VARIABLE BLOOD VOLUME (VBV): A GOOD SOLUTION TO A BAD PROBLEM IN THE MEDICAL MARKETPLACE

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The Best and the Worst of Times

First, the good news: blood banking is not in the news. Because its leaders have done their jobs well over the past several decades, the blood business does not get the bad press consistently aimed at the rest of the medical marketplace—no allegations of overcharging (like pharmaceuticals), no criticism of inadequate reimbursement (like health plans), no persistent questions about quality of care (like providers).

No news may be good news, but being out of the limelight does not mean that all is well. Blood and blood products quietly save millions of American lives every year—making the nation's blood supply one of the most valuable contributors to population health—but serious problems are only one disaster away. Blood banks must constantly be on the lookout for financially viable ways to continue staying out of the news by preventing problems before they occur.

Survival will not be easy. An in-depth study published in 2016 by the RAND Corporation, Toward a Sustainable Blood Supply in the United States [1], concluded that the future of the blood system is tenuous for several significant reasons:

 Due to improvements in surgical techniques and transfusion practices, the demand for blood has fallen nearly 12% over the past decade and is not expected to return to previous levels. The prices that hospitals

The resulting decline in available blood and blood products raises serious concerns about emergency preparedness.

are willing to pay for blood have declined correspondingly.

- At the same time, blood centers' operating expenses have increased substantially due to new testing requirements for pathogens (e.g., Zika virus) and rising costs of donor recruitment. Reduced or negative operating margins have caused many suppliers to consolidate or leave the market.
 - Because health reform is accelerating the shift from fee-for-service reimbursement to bundled (i.e., fixed) payment, hospitals have fewer resources to maintain inventory of key supplies. The resulting decline in available blood and blood products raises serious concerns about emergency preparedness.
 - Given the historically private structure of the market for

blood, governments have very little information that can be used to study this problem and develop responsive solutions. New approaches are clearly needed, sooner rather than later, to avoid a serious public health crisis due to a declining supply of safe blood.

The New England Journal of Medicine published an updated analysis in 2017, "Crisis in the Sustainability of the U.S. Blood System" [2], that identified our nation's blood supply as a public trust and strategic resource—an "essential medicine," in the words of the World Health Organization. The authors found that the nation's blood supply continued to decline at an increasing rate, further elevating concerns about meeting needs in a crisis. Equally compelling evidence and calls for action have been published in Transfusion [3].

Even more disturbingly, the article identified economic and political forces that seriously hinder blood banks' abilities to expand supply through conventional marketplace mechanisms like raising prices and creating economies of scale. The authors focus attention on emergency preparedness as an imperative for public policy and health reform.

They conclude, "Allowing the system to continue to function as it has while it is losing stability, resilience, and surge capacity is not a responsible option."

More of the Same Won't Do

The RAND and NEJM reports are not alone. Every other published study of our blood supply reaches comparable findings and makes similar recommendations. And for better or for worse, persistent paralysis in Washington suggests that government-driven health

reform will not solve the problem in the foreseeable future (if ever). Indeed, many of blood banking's new operational problems were caused by old political solutions.

More "one size fits all" laws and regulations do not offer hope because the blood business is remarkably diverse; it embodies a wide range of differences in products and geographic markets [4]. And unlike the public (i.e., government) oversight of blood banking in most other countries, it is a private enterprise in the United States. Our solution consequently lies in American exceptionalism. Because our health system is unique, we cannot turn to other countries for solutions. Innovations—lots of them, consistent with the remarkable creativity that has transformed other

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industries—are needed to restore stability for blood banks in the United States.

Fortunately, medical economics (this author's profession for almost 50 years) provides guidance for improving operational efficiency in health care, that is, increasing output for a fixed set of inputs or reducing inputs required to produce a fixed output. The potential economic benefits of performance improvement include reducing costs, eliminating waste, improving employee productivity, and finding other solutions to the problems that now threaten blood banks.

One extremely promising innovation would be

promoting technology and procedures to vary the volume of blood collected from donors, resulting in an increased supply of blood and lower overall production costs per unit. More blood could be collected from the same number of people, or the same quantity could be collected from fewer people, if blood centers were able to draw larger samples from people with more donation-available blood.

Optimizing the American blood supply by implementing a variable blood volume (VBV) collection procedure is an elegantly simple, private sector solution to meeting

our nation's needs for blood. VBV could generate more blood for emergencies when demand is rising and maintain a constant supply when the number of donors is declining. Establishing VBV-based collection is an ideal solution to the problems reported in the latest published studies.

The Variable Blood Volume Concept

Collecting a standardized quantity of blood from each donor is a long-standing practice of blood collection throughout the United States. The standard unit is approximately one pint (~470 milliliters, although many blood centers have changed to 500ml as the collection volume in recent years). The unit of blood is therefore a rate-limiting factor that prevents essential innovation. The donation is standardized, but donors are not. Their actual blood volumes vary substantially by gender, height, and weight. The loss through donation of a standardized unit represents a much larger portion of total blood for a 5'2" female than for a 6'4" male, for example.

Blood donations are possible because most people do not need all their blood for healthy function, but collecting too much from an individual donor can cause adverse reactions. Syncope (fainting) is the most common one, and it creates a variety of significant problems for the donor and the blood

center. A verv small number of people experience syncope or other serious problems with the loss of one pint of blood, so it has become the acceptable standard unit for donation. However, a uniform standard that protects smaller patients with relatively low volumes of blood also prevents blood centers from collecting greater quantities from larger donors with more blood-blood that could be collected without creating disproportionate risk of syncope or other adverse reactions.

†327mL Average plasma yield increase from 290mL **6,213** Actual WB Allogenic units collected in September 2015 **6,213** = **229,881**

CENTER 1 - WITH VBV

x 37mL

 $550,000 \times 37mL = 24,050,000 \times .10C/mL$ = \$2,405,000

extra mL of plasma

evenue increase

Establishing a VBV donation protocol is possibly the best immediate response to the problems reported in the latest studies of the American blood supply.

Proof of the VBV Concept

Applied Science, Inc. (ASI) has added the VBV capability to its comprehensive HemoFlow system in numerous American blood centers over the past few years. Using Nadler's Formula, a standard practice in the business, an enhanced HemoFlow unit calculates how much blood an individual can donate

at an acceptable level of risk and controls the donation process accordingly, all based upon the individual's gender, height, and weight. If the blood center uses an electronic registration system, the gender, height, and weight can be automatically captured from each patient's electronic registration form and then used to stop collection when the individually appropriate volume has been drawn.

Initial results of implementing VBV have been studied at three

In terms of operational efficiency, more blood could be collected from the same number of people, or the same quantity could be collected from fewer people, if blood centers were able to draw larger samples from people with more donation-available blood. Optimizing the American blood supply by implementing a variable blood volume (VBV) protocol is therefore an elegantly simple solution to meeting our nation's varying needs for blood. VBV could generate more blood for emergencies when demand is rising and maintain a constant supply when the number of donors is declining. blood banks. The impact of VBV-based collections were measured differently at the three sites, but the data confirm expected improvements in overall performance at each blood center using the HemoFlow VBV capability:

• At one large center, average collection of plasma was 37 ml. greater per donation when VBV was used. At this rate, average monthly collections would be increased by 229,881 milliliters, which would produce additional annual revenue of \$2,405,000 when sold at 10 cents per milliliter.

- At a smaller center, average blood collection per donation increased by 23 ml. after the VBV system was implemented. Syncopal reactions fell by 539 instances and revenue for the year increased by \$148,678.
- At the third center, 63% of collections were above 500 ml., the usual end point before VBV was adopted. The average increase per donation was 38 ml. Annual revenue

from sales of the additional plasma was \$507,346, and syncopal reactions did not increase.

The estimated return on investment for VBV with additional plasma generation of 10, 20 and 30ml, was 45%, 72%, and 82% inclusive. in the first year. In addition, the blood centers' managers perceived that VBV improved donors' experience (especially through the reduction in reactions) and improved staff productivity. No negative impacts were perceived or identified. Based on the initial results. all three centers decided to continue using the HemoFlow VBV system. (Additional studies are being conducted at several other blood centers.

↑23mL Average plasma yield increase ↓539 Syncopal reactions fell

CENTER 2 - WITH VBV

= **\$148,678** revenue increase

CENTER 3 — WITH VBV

†38mL Average plasma yield increase

> **NO CHANGE** To Syncopal reactions

= \$507,346

Preliminary analysis of data from the additional sites reveals benefits comparable to those identified in the original studies.)

Conclusion: System-wide Benefits of VBV Adoption

Unlike solutions that generate bad news about the

medical marketplace (i.e., private gains on one side tied to socially undesirable losses on the other), VBV creates uniformly positive benefits for both suppliers and consumers of blood products. VBV offers an immediate opportunity to increase efficiency in collections while simultaneously improving blood banks' financial stability and ensuring a sustainable supply of blood to meet Americans' changing and unpredictable needs. From the perspective of economic analysis, VBV is an existing and proven step that can be taken right now to address the well-documented crisis in our blood supply. That's good news. Therefore, VBV should be promoted as a matter of public policy.

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About the Author

Dr. Bauer is an internationally recognized health futurist and medical economist known for his specific proposals to create efficient, effective health care through multi-stakeholder partnerships and other initiatives focused in the private sector. Dr. Bauer has authored more than 250 publications on health care delivery. He has been an independent consultant since 2010. He previously served as vice president for health care forecasting and strategy for two Fortune 500 companies and was a professor of statistics and research at two state medical schools. He received his Ph.D. in economics from the University of Colorado-Boulder.