Review Article

Development and certification of a patient blood management program

Mark T. Friedman[1], Katya Dayot[2], Ram Mohan Jaiswal[3], Divjot Singh Lamba[4], Deborah Tolich[5]

[1]NYU Langone Health, Department of Pathology, Transfusion Medicine Service, Long Island School of Medicine, Mineola, NY, USA; [2]St. Bernardine Medical Center, San Bernardino, CA, USA; [3]Blood Centre and Transplant Immunology Lab, Mahatma Gandhi Medical College and Hospital, Rajasthan, India; [4]Department of Transfusion Medicine, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India; [5]Cleveland Clinic, Patient Blood Management, Cleveland, OH, USA

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Correspondence to: Mark T. Friedman, DO. NYU Langone Health, Department of Pathology, Transfusion Medicine Service, Long Island School of Medicine, 259 First Street, Mineola, NY 11501, USA. Email: mark.friedman@nyulangone.org.

Abstract: Despite calls for the implementation of patient blood management (PBM) programs by various organizations, including the World Health Organization (WHO), and the availability of PBM certification by the Association for the Advancement of Blood & Biotherapies (AABB)/The Joint Commission (TJC), hospitals have been slow to fully develop such programs. Yet, increasingly, published evidence points toward the vast benefits of these multidisciplinary, bundled strategies that focus on blood conservation, blood loss minimization, and anemia management in a patient-centered manner. Such strategies, which have been shown to improve patient outcomes and reduce healthcare costs, have evolved from being mainly product focused (i.e., transfusion avoidance) to being patient outcome focused. However, developing a PBM program is a complex process involving multiple stakeholders and challenges to overcome. Drafting of a sound business plan detailing goals and necessary resources along with getting key stakeholder support are critical first steps toward successful implementation. Education and training of clinical staff in PBM strategies as well as identifying several key metrics to track program success are important steps that follow. While certification is a crowning achievement in program implementation, programs may continue to evolve, adding resources to achieve to a higher level of certification. The level of certification, however, is a reflection of the complexity, not the quality, of a PBM program. This article reviews all aspects of PBM development, from creating a business plan with key stakeholders' acceptance to education and training, key metrics, implementation, and finally, certification.

Keywords: Patient blood management (PBM); PBM certification; PBM program development

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Introduction

The global definition of patient blood management (PBM) is a "patient-centered, systematic, evidence-based approach to improve patient outcomes by managing and preserving a patient's own blood, while promoting patient safety and empowerment" (1). PBM was introduced to shift focus from product to patient. Although it was introduced for the adult perioperative setting, the concepts are relevant and applicable to many aspects of different patient subgroups in various medical and surgical specialities. Key strategies or concepts of PBM are based on three pillars: optimizing red cell mass, minimizing blood loss, and managing anemia (2).

In adult settings, PBM programs have been associated

with reduced red blood cell (RBC) transfusion rates, reduced complication rates, decreased mortality, shortened hospital length of stay (LOS), and product-related cost savings (3). Yet PBM programs are less well established in particular patient subgroups and face many challenges and barriers to effective implementation (4). There are several transfusion and PBM guidelines as well as resources to help inform and guide transfusion practice in medical patients using a patient-centered model of care based on laboratory findings and clinical evaluation, including guidelines published by the Association for the Advancement of Blood & Biotherapies (AABB) and by the Society for the Advancement of Patient Blood Management (SABM) (5,6). However, these need to be more consensus- and evidence-based as well. Regular audits should also be part of PBM to optimize blood use in combination with transfusion guidelines.

Anemia is common in patients of medical and surgical specialities due to nutritional deficiency (i.e., iron and vitamin B12). Treatment of anemia in these patients may require RBC transfusions below a certain hemoglobin level and form an important supportive therapy. However, transfusion decision-making needs to be carefully considered, involving appropriate management of anemia to reduce inappropriate transfusions. Restrictive RBC transfusion thresholds are recommended. Transfusion thresholds need to be followed judiciously (i.e., keeping the hemoglobin level near to 7.0 g/dL for patients with anemia but who are otherwise stable) with single-unit transfusions, rather than two units, administered as necessary in non-bleeding patients (7).

It is important to consider the inherent transfusion-related risks specific to a particular group of patients as well. PBM programs need to review patient outcomes and the risks associated with transfusions. While traditional risks focused on transfusion transmissible diseases (TTD's), such as human immunodeficiency virus (HIV) and viral hepatitis (i.e., hepatitis B and C viruses), more emphasis has been placed on other established acute risks as the risk of TTD's has diminished due to increased screening and the introduction of highly-sensitive nucleic acid tests. These include acute hemolytic reactions due to patient mis-identification, transfusion-associated circulatory overload (TACO), and transfusion-related acute lung injury (TRALI), among others. Nevertheless, PBM also assumes importance since various emerging pathogens do pose a threat to the blood supply chain (e.g., Zika virus outbreak in South America, hepatitis E, chikungunya, dengue outbreak in Southeast Asia, and the global COVID-19 pandemic) (8-10). Chronic risks include iron overload, alloimmunization, and transfusion-related immunomodulation (TRIM) effects. More studies are needed to evaluate these risks.

Other strategies include use of erythropoiesis-stimulating agents (ESAs) for anemia of chronic kidney disease when the hemoglobin falls below 9 to 10 g/dL (11). Iron replacement may also be useful with or without iron deficiency in conjunction with ESAs to improve hemoglobin response and to reduce total RBC transfusions. A few studies have advised against use of ESAs due to venous and thromboembolic events (12).

Thrombopoiesis-stimulating agents (TSAs, i.e., eltrombopag and romiplostim) can be used for patients with thrombocytopenia. However, there are not enough studies to support this use, and many studies have not recommended TSAs for this reason and have cautioned against use due to the risks of thromboembolic events similar to use of ESAs (13,14).

Efforts must be made to optimize hemostasis by treating reversible causes of coagulopathy. To assess for coagulopathy in intraoperative settings, point-of-care (POC) devices can be utilized. The latest guidelines recommend against routine correction of minor coagulation abnormalities [i.e., a minimally elevated international normalized ratio (INR)] prior to surgery (15).

This article will further discuss PBM development and certification, including creation of a PBM business plan, key stakeholders' acceptance, education and training, key metrics, implementation, and levels of certification.

Business plan

Like any other endeavor, the road to a successful PBM program begins with a sound business plan. In simple terms, a business plan defines goals and how these goals will be achieved. It provides a template for defining key stakeholders (i.e., organization and management), necessary resources, expected costs and funding, anticipated challenges, and benchmarks and milestones for measuring success at key points in time. A traditional business plan begins with a well-written executive summary that serves to describe the problem as well as the scope and value of the proposal in providing a solution to the problem. In terms of PBM, the identified problem is non-evidence-based transfusions resulting in overutilization of blood products, increased risk of adverse events, poorer patient outcomes, and higher healthcare costs. However, although PBM has

traditionally focused on minimizing overutilization of blood product transfusions (i.e., blood product-centered focus), its focus has shifted toward optimizing patient outcomes using medical and surgical interventions, with evidence-based reductions of transfusions as a means and not an end to patient-centered care (16). When considering the scope of a PBM program, one should, therefore, endeavor to include interventions that will maintain hemoglobin concentrations, optimize hemostasis, and reduce blood loss to improve patient outcomes. Examples of such interventions include minimally invasive surgical techniques, specialized anesthetic techniques (e.g., hypotensive anesthesia), intraoperative cell salvage and normovolemic hemodilution, POC hemostasis (i.e., viscoelastic) testing, and preoperative anemia management. Thus, the scope of a PBM program extends well beyond the transfusion service, and a comprehensive business plan must be broad enough to include these clinical services and interventions.

One of the first hurdles to overcome in getting a successful PBM program up and running is getting buy in from key stakeholders. Since PBM is a multidisciplinary effort, identifying key stakeholders from various departments and services, is essential. Yet, beyond identifying the stakeholders, it is important that PBM champions be identified who will promote the program and its goals within each key support area. Clinical champions can make a strong case for implementing PBM based on improved patient outcomes and healthcare cost savings (17).

A business plan must also include a financial statement. This is important in the context of a PBM program, given that although there are expected long-term cost savings, there will be significant upfront costs necessary to acquire resources to implement and support the program. Upfront costs include dedicated PBM personnel [e.g., PBM coordinator, transfusion safety officer (TSO)], information technology (IT) enhancements [e.g., computer physician order entry/clinical decision support (CPOE/CDS), data analytics], laboratory testing equipment (e.g., viscoelastic testing), and clinical services (e.g., cell saver, preoperative anemia clinic). However, the budgetary impact can be softened if a phased approach is taken toward PBM implementation, with start-up execution of some basic strategies, such as provision of PBM education, minimizing lab draws to prevent hospital-acquired anemia, and CPOE/CDS enhancements. The costlier interventions can be added according to a planned timeline. In fact, successful PBM programs often start with small but achievable quality improvement projects that demonstrate evidence of improved patient outcomes and/or cost savings and lead to resource commitment from the hospital's executive leadership for a more formal program (17).

Finally, traditional business plans include a market analysis. For a PBM start-up, this might consist of an analysis of other PBM programs in local or regional healthcare facilities, to compare their strengths and weaknesses. Such an analysis can circumvent initial and costly mistakes in planning while helping to focus the program on successful long term and achievable interventions.

Stakeholders

A stakeholder is a person with an interest or concern in an organization or a business and one who is involved or is affected either directly or indirectly by any action or change occurring in the organization (18). Stakeholders can be divided into primary and secondary stakeholders. For a PBM program to be implemented effectively, the role of key (primary) stakeholders is very important. These stakeholders are directly involved in various decisions and policy changes being implemented to establish a PBM program in a hospital or hospital system and are impacted by the decisions and policy changes. Key (primary) stakeholders notably include patients, hospital leadership and administrators (i.e., chief medical officers, chief executive officers), clinicians (i.e., surgical specialists [e.g., general surgeons, cardiothoracic surgeons, neurosurgeons, orthopedic surgeons, vascular surgeons, etc.], anesthesiologists, intensive care specialists, internal medicine specialists [e.g., cardiologists, gastroenterologists, hematologists, etc.], and obstetricians/gynecologists, among others), transfusion medicine specialists, clinical laboratory scientists, nurses, advanced level nursing providers, clinical pharmacology specialists and clinical pharmacists, allied health professionals, finance administrators, IT managers, and quality management personnel (19).

Secondary stakeholders are those who are involved in decisions and policy change implementations but are not directly affected or may be affected to a lesser extent (e.g., government and professional organizations, media, the hospital's public relations office and medical journalists). They have a role to issue public communications in the form of PBM fact sheets, PBM columns, and social media to educate the masses regarding patient safety and outcome improvements (20). These should in turn help the patients and patient communities to make informed transfusion decisions, thus aiding in the implementation of

PBM among the key stakeholders. PBM fact sheets should include information relevant to the patient and help advise patients to:

- Question their physician regarding how they would be treated for anemia before any surgical or medical procedure;
- Know what medical alternatives are available to avoid transfusions;
- Know whether there is a possibility for transfusion during or prior to any scheduled procedure;
- Understand the risks and complications involved if a transfusion is given;
- Know if transfusion is essential or lifesaving and whether the number of transfused units can be limited or not.

The role of media, the hospital's public relations office, and medical journalists is highly essential to effectively promote the PBM program to the masses and to the patient populations. Press releases, printed materials and patient brochures, posters, and newsletters can be effective resources for publicizing the program. Furthermore, the hospital's public relations office should be involved in promoting the PBM program through the hospital website (for both employees and the public) and patient information brochures along with featuring PBM in the hospital annual report.

Once the primary and secondary stakeholders are identified (*Table 1*) and actively involved in the PBM program, the next important task is to effectively implement the program by establishing PBM infrastructure, benchmarking, and reporting systems to continuously monitor PBM activities.

Education and training

Risks associated with blood components and the advantages of PBM are well known and documented. A significant challenge is ensuring that every member of the multidisciplinary team working in therapeutic areas that use blood products is aware of the risks, advantages, and guiding principles and that they carry out transfusion practices effectively, safely, and efficiently (21). In line with the practitioner's specialty area and professional path, this is mainly accomplished by education and training throughout the practitioner's career. To implement PBM practice improvement efforts inside of a clinical division or healthcare service, one must first develop the knowledge and leadership abilities required, which necessitates ongoing training and education. Staff members like residents and nursing officers play a critical role in supporting patients and caregivers in being active partners in decision-making as part of their care and treatment by providing them with information about the risks, benefits, and options involved (22).

Preoperative anemia is common with rates varying from 20% to 75% and is frequently made worse by hospital-acquired anemia (23). Most of the time, anemia is not seen as a clinically relevant illness, goes unnoticed in hospitalized patients, and, consequently, is left untreated. Anemia, blood loss, and transfusion, however, are independent risk factors for unfavorable outcomes, including morbidity, death, and increased LOS.

In addition to the global definition, the World Health Organization (WHO) defines PBM as "a set of evidence-based practices to optimize medical and surgical patient outcomes through diagnosis and etiology-specific treatment of anemia and preserving the patient's own blood by minimizing blood loss while prompting patient safety and empowerment" (24). While these two PBM definitions slightly differ, they are both equally of importance. The entire clinical staff, including clinical specialists, nurses, pharmacists, and others who influence decisions about PBM, needs to receive training and communication on PBM to prevent information asymmetry and conflicting behaviors within the hospital. Implementers recommend that clinical expertise and abilities for PBM be included in undergraduate, postgraduate, and other education programs, including medical school curricula, accredited continuing medical education programs, PBM academies, as well as e-learning and information platforms. However, except for Western Australia, medical students' undergraduate curricula do not currently include PBM education (24). As such, in order to incorporate PBM into an undergraduate education by the federal ministries of health and education, where appropriate, implementers should communicate with the leadership of academia and medical schools (24).

The expanding number of research publications demonstrates that PBM offers a wide range of novel experimental, clinical, epidemiological, and health-economic research options.

Insights into the clinical and financial results of PBM can be gained by benchmarking and reporting key performance indicators. Global thought leaders have underlined the need for more research and national and international exchange for better PBM strategies. Implementers have requested that local evidence be created and shared to connect

Table 1 Primary and secondary stakeholders

Stakeholders	Description
Primary stakeholders	
Patients	• Directly affected by PBM decisions but usually do not have the awareness of being primary stakeholders
	• May receive transfusions of various blood components and should be aware of their primary stakeholder status
	• Should make active decisions regarding treatment options, including transfusion alternatives available to them
Clinicians and advanced level nursing providers	• Provide treatment to patients; thus, need to understand three-pillars principle of PBM
	• May need to change practice principles and treatment protocols to include PBM
	• Should take the lead to implement PBM principles by educating peers, emphasizing the importance of peer-reviewed evidence, and coordinating with other primary stakeholders to sustain the PBM program
Transfusion medicine specialists	• Help clinicians to adhere to transfusion guidelines
	• Gather PBM metrics, such as total number of transfusions, transfusion threshold adherence, transfusion ordering rate, etc.
	• Play an essential role in implementing and continuously monitoring the PBM program
	• Incorporate PBM principles into the hospital's transfusion and hemovigilance committee meetings
Hospital administrators and leadership (chief medical officer, chief executive officer)	• Include the administration head (chief executive officer), chief financial officer, chief medical officer, chief nursing officer, chief quality officer and chief information officer
	• Decide the infrastructure and budget requirements for effective PBM implementation
	• Parameters of most importance to them include costs, mortality rates, readmission rates, complication rates, and patient average LOS
	• Should understand the positive impact of PBM on the financial cost to the institution as well as the reduction in all of these parameters by implementing an effective PBM program, as demonstrated by various studies (15-17,19,20)
Clinical laboratory scientists	• Directly responsible for performing routine and complex testing in the immunohematology lab and communicating with the clinical team for the implementation of PBM
	• Troubleshoot technical difficulties using experience and available resources to arrive at the desirable solution
	• Collaborate very closely with transfusion medicine specialists, clinicians and medical laboratory technicians in diagnosing and monitoring disease processes, as well as monitoring the effectiveness of PBM
Nurses and allied health professionals	• Directly involved in patient care and, thus, can report bleeding episodes in patients
	• Need to be primed for the principles of PBM to be effectively implemented by following beside strategies, such as minimizing blood specimen losses by restricting sample volumes and frequency and for monitoring adherence to restrictive transfusion thresholds
Clinical pharmacology specialists, clinical pharmacists	• Can advise on use of certain pharmaceutical agents that can be useful for managing anemia or controlling bleeding, including hematinic agents (i.e., iron, vitamin B12, and folate), ESAs, antifibrinolytic agents (i.e., tranexamic acid, epsilon-aminocaproic acid), and various factor concentrates to control bleeding in coagulopathic patients
	• Clinical pharmacists work in liaison with the clinicians to ensure that medications are being used effectively to help the patients achieve intended outcomes
Secondary stakeholders	
Government organizations, media, medical journalists, hospital's public relations office	• Promote PBM programs to the public and patients via press releases, patient brochures, posters, newsletters, etc.

PBM, patient blood management; LOS, length of stay; ESA, erythropoiesis-stimulating agent.

implementation across hospitals and support national strategies (i.e., proof of results and cost-effectiveness in the local environment at local cost structures) (24). In addition, providing information on key performance indicators will provide valuable insights into the clinical and financial results of PBM.

One example is in Brazil, where the goal of the social media and e-learning initiative, EducaSangue, is to disseminate accurate, evidence-based medical information by quickly and easily communicating ethical concepts linked to transfusion prescription and accompanying treatment (25). Additionally, the initiative promotes PBM educational videos featuring prominent medical professionals in internal medicine, surgery, hematology, critical care, liver transplantation, obstetrics/gynecology, and neonatology.

The extensive training programs, including lectures, seminars, and online courses, offered to medical and nursing professionals at the undergraduate and postgraduate levels are the key to success (26). The hospital or institution may carry out this educational endeavor locally, but national implementation, at least in some countries, would likely yield superior outcomes.

Metrics and analytics

PBM metrics and analytics extend beyond the number of blood products transfused and are useful for identifying areas needing improvement and validating program outcomes. The AABB PBM Standards Guidance provides several suggestions for metrics (27). Metrics should change over time based on the areas of focus and program-sponsored projects while retaining a high-level metric such as case-mix index (CMI)-adjusted 1,000 patient days by blood product. Three or four well-developed metrics can effectively meet the needs of a program (*Table 2*) (28,29). Complicated dashboards or multiple reports may be useful to PBM personnel; however, universal access can detract end-users from making the connection from interpretation to practice application. A well-developed metric is one that is clearly understood and includes distinct action steps. Metcalf and Lex described development of novel data visualization derived from a 3-h workshop including key stakeholders and end-users (30). The outcome was that users wanted a practice comparison against a standard or benchmark. Yet, national benchmarking for PBM does not exist; therefore, organizations measure internal comparisons longitudinally. It is challenging for health systems to compare hospitals with variations in service lines, number of beds, and severity of illness. A moderate to strong correlation was found by Metcalf *et al.* for RBC utilization to all patient refined (APR) diagnosis-related groups (DRGs) (31). Meanwhile, Stonemetz *et al.* found a direct correlation between CMI and utilization of RBCs, platelets, and plasma in patients undergoing surgery (32). It is possible to adjust for both severity of illness and in-patient volume by using DRG-based CMI and acute patient days or LOS.

Demonstrating to key stakeholders and leadership hospital-to-hospital comparisons creates an atmosphere of transparency. Deciphering high-level metrics into action steps occurs by the process of identifying the drivers of a trend or outliers. Further investigation includes review of clinical practices such as laboratory triggers and targets, quantity ordered, reason for the transfusion, and quantity transfused. An outlier performing unfavorably warrants a closer analysis to determine contributing factors and potential opportunities for improvement. Best practices may be reflected in strong performance measures that can be replicated throughout a health system.

Initiative-directed metrics are created from the prospect of improvements such as correction of preoperative anemia, weight-based plasma dosing, and usage of a PBM method. The third edition of the AABB PBM Standards added activities for medical patients, obstetrics, outpatient transfusions, and pediatrics (33). Possible measures for these added populations are the number of outpatient non-oncology RBC transfusions with a nutritional deficiency evaluation or the percentage of obstetrical patients with anemia at time of delivery.

Effective visualization and dissemination provide the ability of the viewer to quickly understand and interpret metrics. The primary aim of data visualization is to diminish the cognitive load on the user, which is accomplished by limiting distracting information and ensuring the value of each element (34). Beyond visualization is the ability to translate data into information, which is used in some meaningful manner. Measuring what matters is a process that generates a structure for implementation. The metric is the starting point to becoming a measure that holds value through interpretation and action. The simplicity of display, ease of access, ability to broadcast, and level of difficulty to act require a systematic approach. Allowing for constructive feedback will advance efforts toward measuring what is

Table 2 Patient blood management metrics

Metric or measure	Definition	Action/value
Blood product CMI weighted by patient days or discharges	Total blood product ÷ CMI × (total patient days/1,000)	High-level comparison; outliers warrant detailed analysis
Transfusion rate	Percentage of inpatient hospital stays for patients ≥65 years that included an RBC transfusion; number inpatient stays with RBC transfusion (patients ≥65 years) ÷ total inpatient stays (patients ≥65 years, transfused and not transfused)	National average 10% (28); used to evaluate strategies such as anemia treatment, intraoperative blood management, thresholds/ targets
Single-unit RBC orders	Percentage of RBC orders quantity = 1 unit; 1 unit RBC orders ÷ total RBC orders	Used to evaluate practice of single-unit ordering for non-bleeding stable patients
Average RBC dose	Number of total RBC units transfused ÷ number of patients transfused	Useful to evaluate outcomes for specific patient populations
Average nadir hemoglobin or platelet count	Lowest hemoglobin or platelet count. Surrogate for transfusion threshold	Used to assess clinical practice of transfusion thresholds. Can be used to identify outliers
Average final hemoglobin or platelet count	Last hemoglobin or platelet count prior to discharge. Surrogate for transfusion target	Evaluates blood product dosage and patient response
Average highest INR (plasma transfused)	Highest INR used as surrogate for transfusion threshold	Threshold measure for plasma transfusion. Useful in identifying transfusions outside of established indications
Final INR (plasma transfused)	Last INR prior to discharge. Surrogate for transfusion target	Used in combination with threshold. Can reflect potential under-dosing or ineffective transfusions
Percentage of single unit plasma	Numerator: number of adult patients receiving total dose of 1 unit of plasma; number of adult patients transfused with 1 plasma unit ÷ total number of adult patients transfused plasma	Identifies potential under-dosing in adults without hereditary angioedema
Percentage RBC transfusions with hemoglobin less than 7 g/dL	Number patients transfused at hemoglobin 7 g/dL or below ÷ total number of transfused patients	Provides a gauge of percent of transfusions within threshold criteria
Percentage of RBCs transfused with discharge hemoglobin greater than 10 g/dL (29)	Number of transfused with discharge hemoglobin greater than 10 g/dL ÷ total number of RBC transfused; consider filtering numerator by transfused 1 or 2 units and length of stay 7 days or less	Identifies potential unnecessary RBCs or dosing opportunities

CMI, case mix index; RBC, red blood cell; INR, international normalized ratio.

most important.

Implementation

There is an increased need to implement PBM in healthcare facilities. Evidence demonstrates that PBM significantly improves outcomes and safety while reducing cost by macroeconomic magnitudes (24). When used properly, patients will not be subjected to unnecessary transfusions. Implementation strategies (*Table 3*) should include early detection of anemia, use of alternatives to allogeneic transfusion (e.g., intraoperative cell salvage and acute normovolemic hemodilution), blood conservation (e.g., using techniques to minimize surgical blood loss, minimizing blood loss through avoidance of excessive blood sampling), and keeping patients informed and allowing them to participate in the decision-making process (i.e., patient-centered care). However, the goal of PBM is not only to reduce blood transfusions but also to ensure a continuous process of quality improvement with the aim

Table 3 Key strategies/concepts of patient blood management implementation based on three pillars: optimizing red cell mass, minimizing blood loss, and managing anemia

Evaluation and treatment of anemia including perioperative management (e.g., oral or intravenous iron and/or ESAs)
Minimizing blood sampling (e.g., use of microcontainers and low volume tubes; avoidance of ordering laboratory tests that do not affect clinical decision making)
Identifying and managing bleeding risk, optimizing patient reserves
Optimizing hemostasis and coagulation (use of antifibrinolytics)
Point-of-care testing devices (e.g., TEG and ROTEM)
Evidence-based transfusion decision making in compliance with evolving guidelines
Minimizing blood loss through perioperative surgical, cell salvage and anaesthetic techniques as well as postoperative blood loss
Patient- and family-centred decision making
CPOE with CDS
Health system and clinical leadership support
Multi-disciplinary clinician engagement
Ongoing staff education with emphasis on restrictive transfusions based on various randomized controlled trials
Hemovigilance
Audit and review on a regular basis

ESA, erythropoiesis-stimulating agent; TEG, thromboelastography; ROTEM, rotational thromboelastometry; CPOE, computer-physician order entry; CDS, clinical decision support.

of improving patient outcomes by different measures (35). To achieve the goals of PBM, implementation must assume immense importance and be at the forefront of strategic planning. PBM goals can be achieved through best practices and multidisciplinary engagement. Implementation must also emphasize the important role of IT in decision support and continuous monitoring of the program aims, particularly so that consistency of PBM practice spreads across the clinical community. PBM implementation will ideally shift focus from volume-based to value-based care with focus on quality, which is the foundation stone upon which the concepts of PBM are laid (36).

There are numerous implementation drivers pertaining to PBM in addition to improved patient outcomes. One of the biggest is blood shortages. Donor centers experience widespread shortages owing to a variety of causes, including seasonal variations in blood donors (i.e., lower donor participation during peak holiday seasons), natural disasters (e.g., hurricanes, flooding, and winter storms), and the ongoing pandemic related to COVID-19 that has interfered with donor participation (i.e., loss of blood donor drives as businesses and other organizations have shut down and/or limited gathering of people) and supply chain issues. Due to limited blood supply, the call for PBM is much greater.

Healthcare cost benefits are another driver for PBM implementation. A recent large European meta-analysis study (17 studies with over 235,000 patients) showed a mean cost savings of over €150 [approximately $163 United States dollars (USD)] per patient and a total benefit of nearly €2 million (approximately $2.2 USD) based on just three PBM interventions (anemia management including iron therapy, cell salvage, and tranexamic acid) (37).

Barriers may exist when implementing PBM. Lack of knowledge on the part of clinicians is one hurdle, for if a provider does not know what alternatives to transfusion exist, they may order a blood transfusion for their patient that could have been avoided. Also, clinicians may pose opposition to PBM tactics since there is a tendency to resist change and institute practices that are likely to be unfamiliar to them. Given the risk of morbidity and mortality associated with blood transfusions, it is crucial that patients only receive blood transfusions where the potential benefit outweighs these risks (38). Clinicians should be educated on this. If a transfusion is needed, the minimum amount to

Table 4 Differences between patient blood management certification levels

Activity	Level I	Level II	Level III
Strategies for service lines with high blood usage	X	X	N/A
Processes and/or equipment for rapid decision-making for anemia and coagulation	X	X	N/A
Evaluation and management of micronutrient deficiencies in patients receiving outpatient red blood cell transfusion	X	X	N/A
Evaluation and management of anemia in non-operative patients	X	N/A	N/A
Program to care for patients who decline use of blood or blood products	X	N/A	N/A
Identification and management of pre-surgical anemia before elective procedures for which a type and screen with or without crossmatch is recommended	X	N/A	N/A
Use of perioperative techniques consistent with current AABB Standards (40)	X	N/A	N/A

Table does not include all certification activities, only those differing between levels. Adapted from reference (40) with permission. X denotes responsibility for activity, adapted from AABB Standards for Patient Blood Management (33). N/A, not applicable; AABB, Advancement of Blood & Biotherapies.

achieve therapeutic effect should be utilized.

Levels of patient blood management certification

PBM certification is a 2-year voluntary certification offered jointly through the AABB and The Joint Commission (TJC) and provides a third-party evaluation of PBM programs (39). The PBM standards committee created a novel strategy for hospitals regardless of size, services, and resources to become certified (39). Three levels of certification were developed and outlined in an activity table designating the program elements included in each level. The stratification is not intended to distinguish one level as superior to another but rather permits hospitals to meet fewer requirements for Levels II and III, making certification more feasible for organizations with limited resources or in the initial stages of PBM program development. Level I certification includes all program activities, including those considered more advanced such as identification and treatment of preoperative anemia in elective surgeries, a formal program for patients declining blood transfusions, strategies to reduce blood loss, plans to manage blood loss for perioperative service lines, processes and equipment for rapid decision-making regarding anemia, and coagulation management. Level II certification requires that 20 out of 24 activities are met, including three advanced elements; evaluating micronutrient deficiencies in patients receiving RBCs in an outpatient setting, processes and equipment for rapid decision-making regarding anemia and coagulation, and strategies for services with high blood usage. Level III certification requires that 17 of 24 activities are met, minus those advanced elements previously mentioned (*Table 4*) (33,40). A recent article emphasized that certification levels reflect the complexity of a program and not the quality of the program (41).

A gap analysis is one tool that can be used in determining which level of certification is best suited for a hospital. This exercise will demonstrate which activities and standards are currently being met, those that are in stages of development, and those that are neither met nor started. From this information, PBM leaders in conjunction with executive leadership are positioned to make decisions regarding the availability of resources, current state, and alignment with a certification level. Beyond consideration for what is needed and how certification will be maintained, a comprehensive plan for certification and re-certification readiness can be embedded into PBM program operations. Beginning certification at Level III and progressing to Level II or Level I abides to predesigned program growth and evolvement. The trajectory of level ascension follows a path of increasing complexity as determined and driven by the organization.

The cost of certification may pose a roadblock for some organizations, especially when the certification would encompass a multi-hospital system. Therefore, it is important to develop a proposal that includes a return on investment (ROI) that demonstrates the value of certification and ensure monies are budgeted. There is an annual fee of approximately $4,000 USD in addition to the surveyor fee incurred once in a 2-year certification cycle. If the organization is not AABB accredited, an additional

surveyor is required. The number of hospitals within a system, though, may add cost based upon the number of days needed by the surveyor. For example, for a three-hospital system that is AABB accredited, the certification cycle would cost approximately $17,000 USD. While this may seem to be a hefty upcharge for a hospital system to absorb, it should be noted that a major driver for PBM certification is that it provides a focal point to engage broad hospital interest in all aspects of transfusion decision making and practice, including transfusion avoidance (41). Hospitals that have achieved PBM certification have reported significant reductions in transfusions and cost savings, including one hospital system that recorded a savings of nearly $125,000 USD in just 1 year, comparing 2020 to 2019 (41). Investment in personnel resources may also enhance cost savings. Levine *et al.* reported a $495,000 USD cost savings over a 2-year span via the addition of a TSO to review all blood orders not meeting approved transfusion guidelines. Although this report predates PBM certification which was only first offered in 2016, certainly the addition of a TSO is a key PBM strategy to bridge communication between the blood bank and the clinical services that spans all certification levels (42).

Limitations and future directions of PBM

While our discussion on PBM development and certification is idealized, it is certainly recognized that resource and financial constraints will play major roles in limiting what healthcare organizations will be able to accomplish toward their PBM goals in the present day. Unfortunately, hospital administrators may focus on short-term savings rather than the bigger picture. In addition, increasing clinician PBM education and getting their acceptance will continue to be a major area of focus. Nevertheless, as evidence mounts against excessive use of blood products and the benefits of targeted anemia management become more evident, PBM integration into routine clinical practice likely will migrate from a fringe program to the mainstream.

Conclusions

It is imperative that hospitals begin developing PBM programs today, if they are not already in progress. As highlighted, such strategies that conserve blood, minimize blood loss, and manage anemia in a patient-centered manner to reduce unnecessary transfusions of blood products are associated with improved patient outcomes in terms of reduced morbidity and mortality as well as shorter LOS. Indeed, PBM has evolved from being mainly product focused (i.e., transfusion avoidance) to being patient outcome focused. These programs also help to curb healthcare costs and overutilization of scarce blood products during ongoing shortages. Hospitals are encouraged to use resources to begin development of a PBM business plan with identification of key stakeholders, provision of PBM education and training, development of key metrics, and ultimately implementation leading to PBM certification.

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