# Patient blood management: the global view

Aryeh Shander, 1,2 James Isbister,3 and Hans Gombotz4

ew medical procedures rival the status of blood transfusion as one of the most widely used and emotion-laden medical treatments. Empirically applied in the 1800s to reduce or eliminate postpartum hemorrhage-related deaths, its use witnessed exponential growth as the world was engulfed in wars of the 20th century. Evidence of certain harmful consequences surfaced over the years,1 but the linkage between transfusions and disease transmission is what ultimately caused concern in both the public and the medical community.2 In response, the blood industry, with the aid of science, has been working to restore the lost confidence in blood by increased surveillance and has stated that blood is "the safest it has ever been," However, randomized controlled and population studies have continued to link transfusions to negative clinical outcomes.4

Blood transfusions may be administered to treat acute severe anemia, which is a precipitous decrease in the patient's red blood cells (RBCs) or hemoglobin (Hb) and threatens oxygen delivery to organs. Acute severe anemia initiates the body's adaptive responses, such as increased cardiac output, reduction in systemic vascular resistance with vasodilation of the vessels to the major organs, and an increase in tissue extraction, all to fail at different stages of progression. Risk of tissue ischemia and injury can become unavoidable because of inadequate tissue oxygen delivery, which leads to tissue hypoxia, multiple organ failure, and death. <sup>5,6</sup>

Appropriate timing and dosing of RBC transfusions became an enigma after the emergence of restrictive versus liberal transfusion studies<sup>7</sup> and still remains a fundamental question lacking a clear answer.<sup>8</sup> The ensuing confusion led many in the transfusion world to question this practice in light both of the shifting risk–benefit ratio of transfusion and of emerging new agents to treat anemia. Some have remained focused on the indications of transfusion—when and for whom it is appropriate. Others have ventured looking beyond the blood components, asking what else can be done beside or even in lieu of transfusion.

Barring the relatively small number of patients who need transfusion due to acute hemorrhage (e.g., trauma), for the vast majority of the recipients of allogeneic blood components, transfusion is the result of ongoing and chronic processes developing over a long period of time.

Clearly for a chronic kidney failure patient on dialysis, sepsis patient admitted to the critical care unit, or an iron-deficient elderly individual who is scheduled for hip replacement surgery in 2 weeks, indication of transfusion is not something that is imminent. Late in the 1990s and beginning of the 2000s, movements were founded in Europe, Australia, and United States that examined transfusion practice, the underlying reasons for transfusion, and competing therapeutic modalities for those reasons. These efforts identified an initial unmet need: the detection, diagnosis, and proper management of anemia.

Paralleling these movements was the accumulating knowledge and experience gained from successful treatment of patients for whom blood was not an option. Their survival with Hb levels considered incompatible with life<sup>9-11</sup> opened new doors into the physiology and biology of anemia and resuscitation of the hematopoietic system. This added knowledge has vastly expanded our scope of attention from the simple physics of the human circulation (mostly flow related) to the intricate interactions of several other players, namely, the contribution of the endothelium and the role of gene expression. Oxygen delivery and

**ABBREVIATIONS:** NBA = National Blood Authority; PBM = patient blood management.

From the <sup>1</sup>Department of Anesthesiology, Critical Care and Hyperbaric Medicine, Englewood Hospital and Medical Center, Englewood, New Jersey; the <sup>2</sup>Department of Anesthesiology, Department of Medicine, Department of Surgery, Mount Sinai School of Medicine, New York, New York; the <sup>3</sup>Sydney Medical School, University of Sydney, Northern Clinical School, Royal North Shore Hospital, Sydney, NSW, Australia; and the <sup>4</sup>Department of Anesthesiology and Intensive Care, General Hospital Linz, Linz, Austria.

Address reprint requests to: Aryeh Shander, Department of Anesthesiology, Critical Care and Hyperbaric Medicine, Englewood Hospital and Medical Center, Englewood, NJ 07631; e-mail: aryeh.shander@ehmc.com.

Each of the authors has contributed to the writing, reviewing, and editing of this manuscript.

doi:10.1111/trf.13529

© 2016 AABB

TRANSFUSION 2016;56;S94-S102

utilization formulas, familiar to all clinicians, should be reconsidered and refurbished to include these and other important contributors.

Several approaches were adopted to limit the use of and need for allogeneic blood transfusion in all at-risk patients. The concept was initially dubbed "blood conservation," emphasizing efforts to preserve the patient's own blood as a valuable resource and protect it from avoidable losses. 12,13 The concept further evolved into "blood management," expanding the scope of the strategies to include other approaches to maintain and optimize Hb level and hemostasis (not just "conservation," but better "management" of patient's blood), and eventually, it emerged as "patient blood management" (PBM) to remind us all that what matters is the patients and their clinical outcomes. 12,13

As expected, the evolution continued. Earlier definitions of PBM revolved around the appropriate provision and use of blood for improved patient outcome. 14 This was later revised to place more emphasis on preventative measures that directly address diseases or conditions that can benefit from multiple treatment modalities. Thus, the emphasis shifted from treatment (transfusion) to disease states such as anemia or coagulopathy. According to the current definition, the goal is not merely avoiding or withholding transfusions, but timely application of evidencebased medical and surgical concepts designed to manage anemia, optimize hemostasis, and minimize blood loss to improve patient outcomes.<sup>15</sup>

As with most reforms, early adoption of PBM was somewhat slow and sporadic. Efforts for establishing practice guidelines date back to the mid-1990s. 16,17 Reports of clinical experiences emerged, which typically evaluated a limited number of strategies such as autologous transfusion and erythropoiesis-stimulating agents and focused on transfusion rates as the primary endpoint.<sup>17</sup> A notable example of such earlier studies is the Orthopedic Surgery Transfusion Hemoglobin European Overview (OSTHEO) study, a survey of almost 4000 patients undergoing hip or knee arthroplasty surgery in 225 centers. 19 The study concluded that better management of perioperative anemia, more accurate estimation and monitoring of blood loss, better adherence to transfusion guidelines, and use of techniques such as autologous transfusion and pharmacologic interventions are effective blood management approaches that can reduce transfusions and lead to lower rates of some complications (e.g., wound infections).<sup>19</sup>

Despite a growing number of reports, studying the impact of PBM programs has remained a challenge. By definition, PBM is a multimodality and multidisciplinary approach that spans the whole duration of the clinical management of patients.<sup>20,21</sup> For a patient scheduled for an elective surgery, this period can start several weeks ahead of the planned procedure (to allow for proper screening and management of anemia and other risk factors),22,23 and it may last well into the postoperative period. During this period, an individualized plan of care should be devised for each patient to address their specific needs and conditions, relying on an expanding array of modalities and interventions.<sup>24</sup> With all this done, the ultimate success should be measured in terms of improved patient outcomes, with or without economic impact.

While it can be difficult to measure the multifaceted approach associated with PBM, it is far simpler to focus on a few rather standardized interventions and examine easily reachable and quantifiable measures such as Hb level and transfusion utilization metrics. Therefore, it is not surprising that there is a dearth of studies that have evaluated PBM to its full breadth.

Clinically relevant patient outcomes are often more complicated to measure and quantify and they are susceptible to several confounders. Mortality and serious morbidity are commonly listed among the clinical outcomes of interest, but given the overall improvements in clinical management of patients and their outcomes, risk of these major events has been generally declining to the point of making mortality rate statistically difficult. This means that larger patient populations (usually several thousands) will be needed to design studies adequately powered to detect clinically significant differences between the study arms.<sup>25</sup> An alternative strategy to reduce the required sample size is to combine various individual outcomes into "composite" outcomes, but this approach comes with problems of its own, given that the various outcomes do not have the same (or even generally accepted relatively fixed) weight and significance (what is the relative importance of death compared with renal failure?), and a PBM program might not necessarily have a similar impact on various components of a composite outcome measure.<sup>26</sup> Indeed the vast majority of the studies reporting on composite endpoints combine drastically different outcomes into single measures without providing much justification for their selection. Further, they do not adequately report the impact of the study intervention on the individual components.<sup>27</sup> Fortunately, individual interventions such as autologous transfusion techniques, hematinic medications, and hemostatic agents have been extensively and effectively studied and many have been in clinical use for years.24

Despite the thorny nature of measuring clinical outcomes, one study has been especially enlightening in this regard. The retrospective study compared the rates of mortality and of complications between propensity scorematched cardiac patients who were treated either at a hospital with a PBM program or at one without. The cohort treated at the former had both lower mortality and lower complication rates. Further, although the hospital with the PBM program has a transfusion rate of only 11% for the cardiac patients, its cardiac program was ranked first in its state for lowest risk-adjusted mortality.<sup>28</sup> Several other studies demonstrating positive clinical outcomes of PBM have focused on either the Jehovah's Witness

population<sup>29-31</sup> or the effects of restrictive versus liberal transfusion policies.<sup>7,26,32-35</sup>

A turning point in the global arena came in May 2010 when the 63rd World Health Assembly on the availability, safety, and quality of blood products adopted resolution WHA63.12, which unequivocally endorsed PBM.<sup>36</sup> The resolution was followed by the World Health Organization Global Forum for Blood Safety meeting in March 2011, which was arranged for the purpose of further exploring PBM and its significance for patient health and safety. The attendees also sought to assess the current challenges in implementing PBM programs and to identify mechanisms for improving the impact of PBM programs.

# THE AMERICAN PERSPECTIVE: IRONING OUT THE POLICIES AND STANDARDS

After the passing of the resolution WHA63.12 and global endorsement of PBM, the U.S. Department of Health and Human Services tasked the Advisory Committee on Blood Safety and Availability to assess the implications of this resolution and its implementation.<sup>37</sup> The Committee recommended to<sup>38</sup> identify mechanisms to obtain data on PBM, utilization of transfusion, and clinical outcomes; support development and promulgation of national standards, for blood use; ask the Agency for Healthcare Research and Quality to evaluate available clinical guidelines and to sponsor comparative effectiveness research in PBM and transfusion; and support demonstration projects on PBM.

These recommendations have not yet resulted in action to date; however, the committee is reevaluating them to implement as many as possible. Although silent on PBM, the Centers for Medicare & Medicaid Services has embarked on a mission to develop integrated care as part of the Affordable Care Act, and a pilot PBM project funded by the Centers for Medicare & Medicaid Services is essential in the United States.

Efforts to integrate PBM as part of regulatory standards in the United States date back to much earlier. Since 2005, the Joint Commission has been working on developing performance measures for PBM programs. 39,40 Even though their measures are not used in the accreditation process, owing to the controversial lack of endorsement from the National Quality Forum, the Joint Commission has made them publicly available and continues to promote them as effective quality improvement tools for hospitals and other health care organizations. 20,41 Since 2014, the Joint Commission has renewed its efforts to revise and update these measures as electronic PBM performance measures—a set of new measures based on data from electronic health records. The candidate measures posted for public comments include preoperative anemia screening, Hb level and type and crossmatch/type and screen, initial transfusion threshold, blood conservation, and outcomes of PBM. Further evaluation and testing of the measures in hospitals was planned for the middle of 2015.42

Efforts for blood conservation, reduced exposure to allogeneic transfusions and caring for patients for whom blood is not an option, were first organized by a few dedicated physicians who formed the first network for transfusion alternatives called NATA. 43 As a pioneer in the field of PBM, the Society for the Advancement of Blood Medicine has also developed its proposed clinical standards for PBM programs. 44 The quality indicators fall under 12 broad categories of standards: leadership and program structure; consent process and patient directives; blood administration safety; review and evaluation of the PBM program; transfusion guidelines and peer review of transfusion; preoperative anemia evaluation and readiness for surgery; perioperative autologous blood collection and administration; phlebotomy blood loss; blood loss associated with surgery, procedures, and underlying medical conditions; massive transfusion protocol; management of anemia in hospitalized patients; and management of anemia in nonsurgical outpatients. Despite important distinctions and the far more detailed nature of Society for the Advancement of Blood Medicine measures, some overall alignments between these and the measures proposed by the Joint Commission can be spotted.

Most recently, the AABB has also come forward with a publication of its own PBM standards, which stipulate that the clinicians responsible for ordering transfusions should have some measured qualifications to do so, that is, educational materials with pre and post assessment, and internal transfusion guidelines must be developed at each PBM program. A three-level accreditation approach, reflective of the varying levels of complexity and ranges of clinical services in different facilities, is provided. 45

While the growing number of PBM measures and standards is a welcomed change that is expected to promote the wider adoption of PBM, the execution of these measures has been dragging. Appropriate transfusion practices and avoidance of unnecessary diagnostic tests, which contribute to the development of hospital-acquired anemia, are common themes in quality initiatives such as the American Board of Internal Medicine's Choosing Wisely campaigns, 46-49 but advocacy of a higher level of integration of these and many other PBM strategies that can improve the outcomes of the patients is missing. Likewise, while quality measures have become the centerpiece of the health care reform and are increasingly implemented and tied to reimbursements, PBM measures are still absent, for the most part, from the established Physician Quality Reporting System measures.

# THE AUSTRALIAN PERSPECTIVE: CLINICIAN-DRIVEN CENTRALIZED APPROACH

The establishment of PBM as a standard of care in the Australian health system is an impressive success story.

This could not have occurred without two decades of groundwork and remarkable cooperation from the clinical workforce through to the highest levels of government. As was the case around the world, it was the AIDS epidemic in the 1980s that brought the focus onto the risk-benefit equation of blood transfusions for the patients. In Australia, the pot was stirred in 1988 by a provocative article in the Medical Journal of Australia, "The Paradigm Shift in Blood Transfusion," advocating a greater patient focus, rather than donor focus, for the blood sector and transfusion medicine. However, it took another 12 years for real interest to emerge.<sup>50</sup> The first Australian comprehensive blood conservation and bloodless surgery program was established at Fremantle Kaleeya Hospital, a private health care facility in Western Australia.

In 2000, a review of the alternatives to homologous blood donation was commissioned by the Australian Health Ministers' Advisory Council recommending implementing a transfusion protocol and minimizing blood loss and blood products. Unfortunately, there was minimal action resulting from the recommendations, as there was no implementation policy to support the report being put into clinical practice. In 2001, a combined initiative of the National Health and Medical Research Council and the Australian and New Zealand Society of Blood Transfusion made progress on the development of clinical practice guidelines for blood component therapy. Unfortunately, these guidelines were blood product focused and, as with many guidelines, translating them into clinical practice was challenging and met with minimal success.

Parallel to the development of these guidelines, the Australian government was becoming concerned about the increasing cost of the provision of donor blood to the community, as well as disturbing aspects of blood sector governance, organization, and clinical practice. In 2001, the Review of the Australian Blood Banking and Plasma Product Sector (the 2001 Stephen Review) was completed. A key recommendation of the Stephen Review was for real clinician-led practice change in hospitals. Its recommendations also included the need for national safety and quality standards, hospital governance arrangements, engaging clinicians and developing guidelines, partnering with the Australian Commission for Safety and Quality in Health Care, and practice in this area to be included in hospital accreditation and national hemovigilance. The 2001 Stephens Report became a pivotal point for change and the recommendations were written into legislation in 2003, resulting in the formation of a National Blood Authority (NBA) with the engagement of the Commonwealth and all state and governments enshrined in a national blood Agreement (2003).

The ensuing progress from legislative changes to dissemination of the concept and principles of PBM as a standard of care occurred over the following decade. In 2002, the Australian and New Zealand Society of Blood Transfusion had a major focus on PBM for its annual scientific meeting, as did the Australian Red Cross Blood Service in 2006. Several Australian states initiated transfusion medicine and PBM educational and clinical practice improvement programs (BloodSafe, BloodWatch, and BloodMatters). These programs became the harbingers for the development of coordinated efforts at a national level with the NBA taking a lead role in PBM.

The year 2008 saw the commencement of the enormous and challenging task of developing patient-focused and evidence-based PBM guidelines, in contrast to the previous traditional product-focused guidelines. Substantial government funding flowed as it was becoming apparent from Australian and international research that the principles and practice of PBM yielded considerable benefits. The development of the guidelines was clinician led, with expert clinical reference groups for each of the six modules. This initiative was a demanding commitment for busy clinicians; regardless, they were engaged enthusiastically in the process. Clinician-led guideline development was, and continues to be, a critical factor in acceptance and facilitation in translating the recommendations into clinical practice. The implementation of the PBM guidelines is complemented by blood and blood products being included as Standard 7 in the National Safety and Quality Health Service Standards. The Standards are the mandated requirement for hospital accreditation. The aim of Standard 7 is to ensure that safe, appropriate, effective, and efficient blood management systems are in place. This aim supports the objectives of the Governments' Statement on National Stewardship Expectations for the Supply of Blood and Blood Products, endorsed by all Australian Health Ministers in 2010.

Six PBM guideline modules have been developed, five of which are completed and available online. The modules cover critical bleeding and massive transfusions, perioperative treatment, medical treatment, critical care, obstetrics and maternity, and pediatrics and neonatology (in final stages). The guidelines have been approved by the National Health and Medical Research Council and are widely acknowledged as the best and most comprehensive references available at this time. They are available free of charge on the NBA website (see Table 1).

The completion of this project has been a milestone in Australia's PBM journey and the challenge now is to keep them relevant and up to date. To this end, methodologies are being reviewed to enable a less laborious and costly process that will achieve online currency.

One of the most important recent PBM initiatives in Australia has been led by the Australian Commission on Safety and Quality in Health Care and has made PBM a national priority by funding a National Patient Blood Management Collaborative. This Collaborative involves health care providers from across Australia. PBM is being promoted as a standard of clinical care, with the current

#### TABLE 1. Resources on PBM available in Australia\*

National websites Jurisdictional websites

http://www.blood.gov.au/ http://www.blood.gov.au/pbm-guidelines http://www.blood.gov.au/resources http://www.safetyandquality.gov.au/

national-priorities/pbm-collaborative/

http://www.cec.health.nsw.gov.au/programs/blood-watch http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/ sa+health+internet/clinical+resources/clinical+programs/ blood+products+and+programs/bloodsafe

http://www.health.vic.gov.au/bloodmatters/

http://ww2.health.wa.gov.au/Corporate/Articles/N\_R/Patient-blood-management http://www.health.qld.gov.au/clinical-practice/guidelines-procedures/ patient-safety/blood-management/default.asp

collaborative focusing on the perioperative setting. The Australian Commission on Safety and Quality in Health Care has a central role in establishing national quality and safety health standards and overseeing the governance of hospital accreditation. Importantly, this included the implementation of a standard for blood and blood products in its 10 national safety and quality health service standards. This, in turn, promoted an increased focus on blood and blood products by hospital executives. One of the central recommendations is that "health-care services should establish a multidisciplinary, multimodal perioperative PBM program." The NBA has also established a national PBM steering committee with an important role in implementation of PBM nationally and facilitating intergovernmental coordination and cooperation.

In 2014, under the theme "Patient Blood Management as a Standard of Care in Australia: Past, Present and Future," the NBA, in association with the Western Australia Department of Health, organized Australia's inaugural national PBM conference in Perth, Western Australia. A further symposium was held in 2015 and showcased excellence in the implementation of the National Safety and Quality Health Service Standards relating to blood and blood products outlined in Standard 7.

#### Evidence of success of PBM in Australia

The comprehensive resources now available in Australia are leading to improvements in PBM quality and safety standards for patients, reduction in RBC usage, cost savings, less donor blood wastage, and fewer inappropriate allogeneic blood transfusions. There are now accumulating supporting data available to substantiate the success of these initiatives. There has been a progressive national reduction in RBC usage of more than 16% since 2012. Using a wide range of change strategies, a PBM improvement collaborative in New South Wales extending over several years achieved an overall 27.4% reduction of the RBC transfusion across five elective surgical groups. This reduction was associated with annual cost savings of over AUD\$8.5 million.<sup>51</sup>

Probably the most successful comprehensive PBM program has been in Western Australia. This was achieved

in the context of that State already having the lowest transfusion rate of the five large Australian jurisdictions and one of the lowest reported in the developed world. The Department of Health initiated the implementation of a sustainable comprehensive health system-wide PBM program. Only 3 years after the program was implemented, the State saved a calculated AUD\$10,725,750 in direct product and hospital-related costs of RBC transfusions in that year.<sup>52</sup> These savings may be considerably greater if hospital-associated costs of RBC transfusion complications are taken into account.53 A preliminary examination of patient outcomes in total knee replacement demonstrated a significant reduction in composite hospital-acquired complications and hospital length of stay associated with the implementation of PBM.54

#### PBM resources in Australia

To ensure translation of the PBM principles and guidelines into clinical practice, jurisdictional PBM programs, the Blood Service and the NBA have collaboratively developed a wide range of resources. The national PBM steering committee described above oversees a coordinated approach. Most information about these resources is available on the Internet and best accessed via the NBA, Blood Service, or jurisdictional government websites listed in Table 1. Appendix A provides further information on several of the resources.

### THE EUROPEAN PERSPECTIVE: MANAGING CHANGE

As PBM is being integrated worldwide into routine practice, in about two-thirds of European countries, a number of hospitals, professional societies, and/or medical associations currently endorse PBM. Nevertheless, the implementation of PBM in Europe has still been limited, and considerable variations continue to exist.<sup>55</sup>

In autumn 2013, the European Commission issued a call for tender for "Good Practices in the Field of Blood Transfusion" via its Consumers, Health and Food Executive Agency. In the evaluation process, the Austrian Institute of Technology (AIT, Vienna, Austria) received the

<sup>\*</sup> Most information about the background and current status of PBM is Australia is available on the NBA website at: http://www.blood.gov.au/.

highest score for its proposal from independent experts. At the end of 2013, AIT was awarded the contract by the European Commission. The aims of the project are to identify and map blood use, local and national differences in PBM strategies and blood utilization, and good practices in PBM in Europe.

In light of the current transfusion practices, which are consistent with remarkably liberal utilization of blood and blood components in numerous European countries, the project's main tasks are to:

- Develop an EU guide for Member States and health professionals;
- Implement PBM programs in five teaching hospitals; and
- Prepare an implementation strategy to help all EU Member States to disseminate and implement PBM in hospitals.

This guide for the implementation of PBM will be available for all medical professions and organizations involved in dealing with anemia, blood loss, and transfusion of blood and blood products. It does not address medical questions or special interventions, which should be part of medical guidelines.

# Implementing PBM as a standard of care in Europe

Developments in Australia have clearly demonstrated that through constructive cooperation among the main stakeholders, such as statutory authorities, practitioners, patient groups, and the blood services, PBM can be implemented on a large scale in clinical practice within a few years. <sup>37,56</sup>

In the past, various change management models (especially for business and industry) have been created.<sup>57</sup>-<sup>65</sup> One early model of change, which was developed by the German-American psychologist Lewin,66 served as a basic concept for Kotter's model. 61,67 Lewin described change as a three-stage process: he called the first stage "unfreezing," the second stage "change," and the third and final one "freezing." John Kotter's eight-step model,68 on the other hand, integrates more important elements that are common in change management processes. It has already been successfully applied in many organizations in the industrial sector and, specifically, it aims to integrate the PBM concept in the Western Australia patient blood management program.<sup>69</sup> Thus, Kotter's model was chosen to be used to create the European PBM implementation guide.<sup>61</sup> His overarching concept will determine all the clinical and organizational measures to be adopted and adapted to the particular institutions. 60,61,70

#### General Hospital in Linz (Austria)

The 900-bed General Hospital in Linz performs approximately 27,000 surgical procedures per year. Although it had already been one of the institutions with the lowest transfusion rates in the Austrian Benchmark Study, a PBM project was initiated in 2008.14

Over a period of 6 years, clinicians reduced blood utilization by 60% to 70%. The General Hospital in Linz reported a reduction of RBC utilization of more than 40% after the implementation of PBM. 71 By the end of 2014, an overall reduction of almost 70% in RBC concentrates was achieved.

Two of the most important steps for this success were the implementation of a premedication outpatient clinic and the establishment of a diagnostic pathway. The latter was developed together with surgical colleagues, including timely assignment of patients and standardized treatment of preoperative anemia. While this was initially only possible in some surgical specialties, the emerging success of this approach eventually led to the commitment of additional surgical partners. As a consequence, more than 80% of patients are currently sent to the premedication outpatient clinic before surgery. The introduction of a standardized operating procedure for PBM resulted in the award of an Austrian quality management certificate. Furthermore, surgical partners have recognized PBM as a trademark and organized PBM meetings to work out instructional material for their professions. By gaining broad acceptance, the need for further necessary changes has been accepted and PBM implementation has become easier.

#### WHAT LIES AHEAD

Considering the promising benefits of PBM strategies for patients and the health care system, it looks hopeful that it will be increasingly viewed and adopted by clinicians and promoted and supported by the regulatory bodies as a standard of care for all patients. As with any change, there are still some clinicians and others with the traditional approach to blood transfusion and blood banking that persist in searching for the Hb threshold ("trigger" in the past) for transfusing RBCs, the so-called holy grail. However, the patient-centered approach incorporates many other treatments with transfusion in its rightful place. PBM does not focus on transfusion, but rather on identifying a medical condition that can be treated appropriately for the best clinical outcome. This approach has been steadily rising in acceptance and implementation throughout the medical community.

Moving forward, PBM should become an integral part of postgraduate training, and players, including the government, should develop demonstration projects to further validate the positive administrative and clinical outcomes associated with the approach. PBM will most plausibly become implemented on a national level through education and reimbursement.

#### **APPENDIX A**

#### Further information on PBM resources in Australia

BloodSafe eLearning Australia

https://www.bloodsafelearning.org.au/

Bloodsafe eLearning Australia provides a vehicle to influence knowledge and provide consistent educational messages to a variety of health care workers and professionals on issues of key importance to governments. This has been a key successful strategic NBA partnership with the South Australian government and has enabled transfusion medicine–related education to be embedded into various curricula in Australia, including nursing, junior medical officer training, and advanced training for anesthetists.

# Tools that have been developed for implementation of PBM

Completed PBM tools include:

- The publication of the Guidance for the Provision of Intraoperative Cell Salvage and accompanying patient materials and a business case and education competency workbook;
- Material to support implementation of a single unit program;
- Point-of-care testing in cardiac surgery cases;
- Guideline companion explaining PBM concepts and interventions;
- The Preoperative Anemia Identification, Assessment and Management Case Study.

#### PBM tools under development include

- The RBC and massive transfusion protocol clinical audits;
- An iron product choice and dose calculation guide;
- A preoperative bleeding risk assessment and intervention resource;
- Tools and information to support to patients;
- Tools and information to support general practitioner involvement in PBM.

### National computer information systems

The NBA operates a range of information and communications technology systems, many of them world leaders in their field. There are currently two key systems implemented and one under development.

The Australian Bleeding Disorders Registry (ABDR) is a clinical tool used on a daily basis by clinicians in all Australian hemophilia treatment centers to assist in managing people with bleeding disorders. It maintains an electronic medical record system including a unique personalized secure smartphone app and website for patients and family.

BloodNet is the national online ordering and inventory management system, enabling pathology laboratories and hospitals to place orders online for blood and blood products, record inventory levels and the final use or non-use of each unit, and produce real-time inventory management reports.

BloodSTAR is a new national system under development to improve the efficiency and effectiveness of authorization arrangements for the supply of immunoglobulin against the guideline criteria for use. This includes electronic support of subsequent ordering and clinical review for continued supply.

#### **ACKNOWLEDGMENTS**

The authors thank Dr Tamara Friedman for her editorial contribution.

#### CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

# **REFERENCES**

- Mosley JW. The surveillance of transfusion-associated viral hepatitis. JAMA 1965;193:1007-10.
- Shander A. Emerging risks and outcomes of blood transfusion in surgery. Semin Hematol 2004;41:117-24.
- 3. Biedrycki BA. Blood transfusions: is "safest ever" safe enough? ONS News 2004;19:8-9.
- Rohde JM, Dimcheff DE, Blumberg N, et al. Health careassociated infection after red blood cell transfusion: a systematic review and meta-analysis. JAMA 2014;311:1317-26.
- Hare GM, Freedman J, David MC. Review article: risks of anemia and related management strategies: can perioperative blood management improve patient safety? Can J Anaesth 2013:60:168-75.
- Shander A, Javidroozi M, Ozawa S, et al. What is really dangerous: anaemia or transfusion? Br J Anaesth 2011;107: i41-59.
- Hébert PC, Wells G, Blajchman MA, et al. A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care. Transfusion Requirements in Critical Care Investigators, Canadian Critical Care Trials Group. N Engl J Med 1999;340:409-17.
- Holst LB, Petersen MW, Haase N, et al. Restrictive versus liberal transfusion strategy for red blood cell transfusion: systematic review of randomised trials with meta-analysis and trial sequential analysis. BMJ 2015;350:h1354.
- Loubser PG, Stoltz SM, Schmoker JD, et al. Blood conservation strategies in Jehovah's Witness patients undergoing complex aortic surgery: a report of three cases.
   J Cardiothorac Vasc Anesth 2003;17:528-35.
- Moskowitz DM, Perelman SI, Cousineau et al. Multidisciplinary management of a Jehovah's witness patient for the

- removal of a renal cell carcinoma extending into the right atrium. Can J Anaesth 2002;49:402-8.
- de Araújo Azi LM, Lopes FM, Garcia LV. Postoperative management of severe acute anemia in a Jehovah's Witness.
  Transfusion 2014;54:1153-7.
- Shander A, Moskowitz DM, Javidroozi M. Blood conservation in practice: an overview. Br J Hosp Med (Lond) 2009;70:16-21.
- 13. Shander A, Javidroozi M, Perelman S, et al. From bloodless surgery to patient blood management. Mt Sinai J Med 2012; 79:56-65.
- Gombotz H, Rehak PH, Shander A, et al. Blood use in elective surgery: the Austrian benchmark study. Transfusion 2007;47:1468-80.
- What is patient blood management? [Internet]. Richmond (VA): Society for the Advancement of Blood Management (SABM); c2005-2014 [cited 10 Feb 2015]. Available from: www.sabm.org.
- Goodnough LT, Despotis GJ. Establishing practice guidelines for surgical blood management. Am J Surg 1995;170:16S-20S.
- 17. Messmer K. Roundtable of experts in surgery blood management–consensus statement. Infusionsther Transfusionsmed 1996;23:143-6.
- Sculco TP, Gallina J. Blood management experience: relationship between autologous blood donation and transfusion in orthopedic surgery. Orthopedics 1999;22:s129-34.
- Rosencher N, Kerkkamp HE, Macheras G, et al. Orthopedic Surgery Transfusion Hemoglobin European Overview (OSTHEO) study: blood management in elective knee and hip arthroplasty in Europe. Transfusion 2003;43:459-69.
- 20. Goodnough LT, Shander A. Patient blood management. Anesthesiology 2012;116:1367-76.
- Shander A, Hofmann A, Isbister J, et al. Patient blood management–the new frontier. Best Pract Res Clin Anaesthesiol 2013:27:5-10.
- 22. Goodnough LT, Shander A, Spivak JL, et al. Detection, evaluation, and management of anemia in the elective surgical patient. Anesth Analg 2005;101:1858-61.
- 23. Goodnough LT, Maniatis A, Earnshaw P, et al. Detection, evaluation, and management of preoperative anaemia in the elective orthopaedic surgical patient: NATA guidelines. Br J Anaesth 2011;106:13-22.
- 24. Shander A, Javidroozi M. Strategies to reduce the use of blood products: a US perspective. Curr Opin Anaesthesiol 2012:25:50-8.
- Chang DC, Yu PT, Easterlin MC, et al. Demystifying samplesize calculation for clinical trials and comparative effectiveness research: the impact of low-event frequency in surgical clinical research. Surg Endosc 2013;27:359-63.
- 26. Gross I, Shander A, Sweeney J. Patient blood management and outcome, too early or not? Best Pract Res Clin Anaesthesiol 2013;27:161-72.
- 27. Cordoba G, Schwartz L, Woloshin S, et al. Definition, reporting, and interpretation of composite outcomes in clinical trials: systematic review. BMJ 2010;341:c3920.

- 28. Moskowitz DM, McCullough JN, Shander A, et al. The impact of blood conservation on outcomes in cardiac surgery: is it safe and effective? Ann Thorac Surg 2010;90:451-8.
- 29. Emmert MY, Salzberg SP, Theusinger OM, et al. How good patient blood management leads to excellent outcomes in Jehovah's Witness patients undergoing cardiac surgery. Interact Cardiovasc Thorac Surg 2011;12:183-8.
- Frank SM, Wick EC, Dezern AE, et al. Risk-adjusted clinical outcomes in patients enrolled in a bloodless program. Transfusion 2014;54:2668-77.
- 31. Vaislic CD, Dalibon N, Ponzio O, et al. Outcomes in cardiac surgery in 500 consecutive Jehovah's witness patients: 21 year experience. J Cardiothorac Surg 2012;7:95.
- Carson JL, Terrin ML, Noveck H, et al. Liberal or restrictive transfusion in high-risk patients after hip surgery. N Engl J Med 2011;365:2453-62.
- Hajjar LA, Vincent JL, Galas FR, et al. Transfusion requirements after cardiac surgery: the TRACS randomized controlled trial. JAMA 2010;304:1559-67.
- 34. Lacroix J, Hébert PC, Hutchison JS, et al. Transfusion strategies for patients in pediatric intensive care units. N Engl J Med 2007;356:1609-19.
- 35. McIntyre LA, Fergusson DA, Hutchison JS, et al. Effect of a liberal versus restrictive transfusion strategy on mortality in patients with moderate to severe head injury. Neurocrit Care 2006:5:4-9.
- WHA63.12 Availability, Safety and Quality of Blood Products. WHA resolution; Sixty-third World Health Assembly. Geneva: World Health Organization; 2010.
- 37. Farmer SL, Towler SC, Leahy MF, et al. Drivers for change: Western Australia Patient Blood Management Program (WA PBMP), World Health Assembly (WHA) and Advisory Committee on Blood Safety and Availability (ACBSA). Best Pract Res Clin Anaesthesiol 2013;27:43-58.
- 38. Advisory Committee on Blood Safety and Availability (ACBSA) Update. Washington (DC): U.S. Department of Health & Human Services; August 2011.
- 39. Gammon HM, Waters JH, Watt A, et al. Developing performance measures for patient blood management. Transfusion 2011;51:2500-9.
- Patient blood management performance measure project -2011 [Internet]. Washington (DC): The Joint Commission; c2015 [cited 10 Feb 2015]. Available from: http://www.jointcommission.org/patient\_blood\_management\_performance\_measures\_project/.
- 41. Implementation guide for the joint commission patient blood management performance measures. Washington (DC): The Joint Commission; 2011.
- Electronic patient blood management performance measures [Internet]. Washington (DC): The Joint Commission;
  c2015 [cited 10 Feb 2015]. Available at: http://www.jointcommission.org/electronic\_clinical\_quality\_measures\_for\_patient\_blood\_management/.
- NATA: Network for the Advancement of Patient Blood Management, Haemostasis and Thrombosis [Internet]. Belfast:

- The Network; c2000-2016 [cited 10 Feb 2015]. Available from: http://www.nataonline.com/.
- 44. Quality guide to the administrative and clinical standards for patient blood management programs. Richmond (VA): Society for the Advancement of Blood Management (SABM); 2013.
- 45. AABB announces new patient blood management standards [Internet]. Bethesda: AABB; 2014 [cited 10 Feb 2015]. Available from: http://www.aabb.org/press/Pages/pr140325.aspx.
- 46. Callum JL, Waters JH, Shaz BH, et al. The AABB recommendations for the Choosing Wisely campaign of the American Board of Internal Medicine. Transfusion 2014;54:2344-52.
- 47. Halpern SD, Becker D, Curtis JR, et al. An official American Thoracic Society/American Association of Critical-Care Nurses/American College of Chest Physicians/Society of Critical Care Medicine policy statement: the Choosing Wisely® top 5 list in Critical Care Medicine. Am J Respir Crit Care Med 2014;190:818-26.
- 48. Hicks LK, Bering H, Carson KR, et al. The ASH Choosing Wisely® campaign: five hematologic tests and treatments to question. Blood 2013;122:3879-83.
- 49. Onuoha OC, Arkoosh VA, Fleisher LA. Choosing wisely in anesthesiology: the gap between evidence and practice. JAMA Intern Med 2014;174:1391-5.
- 50. Isbister JP. The paradigm shift in blood transfusion. Med J Aust 1988;148:306-8.
- 51. Harrison BT, Chen J, Der VC, et al. Improving red cell transfusion in the elective surgical setting: an improvement collaborative with evaluation. Vox Sang 2015;108:393-402.
- 52. Leahy MF, Mukhtar SA. From blood transfusion to patient blood management: a new paradigm for patient care and cost assessment of blood transfusion practice. Intern Med J 2012:42:332-8
- 53. Trentino KM, Farmer SL, Swain SG, et al. Increased hospital costs associated with red blood cell transfusion. Transfusion 2015;55:1082-9.
- 54. Farmer SL, Trentino K, Hofman A, et al. A programmatic approach to patient blood management - reducing transfusions and improving patient outcomes. Open Anesthesiol J 2015;9:1-11.
- 55. Shander A, Van AH, Colomina MJ, et al. Patient blood management in Europe. Br J Anaesth 2012;109:55-68.

- 56. Hofmann A, Farmer S, Towler SC. Strategies to preempt and reduce the use of blood products: an Australian perspective. Curr Opin Anaesthesiol 2012;25:66-73.
- 57. Berwick DM. Disseminating innovations in health care. JAMA 2003;289:1969-75.
- Boyatzis RE. The ideal self as the driver of intentional change. J Manag Dev 2006;25:18.
- 59. Campbell RJ. Change management in health care. Health Care Manag (Frederick) 2008;27:23-39.
- 60. Kotter JP. What leaders really do. Harv Bus Rev 1990;68:103-11.
- 61. Kotter JP. Leading change: why transformation efforts fail. Harvard Business Review 1995.
- Reinhardt AC, Keller T. Implementing interdisciplinary practice change in an international health-care organization. Int J Nurs Pract 2009;15:318-25.
- 63. Silversin J, Kornacki MJ. Implementing change: from ideas to reality. Fam Pract Manag 2003;10:57-62.
- Stoller JK. Implementing change in respiratory care. Respir Care 2010;55:749-57.
- 65. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362:1225-30.
- 66. Lewin K. Group decision and social change. In: Maccoby EE, Newcomb TM, Hartley EL, editors. Readings in social psychology. New York: Holt, Rinehart and Winston; 1958. pp. 197-211.
- 67. Suc J, Prokosch HU, Ganslandt T. Applicability of Lewin s change management model in a hospital setting. Methods Inf Med 2009;48:419-28.
- 68. The 8-step process for leading change [Internet]. Cambridge (MA): Kotter International; c2016 [cited 2014 Nov 19]. Available from: http://www.kotterinternational.com/the-8-stepprocess-for-leading-change.
- 69. Patient blood management [Internet]. Perth: Government of Western Australia, Department of Health; 2014 [cited 2014 Nov 19]. Available from: http://ww2.health.wa.gov.au/ Articles/N\_R/Patient-blood-management.
- 70. Kotter JP, Schlesinger LA. Choosing strategies for change. Harv Bus Rev 1979;57:106-14.
- 71. Muller MM, Fischer D, Stock U, et al. [Patient blood management-the preoperative patient]. Anasthesiol Intensivmed Notfallmed Schmerzther 2014;49:246-53; quiz 254. [German]