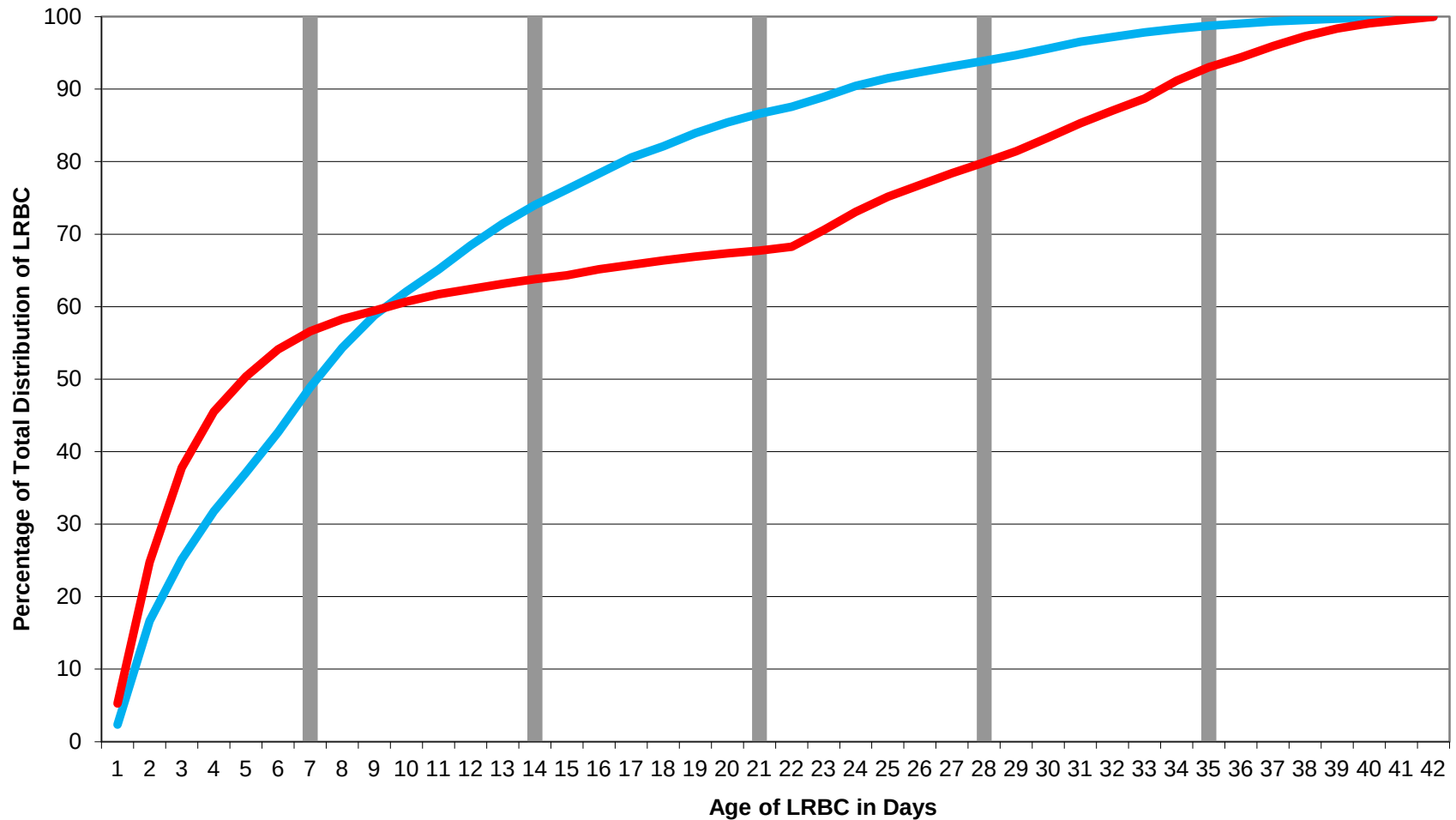


Total LRBC and O Neg LRBC Distributions to Hospitals (26,375 Units) by Age



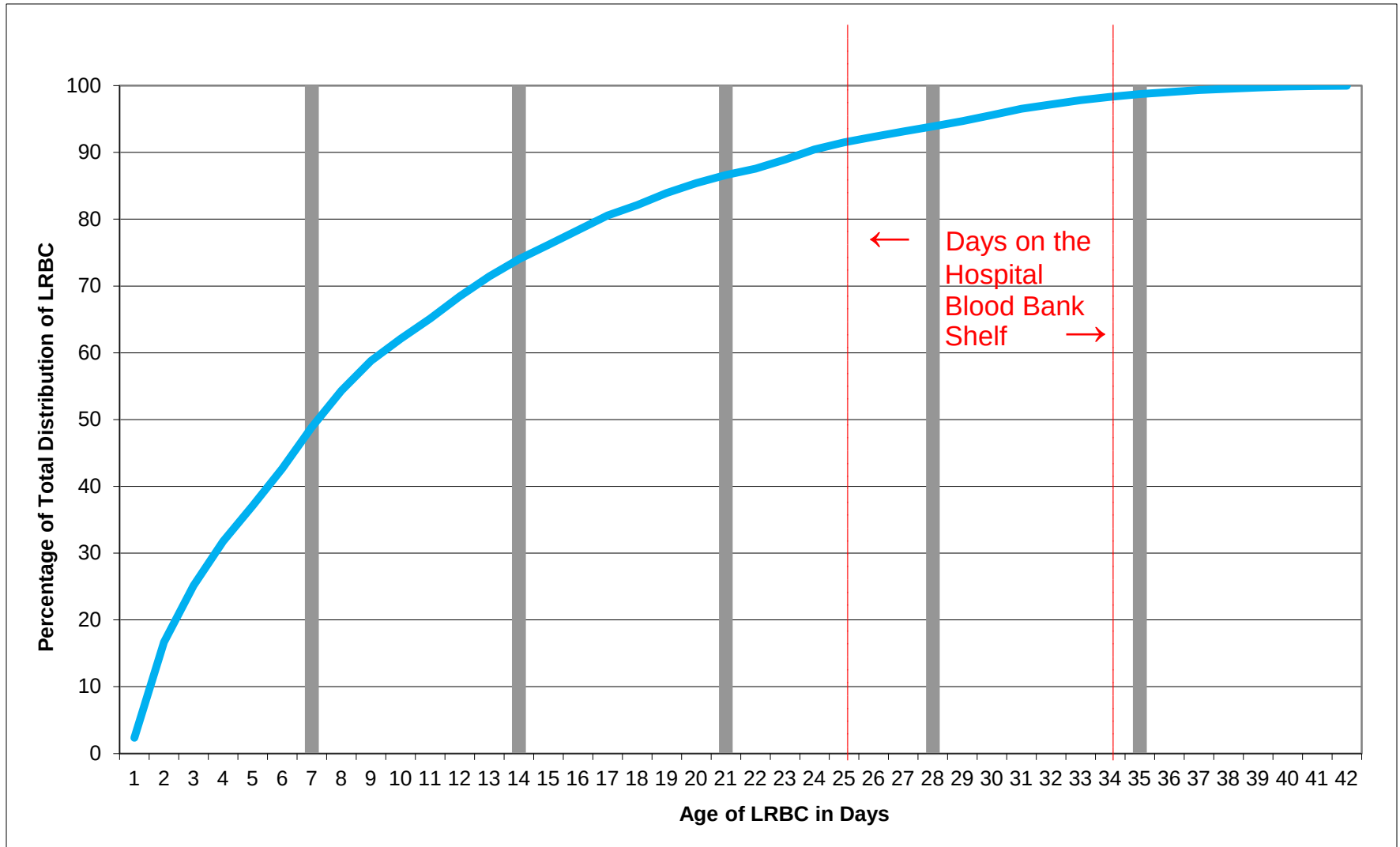


Total LRBC and B Neg LRBC Distributions to Hospitals (4,564 Units) by Age





Total Leukoreduced Red Blood Cell (LRBC) Distributions (260,336)



Title 21--Food and Drugs
Chapter I--Food and Drug Administration
Department of Health and Human Services
Subchapter F--Biologics
Part 606 Current Good Manufacturing Practice for Blood and
Blood Components

Subpart B--Organization and Personnel

Sec. 606.20 Personnel.

- (b) The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.**