

NATIONAL STAKEHOLDER DIALOGUE

Inefficiencies in Blood Utilization: Opportunities for Improved Outcomes and Policy Action

Meeting Highlights

Washington, DC

June 18, 2018

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I. SUMMARY

The burden of bleeding in the United States is costly for patients and for the healthcare system. Patients with uncontrolled intraoperative bleeding can be four times more likely to die from a surgical procedure (Stokes et al). These patients, unfortunately, receive more blood transfusions, have longer hospital stays and have statistically worse outcomes, including significantly higher morbidity rates. The American Medical Association and the Joint Commission have identified blood transfusions as one of the top five over-utilized therapeutic procedures in the U.S. (Koren, RR, et al Physicians' lack of knowledge could be a possible reason for red blood cell transfusion overuse? *Isr J Health Policy Res.* 2017; 6: 49). Efficient surgeries with limited bleeding could be one potential solution. Notable national health organizations like the Joint Commission and the American Society of Anesthesiologists have begun to approach the question of how to ensure more appropriate use of blood transfusions. There are few policies that attempt to address the challenges associated with inconsistent management of patient bleeding and blood utilization.

Baxter recognized this challenge and sought a group of stakeholders that would join in examining and educating the public on the problem. Through a one-day dialogue session focused on the best use of national policy levers for this challenge, stakeholders from the provider, patient, national health advocacy and Baxter discussed the importance of educating clinicians and hospitals on the importance of surgical efficiency. The session focused on innovations like the Validated Intraoperative Bleeding evaluation (VIBe) scale and the possibility of establishing quality and reimbursement metrics to reinforce the importance of bleeding control.

At the meeting, experts on key trends in bleeding management, stakeholders and advocates acknowledged the need for cross-functional and interdisciplinary education on the issue of bleeding management. Recommendations included use of electronic medical records to better inform clinicians and care teams about the post-operative impact of intraoperative bleeding. Meeting participants stressed the need to incorporate blood loss into quality metrics and to enable intraoperative interventions through devices like the VIBe scale to stop bleeding earlier. The meeting ended with a clear call to engage a variety of clinical, regulatory, and industry organizations as well as policy-makers in a comprehensive cross-stakeholder education program.

As a result of the meeting, Baxter and other stakeholders are seeking society partners that are interested in advancing the reduction of intraoperative bleeding and improving surgical outcomes in their respective societies. With a broad coalition across a variety of specialties, Baxter and its partners can develop recommendations for clinicians, hospital systems, and policy makers that are consistent and achievable.

II. MEETING RATIONALE AND OBJECTIVES

A growing universe of clinicians and stakeholders have come to recognize that the healthcare system has not yet sufficiently addressed the challenges of patient bleeding and blood utilization. More specifically, there is increasing recognition across interests that a lack of consistent practical and policy guidelines for what level of bleeding should be allowed during surgical procedures has caused hospitals to over-transfuse patients. As previously noted, this is a serious issue as blood transfusions make the AMA's top 5 list of over utilized treatments for U.S. patients.

Though the nation's blood management organizations have worked tirelessly to improve the safety of the U.S. blood supply – something the Food and Drug Administration (FDA) has declared has never been safer – it is still true that patients who receive blood transfusions have a substantially higher risk of adverse events and stay in the hospital three times longer than patients who do not receive transfusions. Furthermore, blood transfusions are expensive, given not only the cost of the product, but also the substantial expense of labor associated with blood management. It goes without saying, then, that by improving clinician management of patient bleeding, we can reduce transfusions and produce substantial benefits for both patients and for the bottom lines of hospitals.

This issue, however, has not been considered in the context of national policy, even though there may be important policy levers – from education and clinical guidelines to reimbursement and provider incentives, among others – that can specifically target these important goals. As a result, stakeholders inside the Beltway met for the first time in Washington, D.C. to:

- Better understand the facts associated with inconsistent management of bleeding and over-transfusion of patients;
- Share their perspectives on the implications of these trends for their own stakeholders, from patient communities to clinical experts to supply chain management firms and hospital groups;
- Learn about new evidence to support policy and clinical change in bleed management and blood transfusion; and
- Identify issues that merit elevation in the policy environment and begin to contemplate opportunities for policy engagement among key stakeholders to promote a patient-centric view of bleeding management and blood utilization.

The summary below reflects important background context for the meeting, as well as elements of the day's discussion, including key take-aways and possible areas for policy action.

III. ISSUE OVERVIEW

Healthcare spending in the United States increased at 4.3%, almost twice the rate of inflation (cms.gov). In 2017, total U.S. healthcare spending was nearly \$3.5 trillion and annual spending is projected to reach \$5.7 trillion by 2026 (Centers of Medicare & Medicaid Services, 2018).

To address this challenge, leaders in healthcare and on Capitol Hill continue to look for ways to rein in spending – particularly ways to reduce costs while improving patient outcomes. One way leaders have discussed as a potential opportunity to address this challenge is by promoting efficiencies in the utilization of rationed resources, like blood.

Since the enactment of the Patient Protection and Affordable Care Act (ACA) in 2010, utilization of healthcare services and resources in the United States has been on the rise – primary care visits are up 3.8 percent, emergency room visits are up 2.2 percent, and inpatient hospital visits are up 3.1 percent (Glied & Ma, 2015). Increases in utilization have risen even more starkly in the Medicaid population, where primary care visits are up 21 percent since 2010 and inpatient stays are up 16 percent since 2005 (Gray et al, 2016, McDermott, et al, 2017). In this environment, healthcare providers are under continuing pressure to more efficiently allocate resources to lower costs, while at the same time providing optimal patient outcomes.

Further exacerbating the stress on the healthcare system is the steady aging of the U.S. population leading to a corresponding increase in the annual number of surgical procedures performed (Semel et al., 2006). Evidence suggests the rate of surgical procedures - both elective and non-elective - is likely to rise despite advances in preventative drug therapies.

The complexity of surgical procedures in an aging population, where surgical blood loss can have devastating consequences, creates challenges for hospitals' resources. If not well managed, intraoperative bleeding in complex procedures can threaten patient near-term and long-term outcomes and expend unnecessary hospital resources.

To address these dynamics and the challenges they present, associations, hospitals, surgeons, and policymakers must consider opportunities to drive new efficiencies in healthcare delivery and doing so in a way to optimize patient outcomes. This is particularly important in high-risk surgeries. While there are several ways to create surgical efficiencies, and improve health outcomes, efficiencies that drive lower utilization of blood can indicate adoption of sustainable improvement initiatives across the hospital resulting in better post-operative outcomes.

In a first step, established and respected institutions like the Society of Thoracic Surgeons, American Society of Anesthesiologists, The Joint Commission, the Society for the Advancement of Blood Management, and the U.S. Department of Health and Human Services and others have recognized the importance of improving blood management and have proposed clinical guidelines to reduce the need for intraoperative transfusions through pre-operative, intra-operative, and post-operative evidence-based recommendations.

As the annual numbers of complex surgeries continue to rise, the intraoperative bleeding management needs to be more urgently addressed to avoid significant post-surgical costs associated with surgical complications. Uncontrolled intraoperative bleeding is often the primary driver for poor outcomes and presents a unique opportunity for hospitals and policymakers to align surgical suites on comprehensive blood management programs. In spinal surgery alone, the use of transfusions following surgery resulted in statistically significant increased risk of heart attacks, dangerous blood clots, longer in-patient hospital stays and overall mortality.

New assessment techniques can offer opportunities to drive toward fewer uncontrolled intraoperative bleeds. Innovations like the VIBe scale can potentially reduce unnecessary transfusions by quickly identifying the right hemostat or sealant for specific bleeds. Both patients and healthcare systems can benefit from a reduction in blood/blood product utilization. This suggests that such opportunities should be considered and acted upon by healthcare system stakeholders, including national policymakers.

a. Blood in the United States: Supply is Finite and Access is Expensive

Blood transfusions have become an increasingly frequent practice in U.S. hospitals. In fact, between 1997 and 2011, blood transfusions have increased 134 percent. That said, current estimates show that as many as 40 to 50 percent of blood transfusions may be unnecessary, potentially putting patients' lives in jeopardy, and could be costing individual hospitals as much as \$1 million per year (Premier, 2017; The Joint Commission, 2017).

Reducing the need for blood transfusions by reducing blood loss during surgery would eliminate wasteful utilization of resources and likely improve patient post-surgical outcomes. According to the report, hospitals can save money by eliminating these transfusions. Additionally, the report notes, blood transfusions are the most frequently performed hospital procedure in the country and cost \$1,000 per unit of blood [transfused] (Premier, 2017). Other estimates show that the price of transfusing blood is more expensive, largely due to shifting acquisition costs of blood. These estimates, when accounting for staff and facility costs associated with performing the procedure, estimate that the cost of transfusing one unit of blood to be \$1,600.

In addition to the supply limitations on blood and the costs associated with transfusions, transfusions may not lead to optimal patient outcomes. Rather, blood transfusions are frequently associated with longer patient length of stay, increased mortality and morbidity, in addition to increased costs and resource utilization.

To this end, study after study have shown the tremendous value of limiting blood transfusions to patients - in terms of saving money through reduced blood acquisition costs and shorter lengths of hospital stays, but also to significantly improved health outcomes for patients. For cardiac surgery patients, in particular, health impacts are meaningfully improved for patients who do not receive blood transfusions - both in short- and long-term mortality.

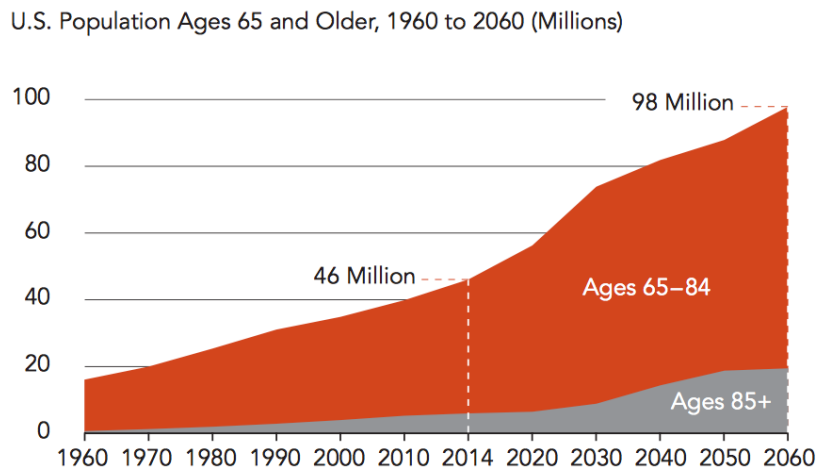
Such positive results - improved patient outcomes, reduced resource allocation, and cost savings for providers - all indicate that facilities who promote more restrictive blood transfusion policies, including by implementing blood management programs that promote the use of hemostatic agents can meaningfully address the challenges posed in the new healthcare environment, prepare for the coming surge in demand created by an aging population, and improve outcomes.

b. Dramatic Demographic Shifts

There is currently a significant demographic shift occurring in the United States as the population is quickly aging. According to a 2015 analysis of U.S. Census Bureau information by the Population Reference Bureau, it is estimated that there will be 98 million Americans ages 65 and over by 2060. For reference, in 2014, there were 46 million Americans ages 65 and older, meaning that this population will more than double in just over 40 years.

In 1960, this demographic accounted for 9 percent of the total U.S. population. In 2014, older Americans comprised 15 percent of the total population. It is estimated that, by 2030, this demographic will be 21 percent of the total population and grow to nearly a quarter (24%) of the total population by 2060 (Colby & Ortman, 2015).

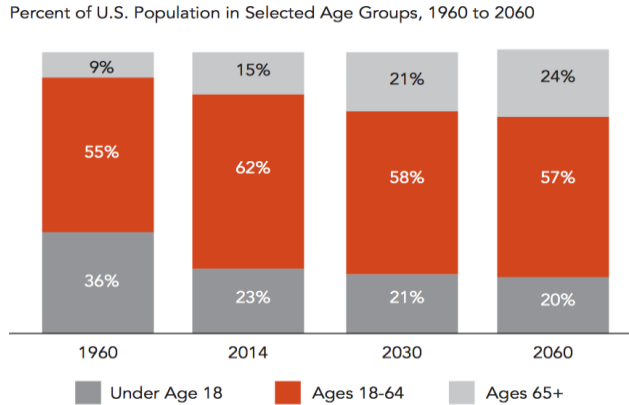
The Number of American Ages 65 and Older Will More Than Double by 2060.



Source: Mather, Jacobsen, & Pollard, 2015

The sub-category of Americans who are 85 and above is also increasing – and estimated to continue to increase over the next few decades. As medical technology continues to improve and life expectancies continue to lengthen in the United States, this demographic is expected to constitute a larger portion of the population going forward.

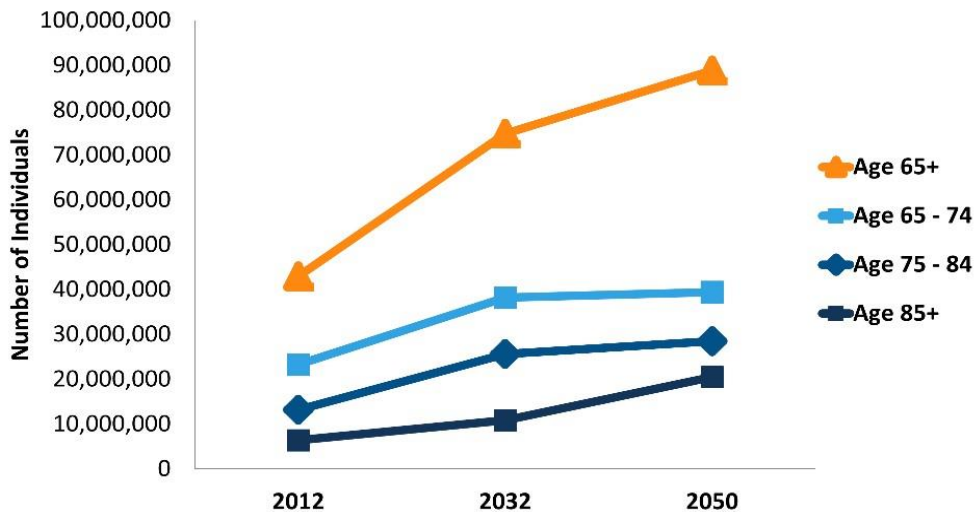
By 2060, Nearly One-Quarter of Americans Will Be Ages 65 and Older



Note: Number may not sum to 100 due to rounding
Source: Mather, Jacobsen, & Pollard, 2015

In 2012, there were 5.9 million Americans ages 85 and over. By 2040, it is expected that there will be 14.1 million Americans over 85 – an increase of nearly 140 percent. The changing demographics increases the overall frailty of the U.S. population and will have significant ramifications on our nation’s healthcare spending – particularly as millions more Americans are enrolled in Medicare. This shift will likely require fundamental shifts in how we deliver care and should prioritize methods that create efficiencies, improve patient outcomes, and save healthcare system resources.

The 65 and Over Population Will More Than Double and the 85 and Over Population Will More Than Triple by 2050



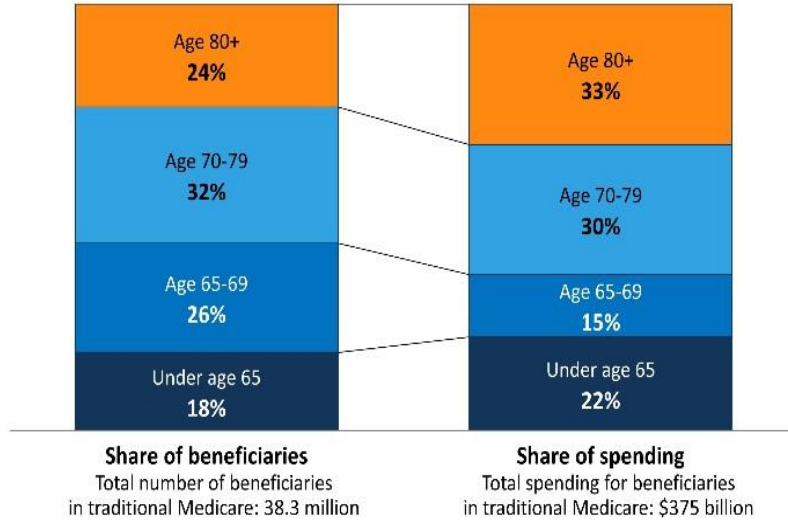
Source: Houser, Fox-Grage, & Ujvari, 2012

The challenge, for policymakers and others, that this demographic shift poses is that older, frailer Americans are more healthcare resource-intensive, as they tend to be less healthy, often struggle with one or more chronic diseases, more frequently visit physicians, emergency rooms,

and require life sustaining surgical procedures. As a result, spending on this portion of the population represents a significant portion of annual Medicare spending.

People ages 80 and older accounted for 24 percent of the Medicare population and 33 percent of Medicare spending in 2011

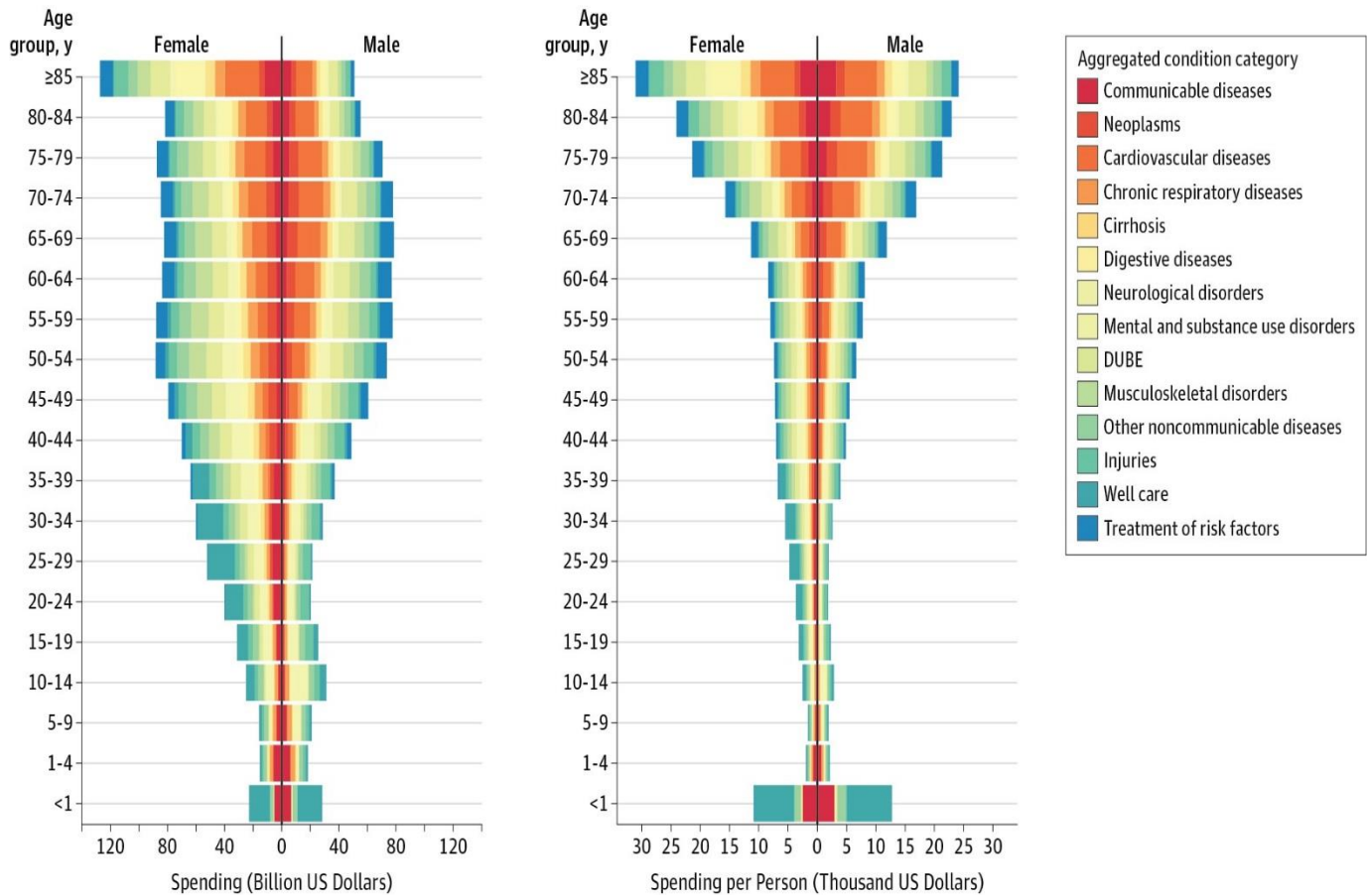
Distribution of traditional Medicare beneficiaries and Medicare spending, 2011



Note: Analysis excludes beneficiaries with Medicare Advantage
Source: Neuman, Cubanski, Huang, and Damico, 2015

Part of this is attributable to the fact that older adults are living longer today than ever before and old age is less likely to mean death or declining function than in previous generations. That said, there are other risk signs that show that older Americans may be in worse health than previous generations, including a growing numbers of older Americans with multiple chronic conditions (arthritis, diabetes, cardiovascular disease, obesity, and others). All of this leads to tremendous demands in healthcare resources and costs for caring for this population.

Personal Health Care Spending in the United States by Age, Sex, and Aggregated Condition Category, 2013

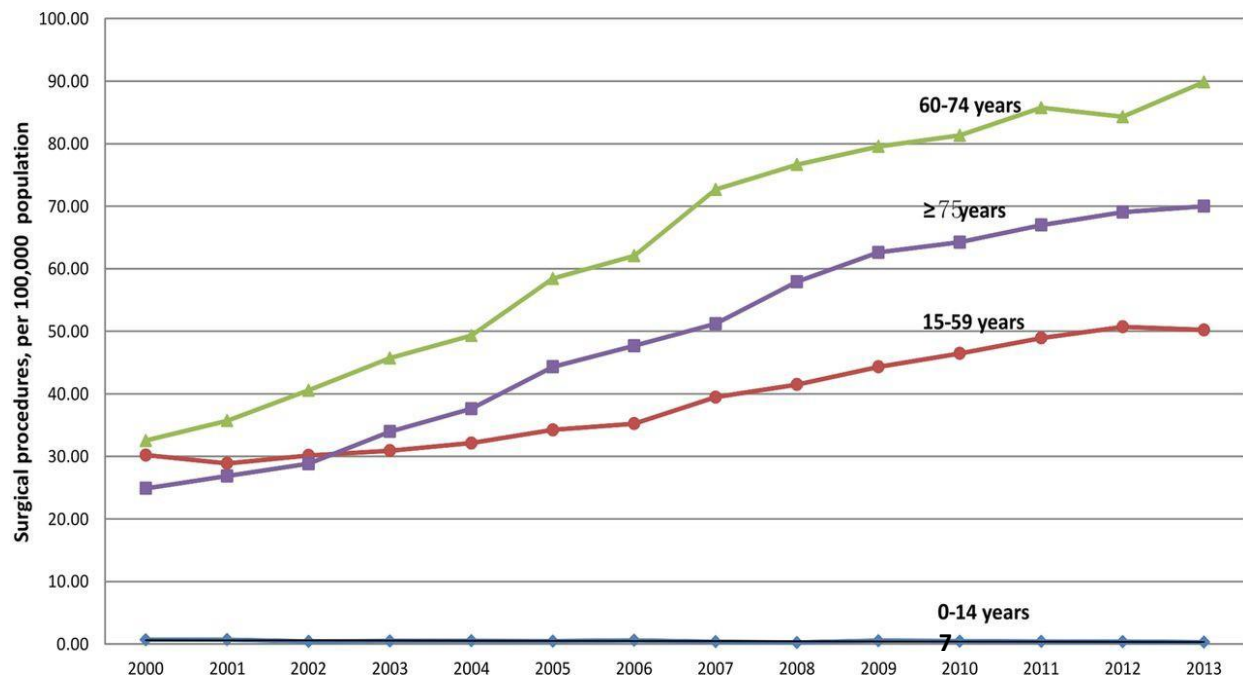


Source: Dieleman, Baral Birger, et al, 2016

c. Opportunities to Create Efficiencies

Over the last 20 years, the number of older adults requiring some sort of surgical intervention – elective or non-elective – has substantially increased. Ongoing demographic shifts in the United States are expected to drive this trend. Currently, older Americans undergo more than 55 percent of all surgical procedures. By 2030, the projected number of surgeries is expected to increase by as much as 600 percent annually, depending on the type of surgery performed.

Trends in hospital admissions and surgical procedures for degenerative lumbar spine disease in England: a 15-year time-series study



Source: Sivasubramaniam, Patel, Ozdemir, et al, 2015

Complex surgical procedures, such as cardiac procedures (especially those involving bypass), trauma surgeries, and spinal surgeries have the potential for significant intraoperative bleeding. Accordingly, these procedures present the greatest opportunity for providers to create efficiencies and protocols for patient benefit.

An analysis of over 80,000 surgeries found that the proportion of surgeries requiring transfusion, across 408 cardiac surgery departments, ranged from 7.8 percent to 92.8 percent, indicating enormous variation and inconsistencies in protocols for the administration of transfusions (Bennett-Guerrero et al., 2010). These inconsistencies lead to inefficiencies – not only in terms of the cost of acquiring unnecessary blood, but also the cost of storage, administration, and monitoring of that blood.

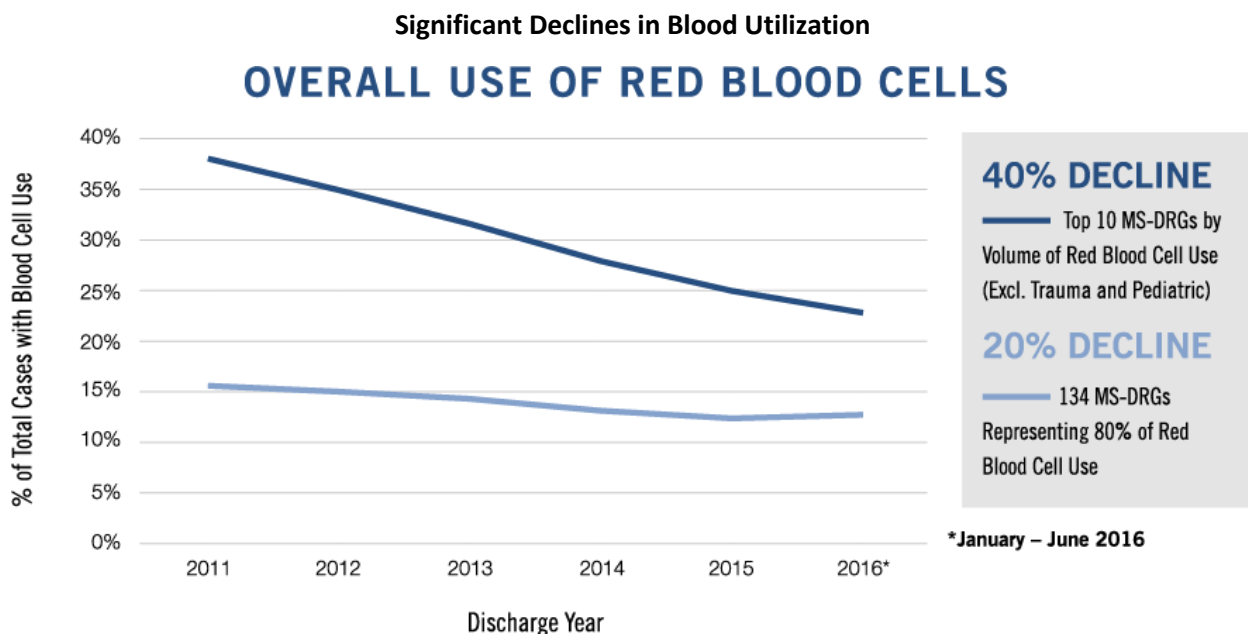
Some hospitals have implemented formal patient blood management (PBM) programs to systematically reduce unnecessary transfusions. Protocols that might be implemented include: instituting lower, evidenced-based, hemoglobin levels at which a transfusion can be administered; utilization of a standardized rating system for the severity of intraoperative bleeding episodes (VIBe scale); advising practitioners to administer transfusions one unit at a time; intraoperative blood salvage; preemptive treatment for anemia using erythropoietin or iron; and increased use of modern surgical techniques, including cautery, hemostatic agents, and surgical sealants (Frank et al., 2017; Clevenger et al., 2015).

Despite this opportunity, only 35 percent of U.S. hospitals have a formally implemented PBM program (Premier, Inc, 2017).

The rate of increase in the aging population adds to the urgency to implement these types of protocols and prepare for potential increases in demand for the surgical suite. As discussed above, there will soon be millions more individuals in Medicare and Medicaid. While evidence shows that these individuals entering the Medicare system have longer life expectancies, other data show that this population is disproportionately unhealthy, with increased prevalence of chronic diseases, many of which could ultimately lead to surgery. As in the past decades, Medicaid reimbursement will continue to be a challenge for hospitals requiring low-burden cost containment measures to reduce inpatient and outpatient costs.

IV. DISCUSSION HIGHLIGHTS

With this context in mind, the day's discussants (see list at Appendix B, page 19) shared the source of their interest in being part of a dialogue on bleeding and blood management, highlighting interests in reducing bleeds among vulnerable patients, promoting a patient-centric approach to blood transfusions, interdisciplinary data exchange, and encouraging the development of a common clinical language framework across healthcare stakeholders for intraoperative bleeds, among other things.



Source: Premier, Inc, 2017

Participants heard a presentation from Premier, Inc. Director Janelle Johnson, who noted that patients who bleed unnecessarily and have more blood transfusions have poorer outcomes. Specifically, blood transfusions increase patient mortality by more than 66%. Her research also

reveals the extreme cost of transfusions, which can run more than \$1,000 per unit. For this reason, Premier launched an effort to help promote more careful management of blood, and that effort led Premier's U.S. hospitals to lower blood utilization by 20%, with a 40% decline in the top 10 Medicare Severity Diagnosis Related Groups (MS-DRGs). Even with this decline, Johnson said, Premier found a significant variation between and among clinical specialty groups in bleed management and transfusion use, reflecting different tolerances of bleeding levels in different surgeries, and reminding participants that there is more work to be done to broaden understanding, metrics and data.

Participants also heard from Dr. Aryeh Shander, an anesthesiologist and professor at Rutgers Medical School and past president of the Society for the Advancement of Blood Management (SABM). Shander, a thought leader on blood management, suggested that intraoperative bleeding should be considered a quality indicator for patients. Reflecting on the fact that blood transfusions extend patient stays and ultimately these extensions can cause additional complications that become even more problematic and costly, Shander shared that:

- World Health Organization classifications of bleeding are overly subjective, and thus not helpful;
- It is disconcerting that patient blood loss during surgery is estimated but not measured, and that estimations of blood loss are often higher than actual loss, which can lead to unnecessary transfusion;
- There is a need for real-time assessment of bleeding, versus the retrospective approach that is more common today;
- Enough science exists to develop evidence-based criteria for bleeding estimation and management with greater sensitivity and specificity than currently exists.

Responding to the inexact nature of blood loss estimation and the need to bring more specificity to this discipline, Dr. Donald Cheatem of Baxter reminded participants that the VIBe scale offers a valuable approach to bringing a common language framework across specialties to measuring intraoperative blood loss and is currently the only prospective scale.

Opportunities for Action

Suggestions from around the discussion table for areas that present potential opportunities to drive improvement in bleeding management and blood utilization included:

- ✓ **The establishment of bleeding and/or blood loss in surgery as a quality measure;**
- ✓ **An emphasis on improved utilization of electronic medical records and other ways to promote system-wide data sharing;**
- ✓ **Considerations of ways to educate stakeholders on the VIBe bleeding scale; and**

- ✓ **Development and promotion of clinical best practices in blood utilization – including for surgical patients.**

V. MEETING TAKE-AWAYS AND NEXT STEPS

The broad range of participants in this preliminary discussion on reducing inefficiencies in blood utilization welcome steps to improve clinical and surgical practices in a way that protects available blood supply and helps control U.S. healthcare spending. The ballooning, aging population will create an unprecedented demand for surgeries in the near future. And the increased patient throughput in operating rooms will undoubtedly highlight the need for more standardization to address the challenges in bleeding management and blood utilization.

As a first step, this initial input from provider, supplier and patient representatives recommends a comprehensive four-part approach that includes policies and programs outlined below:

- **Challenge awareness:** Educate clinician stakeholders about the current and looming challenges of bleeding management and blood utilization to prompt broader and richer dialogue regarding policy and practical steps that can yield improvements and savings;
- **Create a common language:** Encourage the development and implementation of a set of clinical standards to assess intraoperative bleeding – a major contributor to use of blood transfusions;
- **Incentivize innovation:** Promote innovative approaches to patient care through new and cutting edge surgical techniques, products, and procedures;
- **Institutionalize alternatives:** Utilize strength of physician groups, hospitals and policy makers to make use of new approaches to blood supply management part of the expectation in healthcare quality and value.

Accomplishing these four steps to reduce inefficiencies in blood utilization, requires engagement from providers, suppliers, hospital administrators, national policy-makers and policy-influencers. In this preliminary meeting, all stakeholders agree that driving out inefficiencies is best accomplished by future partnerships and cross-stakeholder collaborations.

As a next step to the initial meeting, stakeholders encourage Baxter to publish the minutes of the meeting and assemble a coalition of stakeholders to support educational programs. In addition, Baxter is seeking physician and physician professional societies to partner with in developing an intraoperative bleeding scale.

Finally, the initial meeting recognized the opportunity to work collaboratively on issues of mutual importance. As such, the group emphasized the need for continued dialogue to identify and pursue shared interests opportunities on Capitol Hill, with regulators, and other health

policy advisory bodies to drive improvements that will yield not only clinical benefits for patients but also cost benefits for the U.S. healthcare system through better blood utilization.

VI. APPENDICES

A) Agenda: Improving Patient Outcomes by Optimizing Blood Utilization

Monday, June 18, 2018

12:30-3:30

Top of the Hill Banquet and Conference Center
1 Constitution Avenue, NE, Washington DC 20002

<i>Time</i>	<i>Topic</i>	<i>Discussion Leader</i>
12:30 pm	Networking Lunch and Introductions	Stephanie Silverman, Chief Executive Officer, <i>Venn Strategies</i>
1:00 pm	Defining the Challenge	Janelle Johnson, Director, <i>Premier Performance Partners</i>
1:30 pm	Opportunities in Patient Blood Management	Dr. Aryeh Shander, Dr. Don Cheatem, and Russ Pagano
2:00 pm	Delegate Discussion	Stephanie Silverman (moderator)
2:30 pm	Identifying the Solution: Improving Outcomes and Lowering Costs	Stephanie Silverman (moderator)
3:00 pm	Next Steps/ Adjourn	Stephanie Silverman

B) Participant List

- **Leah Mendelsohn Stone**, *Director, Public Policy and Advocacy*, American Association of Blood Banks (AABB)
- **Rick Garcia**, *Director of Nursing Education*, American Association of Colleges of Nursing
- **Rachel Gandell Tetlow**, *Director, Federal Affairs*, American College of Obstetricians and Gynecologists (ACOG)
- **Deidre McDaniel**, *Program Manager, Alliance for Innovation on Maternal Health (AIM)*, American College of Obstetricians and Gynecologists (ACOG)
- **Betsy Wieand**, *Program Director, Payment and Delivery System Policy*, American College of Obstetricians and Gynecologists (ACOG)
- **Kate Fry**, *Chief Executive Officer*, America's Blood Centers
- **Dr. Don Cheatem, M.D.**, *Lead, Global Medical Affairs, Regional MA Lead Americas, Global Clinical Strategy, Advanced Surgery*, Baxter Healthcare
- **Kathryn Conner**, *VP Global Marketing*, Baxter Healthcare
- **Russell Pagano**, *Senior Director*, Baxter Healthcare, Inc.
- **Todd Ebert**, *President and Executive Director*, Healthcare Supply Chain Association
- **Pedro Montenegro**, *Policy and Program Associate*, The National Hispanic Medical Association
- **Dr. Elena Rios**, *President and Chief Executive Officer*, The National Hispanic Medical Association
- **Rob Purvis**, *Senior Vice President and Chief Marketing Office*, New York Blood Center
- **Mickayla Stogsdill**, *Intern*, Office of Senator Lamar Alexander
- **Margaret Reagan**, *Corporate Vice President*, Premier, Inc.
- **Janelle Johnson**, *Director*, Premier Performance Partners
- **Thair Phillips**, *President and CEO*, RetireSafe
- **Dr. Aryeh Shander, M.D.**, *Advisory Director*, Society for the Advancement of Blood Management
- **Dawn Latham**, *Senior Director Government Relations*, The American Red Cross
- **Dr. Barry Siegfried**, *Medical Director, Great Lakes, Indiana-Ohio and Southeastern Michigan Blood Services Regions*, The American Red Cross
- **Kathryn Spates**, *Director, Federal Relations*, The Joint Commission
- **Amanda Grimm Wiegrefe**, *Assistant Director of Government Relations*, The Society of Thoracic Surgeons
- **Stephanie Silverman**, *Chief Executive Officer*, Venn Strategies

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