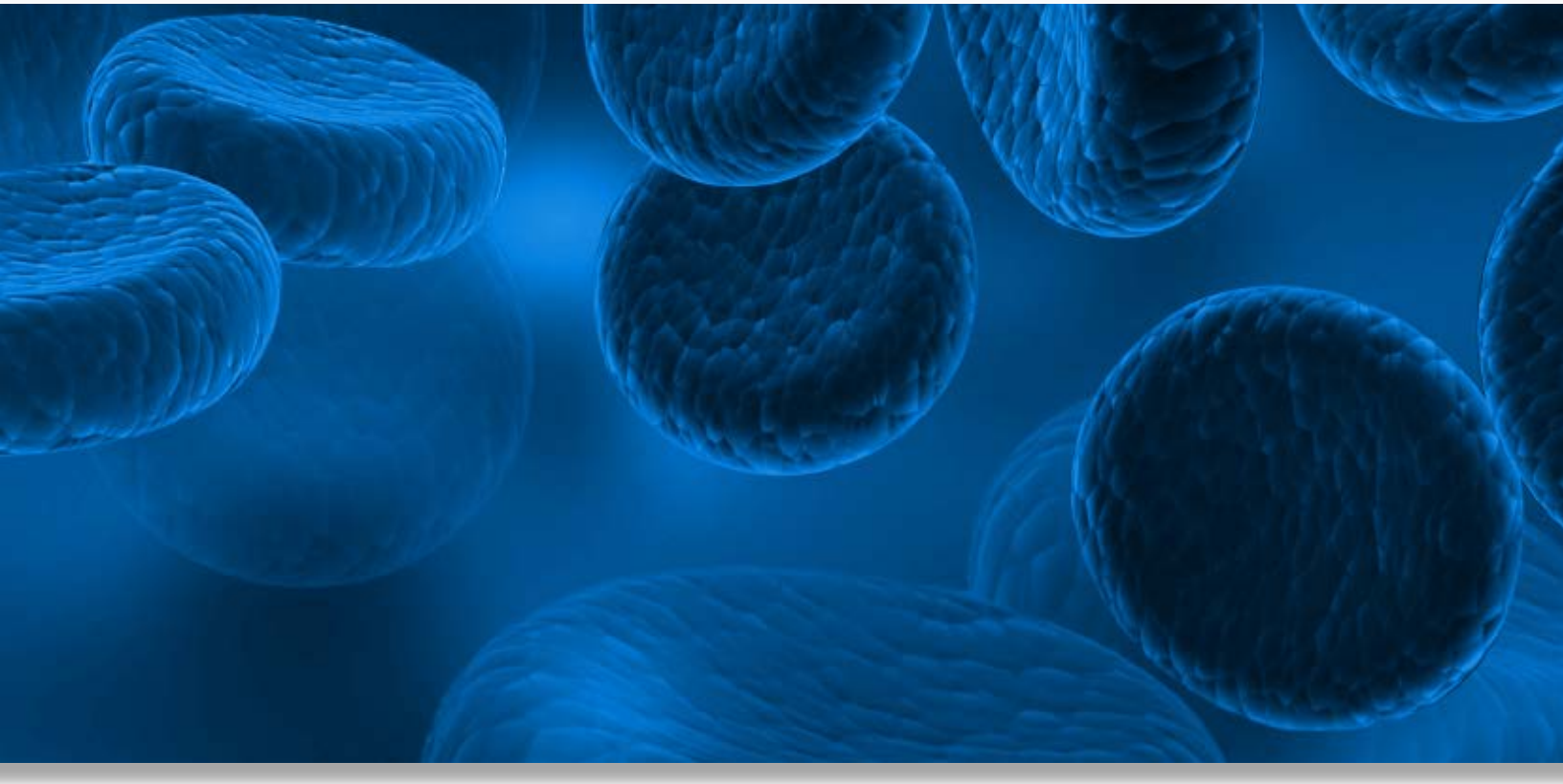
Value of Blood
to the U.S. Healthcare System



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This white paper will examine the current resilience of the U.S. blood supply and affirm its safety while highlighting areas that warrant further attention and support.

Introduction

What is the value of blood?

Perhaps the value of blood is best demonstrated by the consequences and costs incurred if needed blood is not available in a timely manner. Examples of such scenarios include but are not limited to the following:

- A life lost
- A surgery cancelled or delayed
- A trauma services program unable to provide blood to critically injured patients
- An active shooting disaster in which consequences cannot be adequately mitigated by timely blood transfusion
- A sickle cell disease patient not able to receive red blood cell transfusions needed to prevent strokes and life-threatening anemia
- A cancer program that cannot support its patients before, during, and after chemotherapy and/or surgery
- A stem cell or organ transplant that cannot take place

The immediate consequences for individual instances of the above scenarios are obvious in most cases, however the long-term costs of chronic blood product shortages to the United States healthcare system and the communities it serves are incalculable in terms of dollars, healthcare system sustainability, program development and peace of mind.

Every two seconds in the U.S., someone needs blood. Blood transfusions are needed to treat patients with acute care needs such as trauma, as well as for ongoing disease management, including cancer, inherited blood disorders, cardiovascular and orthopedic surgeries, and organ and bone marrow transplants.

More than 11 million transfusions occur in the U.S. every year [1], however, little attention is given to the requirement for a ready-to-use supply of blood. A more thorough recognition of the value of blood will drive allocation of adequate resources for a robust, safe blood supply and sustain the blood community's infrastructure, personnel, and ability to innovate and adopt new technologies.

This white paper describes the value of blood, both in the immediate clinical context of transfusions to patients, and also its so-called "insurance value" which includes meeting the requirements for:

- Day-to-day U.S. healthcare system operations: A robust, ready-to-use, blood supply is essential to support the US healthcare system and provide assurance that enough blood is available to start a surgical or medical intervention; and,
- Disaster response: A minimum inventory of fully processed, transfusable components is critical in order to respond adequately to man-made and/or natural disasters that range from supplying immediate patient needs following a mass trauma incident to ensuring an adequate blood supply during extended local or regional system disruptions (e.g. hurricanes, new emerging diseases, etc.) that result in an inability to collect and process blood normally.

The ability to unfailingly supply the right blood, to the right person regardless of time and location is a measure of the "resilience" of the blood supply.

A more thorough understanding of these areas will promote optimal use of blood as an invaluable resource, and maintenance of the inventory levels and infrastructure needed to assure continued resiliency of the U.S. blood supply.

Current Challenges

The adequacy, resiliency, and production capacity of the blood supply to meet the nation's day-to-day needs and maintain adequate resources for surge capacity in the event of disasters is increasingly challenged by several dynamics:

1. Dangerously low to no or negative margins on blood products and services

The U.S. blood supply is currently maintained by:

- A network of independent not-for-profit community blood centers (represented by the trade association America's Blood Centers (ABC)), which supply approximately 60% of the nation's blood products and
- The American Red Cross, which provides most of the remaining 40% of the blood supply.

Over the past decade, the blood banking community has become increasingly competitive due to commoditization of blood products by healthcare system supply chain purchasers. As a result, approximately 50% of U.S. blood centers are now reporting dangerously narrow or negative margins which jeopardize their ability to continue optimum operations and inhibits innovation.

2. Inadequate reimbursements for the cost of blood products and transfusion

Current methods of reimbursement, such as "bundling" of payments (i.e. including blood transfusion cost in a single payment intended to cover all costs of care for a patient) do not adequately cover the costs of blood transfusion. This results in transfusion being treated as a loss-leader in the hospital setting and puts unrealistic pressure on blood pricing which inhibits blood centers from charging enough to adequately cover their costs for collection, processing and distribution of blood. It also hinders investment in new technologies and innovations and in worst case scenarios, limits patient access to needed transfusions.

CURRENT CHALLENGES

1. **Dangerously low to no or negative margins on blood products and services**
2. **Inadequate reimbursements for the cost of blood products and transfusion**
3. **Lack of a robust nationwide database on blood product collection and utilization**
4. **Limited shelf life of blood products**
5. **Aging and loss of the donor population**

3. Lack of a robust nationwide database on blood product collection and utilization

Currently there is no comprehensive source of data collection for the national blood supply. Such a system is needed to enable monitoring of trends, evaluation of population health and utilization of risk-based decision-making for new rules and regulations.

4. Limited shelf life of blood products

The blood supply consists of several types of products, including whole blood, red blood cells, platelets, and plasma, as well as numerous specialty products such a stem cells, immunoglobulin, cryoprecipitate and albumin, among others. Each of these types of products have specific uses for different clinical and surgical problems. Each of the products has unique collection, manufacturing, storage requirements and shelf lives. Individual patients may require special blood types, some of which can be very rare. The U.S. healthcare system is dependent on the availability of each of these products on a 24/7 basis.

The very short shelf life of platelets (5-7 days) and red cells (21-42 days) presents the biggest challenge to the U.S. blood supply, as it necessitates the maintenance of a continuous replacement inventory of diverse donors and donations, regardless of the time of year, weather, or other challenges affecting the collection of blood products.

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5. Aging and loss of the donor population

World War II era ("the Great Generation") and baby boomer donors have supported the blood supply for decades, but as they age, they drop out as blood donors for various reasons. Continuously promoting the value of altruistic volunteer donation is essential to achieving resiliency of the blood supply and must be a national priority.

The Safety of the Blood Supply

Any discussion of the value of blood must start with and emphasize the safety of the blood supply and highlight the advancements that have been made in the past 20+ years. The key points surrounding the issue of safety are:

Infections due to blood transfusions were a public concern for many years, extending from the 1960s through the 1990s. Blood centers now select for safe donors more effectively, extensively test their blood, and use validated FDA-approved computer systems to control processes and eliminate mistakes during the testing, distribution, and administration of blood. The result is that the risks of infection transmitted by blood transfusion have been greatly reduced in recent

decades. For example, the chance of getting the AIDS virus or hepatitis B or C viruses from a blood transfusion are now around 1 in 3 million.[2] In the last 20 years, the blood community has also identified and responded to new threats that have included West Nile Virus (WNV), Chagas disease, Zika virus, and babesiosis, showing that the blood banking industry can rapidly respond to protect the blood supply from infections. When WNV emerged in 2002, and Zika emerged in 2016, the blood community responded quickly and partnered with test manufacturers to develop and implement donor screening assays to detect these infections, in less than one year.

THE SAFETY OF THE BLOOD SUPPLY

Transfusions are safer now than at any time in the past, even with multiple emerging infections (e.g. Zika, West Nile Virus) that have entered the blood supply.

Transfusions are among the safest medical interventions in wide use.

Because of this greatly decreased risk of infection from blood transfusion, a noninfectious complication resulting from simply transfusing too much volume of otherwise safe blood to a patient (known as "transfusion-associated circulatory overload" or TACO), has replaced infection as transfusion's most common serious adverse effects. With support for increased surveillance, we can educate physicians and medical care teams to prevent, recognize, and treat these TACO events. ABC works with multiple organizations, including the national "Choosing Wisely" initiative, AABB, the U.S. Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), to help raise awareness of transfusion risks with the goal to improve surveillance and ultimately transfusion practice. This work has begun under the auspices of the CDC as a component of the National Healthcare Safety Network.

Blood transfusions offer immense benefits to the patient, however as with any medical or surgical treatment, blood transfusion will never be entirely free of risk. Nevertheless, blood transfusion is among the most common treatments used every day in U.S. healthcare.[3]

The Clinical Value of Blood

How Blood Benefits Patients

Blood has many functions, but transfusion medicine addresses mainly the role of blood in delivery of oxygen throughout the body and control of bleeding at sites of injury. Red Blood Cells (RBCs) meet the body's demand for oxygen by carrying it from the lungs to the tissues. If the supply of oxygen drops too quickly, or too low as in severe anemia and blood loss, the body is unable to compensate and symptoms such as low blood pressure, weakness, faintness, tissue damage and death may result. RBC transfusion improves the supply of oxygen to critical tissues

and can prevent these complications. Platelets and plasma are transfused to support blood clotting and prevent bleeding for patients ranging from those undergoing cancer chemotherapy, bone marrow and stem cell transplants, to trauma victims and those with liver disease.

Figure 1 lists the 15 most frequent conditions for which RBC transfusion was given in 2013. In aggregate, 14% of these patients received RBCs. It demonstrates the wide spectrum of patients whose care requires the immediate availability of a safe and robust blood supply.

Figure 1

Where do RBCs go: U.S. 2013	RBCS TRANSFUSED DURING ADMISSION		
Principal condition for inpatient stay	**Number**	**Percent**	**Total stays**
Septicemia (except in labor)	174,740	13.7	1,276,805
Gastrointestinal hemorrhage	171,995	47.6	361,375
Anemia (hereditary, nutrient, hemolytic, marrow failure)	141,225	73.2	192,885
Fracture of neck of femur (hip)	87,590	29.1	301,190
Complication of device; implant or graft	81,865	13.4	608,920
Osteoarthritis (primarily for total joint replacements)	79,410	7.8	1,022,945
Acute and unspecified renal failure	54,830	11.1	495,000
Complications of surgical procedures or medical care	52,205	11.7	447,230
Congestive heart failure; nonhypertensive	49,365	5.6	880,629
Pneumonia (not TB or STD)	48,840	5.7	862,234
Acute myocardial infarction	38,565	6.4	602,235
Diverticulosis and diverticulitis	37,885	12.8	295,955
Coronary atherosclerosis and other heart disease	32,440	7.1	458,295
Acute posthemorrhagic anemia	31,485	75.6	41,650
Heart valve disorders	27,800	22.8	121,825

Source: Agency for Healthcare Research and Quality, Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National (Nationwide) Inpatient Sample.

Acute Blood Loss

As indicated in Figure 1, blood transfusion has its greatest benefit in acute blood loss. Whether from trauma, surgery, or childbirth, bleeding patients are saved every day by transfusions. This has led to the very early use of transfusions—with the knowledge that literally minutes of delay can be fatal. This approach uses balanced ratios of RBCs for oxygen, and plasma and platelets to support blood coagulation, and have led to substantial improvements in patient survival rates in acute bleeding. Better outcomes with early use of blood components in hospitals has also led to increased use of blood components in pre-hospital settings. Pre-hospital blood use has

Blood transfusion has its greatest benefit in acute blood loss. Whether from trauma, surgery, or childbirth, bleeding patients are saved every day by transfusions.

resulted in improved clinical outcomes in high quality studies. As a result, medical helicopter and ambulance services in many cities have begun carrying RBCs, plasma, platelets, and, more recently, whole blood for the logistical ease of carrying one blood product versus RBCs, platelets, and plasma.

Cancer

Transfusion also greatly benefits patients who are unable to make blood cells in their bone marrow. Circulating red blood cells have short life spans of 100-120 days and must be constantly replaced by the bone marrow. Cancer patients, because of their disease and/or its treatment, are unable to manufacture their own red cells and platelets and are often dependent on blood transfusions to survive. Without blood transfusion, patients will not tolerate treatments being used to treat their cancers.

Sickle Cell Anemia

Many of the estimated 100,000 people in the U.S. with the hereditary disease sickle cell anemia are chronically dependent on transfusion, both to prevent symptoms of anemia like fatigue and exercise intolerance, but also to prevent very specific, disabling, and sometimes deadly complications such as pain crises and strokes. Their needs for transfusion are complicated by the genetic make-up of sickle cell patients which necessitates a greater mix of donors from various racial/ethnic backgrounds to supply very specific and rarer blood types.

Trends in Blood Component Utilization

As described in **The Safety of the Blood Supply** section of this paper, blood transfusion is one of the most common medical procedures performed in the United States.

A recent study (using the different methods of the National Inpatient Sample) found that in 2014, 5.8%, 0.9%, and 0.7% of inpatients stays included the transfusion of RBCs, plasma, and platelets respectively. [4] These data attest to the wide acceptance of transfusion's clinical value by both clinicians and patients.

However, over the past 10 years, various studies have demonstrated equivalent patient outcomes for certain clinical benchmarks whether physicians transfuse blood liberally, i.e. as soon as laboratory values indicate the patient's red cell level is below a certain threshold, or they restrict transfusions until signs and symptoms of anemia are present at even lower red cell levels.[5] This has resulted in a trend toward decreased use of transfusion and a marked decline in blood use. The steep decline, beginning in 2008 and continuing to date, is demonstrated in the CDC biennial National Blood Collection and Utilization Survey, which shows Red Blood Cell (RBC) collection and transfusion trends since 1992, with the steep decline beginning in 2008 and continuing to date (Figure 2).

Figure 2

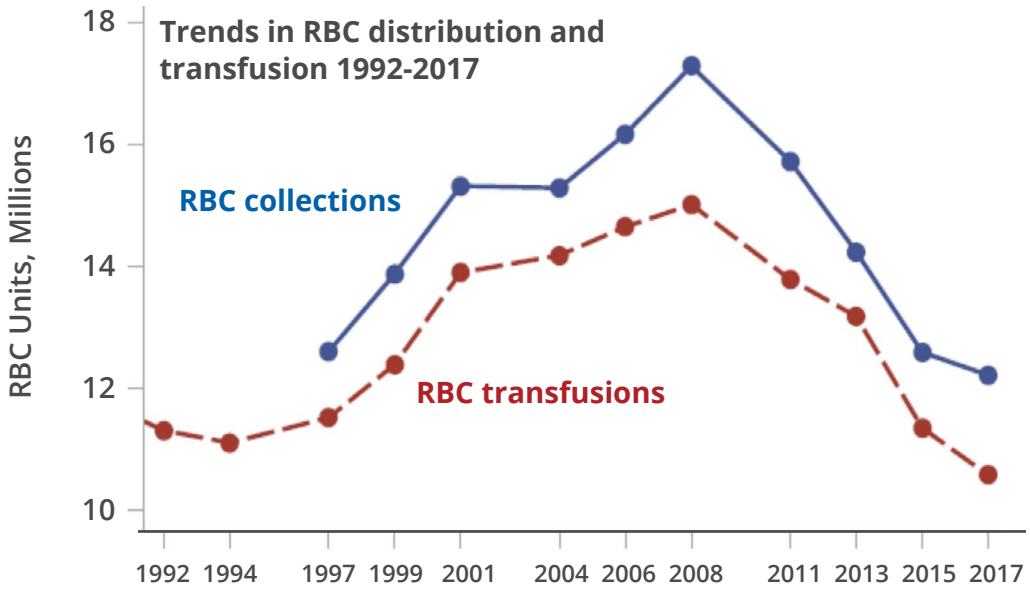

Fig. 2: Adapted fom Jones J. NBCUS 2017, AABB Annual Meeting, 2018.

Liberal Versus Restrictive Transfusion

Few would argue that blood and blood components are not lifesaving to the hemorrhaging patient or the patient with leukemia and low platelets at risk for hemorrhage. However, in less dramatic clinical situations the decision to transfuse becomes more complicated. Debate is occurring on the most appropriate combinations of bedside clinical evaluation and laboratory studies that should be used before transfusion is undertaken. Much of the debate is due to the absence of high-quality studies addressing diverse patient populations that must be integrated into decision-making if appropriate use of blood is to be assured. These are enumerated below in **Areas of Needed Research**.

For an in-depth discussion of studies involving liberal vs restrictive transfusion strategies ***click here***.

The Areas of Needed Research

This section highlights major areas where additional research is needed that will require more resources than are currently available to the blood banking community. Provided below are examples pulled from only the *most frequently* transfused clinical situations. There are many more clinical populations and specific niches for which similar comments would be justified, giving an indication of the depth and breadth of the support needed for ongoing study.

Transfusion and "Quality of Life"

Blood transfusions may improve a patient's quality of life beyond medical outcomes. For example, fatigue is a subjective symptom, so it is very difficult to study. However, it is well recognized by physicians ordering blood transfusions that they lessen the feeling of fatigue and improve the ability of the patient to participate in activities of daily living. The impact of transfusion on other quality of life measures, such as time to return to work or ability to perform daily tasks independently, has rarely been evaluated in high quality studies, so additional research to measure benefit for these outcomes should be a priority.

Transfusion positively affects the clinical course of patients who receive blood.

Transfusion positively affects the clinical course of patients who receive blood. This is most obvious during active bleeding and when used to relieve the signs and symptoms of very severe anemia. Many patients have less acute or dramatic needs for blood, and transfusion is used to make them feel and function better. Both clinical and physiologic reasoning suggest that transfusion, which increases hemoglobin concentration and oxygen delivery to the tissues, should improve fatigue and functional deficits caused by anemia. The effect appears to be associated with the severity of fatigue and the level of the patients' hemoglobin. That is, both hemoglobin and the clinical assessment of fatigue were necessary to identify which patients would benefit most from transfusion, not solely a hemoglobin trigger. Guidelines clearly support RBC transfusion for symptomatic anemia, but granular data are limited, and previous studies are of variable quality. They do not clearly define thresholds at which transfusion has maximal effects for diverse clinical populations and represent an area which requires further high-quality studies.

Larger, well designed, and powered studies are needed to identify variation in the effect of transfusion on outcomes in diverse diagnostic populations with different comorbidities, ages, and service types (i.e. surgical vs. medical patients and inpatients vs. outpatients). Future work should focus on the effects of transfusion on diverse outcomes, for example hospital length of stay, symptoms and functional status by transfusion indication, patient age, and other demographics, as well as the effect of transfusion on patient-centered outcomes that are less objectively defined.

Cancer Patients

This is a large and growing, if diverse, patient population. Hematology/oncology patients often receive RBC transfusions for anemia. Anemia in this patient group can be due to chemotherapy and other treatments or from inadequate RBC production due to the underlying disease. Large scale, high quality clinical trials do not yet exist for patients undergoing cancer treatment or those receiving palliative care. As cancer treatments continue to improve, randomized controlled trials are needed to evaluate optimal transfusion practices in this important patient group.

Acute Cardiac Ischemia

An area of ongoing controversy has been the appropriate use of RBC transfusions in the very large population of patients with coronary artery disease, i.e. patients with acute coronary syndromes including heart attacks. These patients have reduced blood flow, and oxygen delivery to the involved heart muscle, and observational data from patients who refuse transfusion suggest that both increased heart damage and death are associated with the severity of anemia.[6] We must ask if the approaches used for general patient populations, especially conservative transfusion triggers, are safe and effective for patients with acute cardiac ischemia. Recent guidelines have not recommended a clear strategy for these patients. A randomized control trial (RCT) is underway exploring this issue, but enrollment is slow and continuing support for such work will be required for the foreseeable future to provide evidence-based guidance for this patient population.

Pediatrics and Neonatology

"Children are not just small adults". This is as true in transfusion medicine as in all other areas of practice. Pediatric patients are a unique and vulnerable segment of transfusion recipients. They are more likely to have adverse effects from transfusion, and likely to be subject to any adverse outcomes for the longest duration.[7] Neonates, proportionately, are the most frequently transfused subpopulation across all ages.[8] Transfusion in pediatrics is not just about using less volume for a smaller patient, but also about their unique physiology. For example, the normal hemoglobin in neonates is higher than in adults. Making practice even more complex is that neonates are different from young children, who are further different from teenagers. What is optimal treatment threshold in one age group is not necessarily optimal in another.

Many transfusion practices in children and neonates are extrapolated from results in adult studies. There remains a critical need for evidence-based guidance in this vulnerable age group to fill these gaps. At the 2015 NHLBI State-of-the-Science symposium, the transfusion medicine community identified neonatal and pediatric randomized clinical trials in RBC and platelet transfusion therapy as urgent, critical areas for investigation.[9] Recent pediatric/neonatal guidelines from the United Kingdom support restrictive transfusion practice, but these studies need to be expanded to encompass a broad spectrum of young patient cohorts including optimal transfusion thresholds in neonates, pediatric cancer patients, and patients with cardiac disease or brain injury.[10]

The "Insurance Value of Blood"

The "insurance value of blood" refers to the clinical and economic benefit realized by the mere availability of blood, as opposed to its administration.

Consider the orthopedic surgeon who will not anesthetize a patient for a hip replacement without blood readily available in the hospital transfusion service or operating room refrigerator. Or the oncologist who would need to delay chemotherapy for a life-threatening lymphoma without the assurance that blood and platelets are readily available. Trauma programs, recognizing the rapid increase in mortality associated with delayed transfusion, have standard protocols using defined mixes of RBCs, platelets, and plasma. When activated, these protocols require the immediate and continuous availability of large inventories of universal donor (type O) RBCs and (type AB) plasma, often far in excess of these donors' representation in the population or of their actual clinical use. Around 10% of hospitalized patients are actually transfused, but **research suggests that almost 25% of hospitalizations are for conditions for which a robust inventory of blood components is required on hand.**[11]

In addition, the value of a robust blood supply to support patients in the event of disaster, manmade or natural, is clear. Extensive experience with shooting events demonstrates that lives are saved using blood already collected, processed, and ready for distribution, since completing those activities requires up to forty-eight hours from the time of collection, long beyond the critical window when transfusion supports immediate resuscitation and survival. Focal events, like recent mass casualty shootings and severe weather, stress the locally collected blood supply and necessitate the emergent importation of blood components from other U.S. blood centers using their additional inventory—i.e. not required immediately by the centers' customers. Further, **the blood community and federal agencies are actively planning for unprecedented events that might stress the blood supply for more extended intervals**. Examples include severe pandemic influenza that might impair the ability to collect donors affecting multiple communities simultaneously or in wave s, or a bioterror or radiation event that might both cause donor deferrals in affected areas and increase transfusion needs as a clinical consequence of the agent involved.

Supporting a Robust Blood Supply

The decreasing demand for RBCs has no real impact on the fixed and sunk costs incurred by blood collection organizations for critical infrastructure, including facilities, computers, and/or laboratory capacity for ever expanding donor and patient testing.

As transfusion volume declines, these costs are being spread over fewer units provided to hospitals. The result is eroding blood center operating margins, giving rise to concerns about the long-term resiliency of the blood supply. This decreased blood use also does not address declines in the availability and eligibility of the U.S. population to donate blood which blood centers are experiencing with the aging of the donor pool. Millennials and younger donors fail to donate at similar rates as the older population. Further, added safety interventions result in increased donor deferrals, thereby reducing the supply of critical blood components. Recently added safety interventions include higher standards for donor hemoglobin, interventions to prevent donor iron depletion, and donor deferrals mandated by the FDA to reduce the risk of donor reactions.

Transfusion support is evolving to increase recipient safety and effectiveness, which both impose significant costs for collection facilities that must eventually be absorbed or passed along to hospitals and payors. Expenditures for new donor testing include advanced and additional testing for recognized viruses such as hepatitis B and C and HIV which are historically associated with transfusion-transmission, and for emerging infections such as West Nile Virus, Trypanosoma cruzi, Zika virus, and Babesia. Research estimated that the 2016 FDA requirement that U.S. blood centers screen all whole blood and apheresis donations for Zika virus (ZIKV) imposed operational costs of more than $100 million annually.[12]

Rapid progress has also been made in advanced molecular methods to improve blood product compatibility between donors and recipients. Patients with transfusion dependent conditions, such as Sickle Cell Disease, build up antibodies as they receive additional transfusions, necessitating precisely-matched components from a broad pool of donors. In order to maintain this progress, blood centers must maintain and continuously invest resources across all areas of blood center operations, including support for current and evolving good manufacturing and laboratory practices and quality systems regulations. Automated component preparation and many other advances impose substantial capital, maintenance, and training expense.

Conclusion

The value of transfusion to patient care cannot be overestimated. We believe that concerted action in the blood and clinical communities, and those agencies of the federal government that regulate and reimburse for blood products, is urgently needed to ensure the sustainability of this resource so that it remains available for those whose lives depend on it.

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