The State of Play of Patient Blood Management: Globally and in Selected European Countries

COLLOQUE PBM, Paris, Oct. 18, 2023





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Disclaimer

Dr Hofmann has received fees, honoraria or travel for consulting or lecturing from the following companies and legal entities:

GOVERNMENTAL & PUBLIC INSTITUTIONS

- Austrian Federal Department of Health, Austria
- European Commission/Austrian Institute of Technology, Austria
- Hong Kong Health Authority, China
- Nova Scotia Health Authority, Canada
- · Ospedale Lugano, Switzerland
- Royal Brisbane Women's Hospital Foundation, Queensland, Australia
- United States Department of Health and Human Services, Washington, USA
- University Hospital Zurich, Switzerland
- Western Australia Department of Health, Australia

BLOOD SERVICES

- Australian Red Cross Blood Service, Australia
- National Blood Authority, Australia
- Saudi Society of Blood Transfusion Medicine & Services
- South African National Blood Service, South Africa

PROFESSIONAL SOCIETIES & NGOs

- Brazilian Society of Anesthesiology (SBA)
- Colombian Society of Anesthesiology
- International Foundation for Patient Blood Management (IFPBM), Switzerland
- Korean Society of Anesthesiology
- Korean Surgical Society
- Mexican College of Internal Medicine
- Network for the Advancement of PBM, Haemostasis and Thrombosis (NATA), France
- Society for the Advancement of Blood Management (SABM), USA
- Società Scientifica dei Medici Legali delle Aziende Sanitarie del Servicio Sanitario Nazionale, Italy
- World Heart Federation, Geneva, Switzerland

INDUSTRY

- Amgen, Switzerland
- Austrian Institute of Technology
- BBraun Melsungen AG, Germany
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- Celgene/Bristol Myers Squibb, Belgium
- Ethicon Biosurgery, USA
- Fresenius Kabi, Germany
- G1 Therapeutics, USA
- Hospira, UK
- IL Werfen, USA
- Janssen Cilag, Belgium
- Novo Nordisk, Denmark
- Ortho Biotech, USA
- PBMe Solutions, Switzerland
- Plasma Protein Therapeutics Association (PPTA), USA
- Swiss Medical Network, Switzerland
- Takeda, South Africa
- UCB Pharma, China
- Vifor Fresenius Medical Care Renal Pharma, Switzerland
- Vifor International, Switzerland

2010

WHO ENDORSEMENT of PATIENT BLOOD MANAGEMENT



Sixty-third World Health Assembly

Date: 17-21 May 2010

Location: Geneva, Switzerland

WHA63.12 adopted by resolution May 21, 2010:

"Bearing in mind that <u>patient blood management</u> means that before surgery every reasonable measure should be taken to optimize the patient's own blood volume, to minimize the patient's blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia following WHO's guide for optimal clinical use (<u>three pillars of patient blood management</u>)"

Pillar 1:

Optimizing the patient's own blood volume

Pillar 2:

Minimizing the patient's blood loss

Pillar 3:

Optimizing the patient-specific physiological tolerance of anaemia

2015

CHALLENGES IN BLOOD SERVICES



Based on GDBS 2015

No blood preparedness system during emergency situation

Poor access to blood during emergency

Inadequacy in policy, regulations, governance & financing

60-70% MSs with blood policy, legislation, oversight system

Insufficient supply of blood products

66 Member States with donation rate <10/1000

Patient Blood Management not in place Sub-optimal clinical practices

Lack of availability of PDMPs

Deficiencies in safety, effectiveness and quality

80% of donated blood was tested in LMICs

Limited use of component Low vol & poor quality of plasma

Slide: Courtesy of Dr. Yuyun Maryuningsih Team Lead Blood and other Products of Human Origin, WHO



2020

WHO's EXTERNAL STEERING COMMITTEE for PATIENT BLOOD MANAGEMENT IMPLEMENTION



Prof. Neil Blumberg



Dr. Irwin Gross Co-Chair



Prof. Jeff Hamdorf



Prof. Axel Hofmann Chair



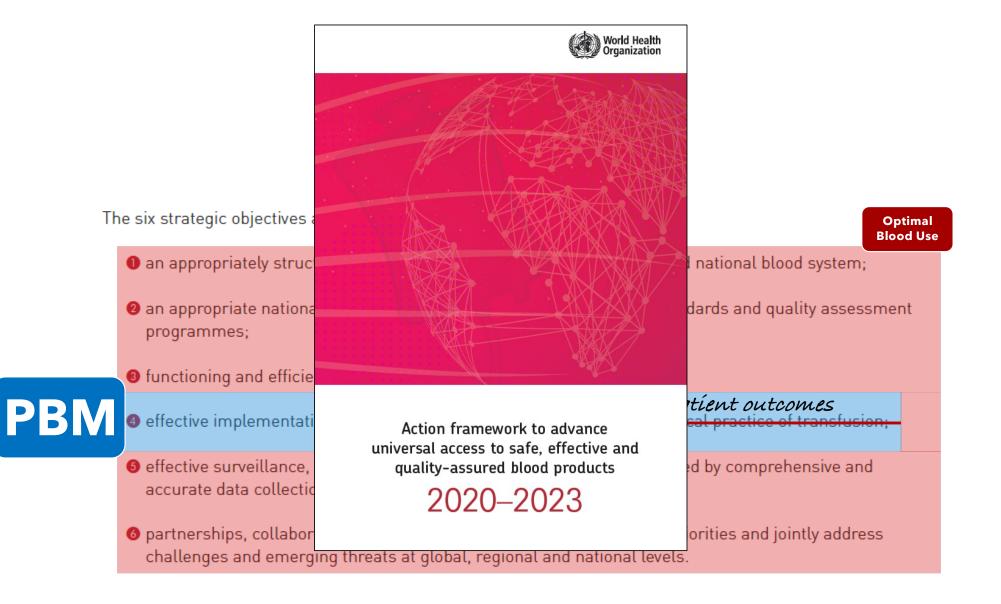
Prof. James Isbister



Prof. Aryeh Shander

Tasked with the development of

- Patient Blood Management Policy Brief
- Patient Blood Management Implementation Guidance, supported by 70+ international PBM experts



The six strategic objectives are:

Optimal Blood Use

- 1 an appropriately structured, well coordinated and sustainably resourced national blood system;
- 2 an appropriate national framework of regulatory controls, national standards and quality assessment programmes;
- In functioning and efficiently managed blood services;

PBM

- patient outcomes

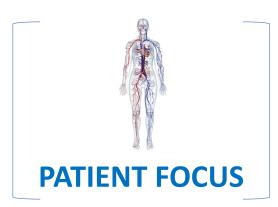
 effective implementation of patient blood management to optimize clinical practice of transfusion;
- 6 effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems;
- 6 partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

Why is this distinction important?



Aiming for **BLOOD HEALTH**through etiology-specific treatment of anemia, blood loss and coagulopathy





Aiming for **FIXED LAB-VALUES** (hb, INR, plt count) through administration of **allogeneic blood components** Optimal

Blood Use



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Aiming for FIXED LAB-VALUES
(hb, INR, plt count) through
administration of allogeneic
blood components

Optimal
Blood Use



[I]nappropriate rates of RBC transfusion of 22-57% in a variety of clinical settings, including hospitalised inpatients, operative units, and emergency departments

Mehta N. et al. Reducing unnecessary red blood cell transfusion in hospitalised patients. BMJ. Apr 6 2021;373:n830.

[P]latelet usage does not appear to be concordant with ... guidelines

Goel R. et al. Platelet transfusion practices in immune thrombocytopenia related hospitalizations. Transfusion. Jan 2019;59(1):169-176.

Optimal Blood Use

Critically ill patients ... more likely to receive blood for major bleeding at night

Aubron C. et al. Day or overnight transfusion in critically ill patients: does it matter? Vox Sang. Apr 2018;113(3):275-282

[W]ide variations in blood product transfusion practices in patients with AL

Pine A.B. et al. Wide variations in blood product transfusion practices among providers who care for patients with acute leukemia in the United States. Transfusion. Feb 2017;57(2):289-295.

[D]iscernible variability in the current practice of blood utilization for a given procedure ..., with no changes in practice patterns for the last decade of paediatric cardiac surgery.

Karimi M. et al. National trends and variability in blood utilization in paediatric cardiac surgery. Interact Cardiovasc Thorac Surg. Jun 1 2017;24(6):938-943.

16.8-fold difference in adjusted blood transfusion rates across surgeons and a 13.2-fold difference [] across hospitals.

Aquina C.T. et al. Large Variation in Blood Transfusion Use After Colorectal Resection: A Call to Action. Dis Colon Rectum 2016;59(5):411-418

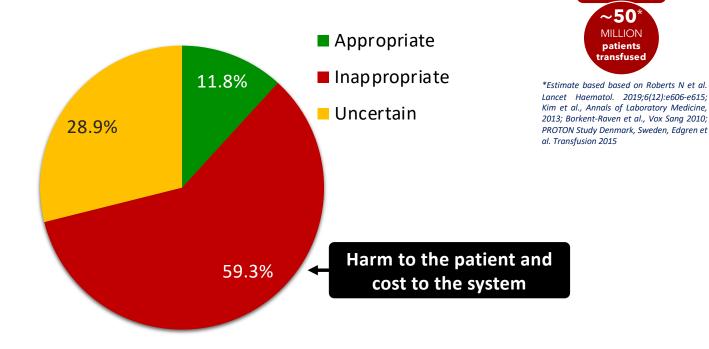
The median lowest Hb level on days with an RBC transfusion [during ICU stays] ranged from 5.2 g/dL to 13.1 g/dL across centers, from 5.3 g/dL to 9.1 g/dL across countries, and from 7.2 g/dL to 8.7 g/dL across continents.

Raasveld S.J. et al. Red Blood Cell Transfusion in the Intensive Care Unit. JAMA. Oct 12, 2023

Transfusion Medicine Reviews, Vol 25, No 3 (July), 2011: pp 232-246.e53

Appropriateness of Allogeneic Red Blood Cell Transfusion: The International Consensus Conference on Transfusion Outcomes

Aryeh Shander, Arlene Fink, Mazyar Javidroozi, Jochen Erhard, Shannon L. Farmer, Howard Corwin, Lawrence Tim Goodnough, Axel Hofmann, James Isbister, Sherri Ozawa, and Donat R. Spahn, for the International Consensus Conference on Transfusion Outcomes Group



Optimal

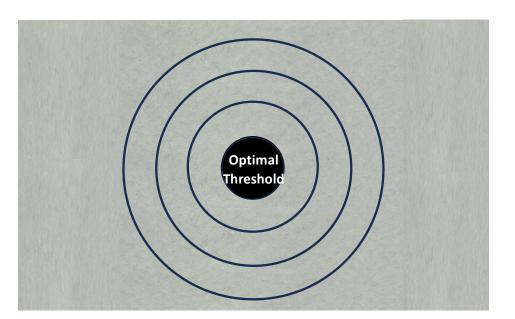
Blood Use

EDITORIAL

Precision in Transfusion Medicine

Matthew D. Neal, MD; Beverley J. Hunt, MD

JAMA. Oct 12, 2023





~50*
MILLION
patients
transfused

*Estimate based based on Roberts N et al. Lancet Haematol. 2019;6(12):e606-e615; Kim et al., Annals of Laboratory Medicine, 2013; Borkent-Raven et al., Vox Sang 2010; PROTON Study Denmark, Sweden, Edgren et al. Transfusion 2015

Good Luck!

July 25, 1990

Influence of Clinical Knowledge, Organizational Context, and Practice Style on Transfusion Decision Making

Implications for Practice Change Strategies

Susanne R. Salem-Schatz, ScD; Jerry Avorn, MD; Stephen B. Soumerai, ScD JAMA. 1990;264(4):476-483. doi:10.1001/jama.1990.03450040072034

"Amount of transfused products was inversely proportional to physician knowledge of transfusion medicine"

JAMA. Jul 25, 1990

Ignorance

Bloody, Dangerous Culture!

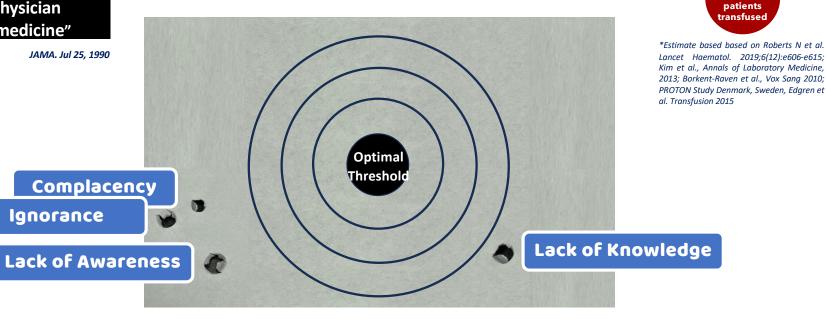
Optimal

Blood Use

~50

MILLION

patients transfused



2.9+ BILLION

individuals with anaemia (2-4,195) and/or micronutrient deficiencies (4-7)

600+ MILLION

Iron deficiency and Lack of Awareness

individuals with chronic or acute lood loss and/or bleeding disorders (32-44)

- Pre-operative anaemia in sur
- Lack of Knowledge

Ignorance

Negligence

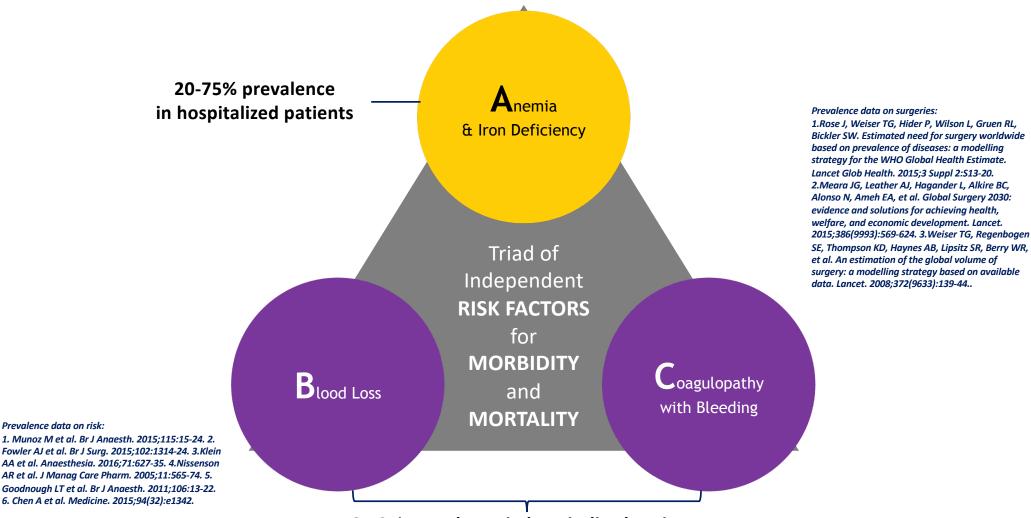
- Anaemia following surgical in
- Anaemia in patients with common
- Complacency
- Anaemia in patients with oncological an malignancies
 - Anaemia in patients with infectious disea (including viral and parasitic infections)
 - Hospital-acquired anaemia in patients without haemorrhage or surgery

- Gastrointestinal bleeding
- Haemoglobinopathies
- Coagulopathies
- Phlebotomy/ venipunctures
- Trauma

Again, Dangerous Culture!



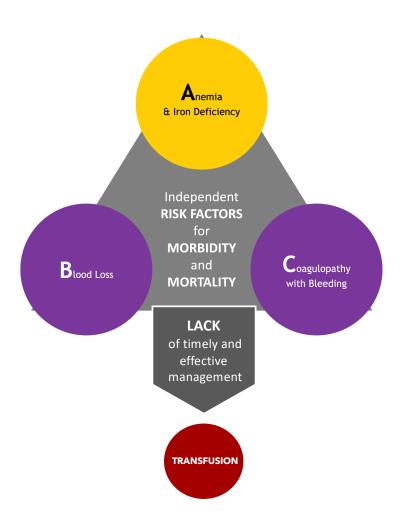
Estimated Global Major Surgeries: 300+ Million



6-12% prevalence in hospitalized patients

Prevalence data on risk:

Figure adapted from Hofmann A, Aapro M, Fedorova et al. Journal of Cancer Policy, 31 (2022)



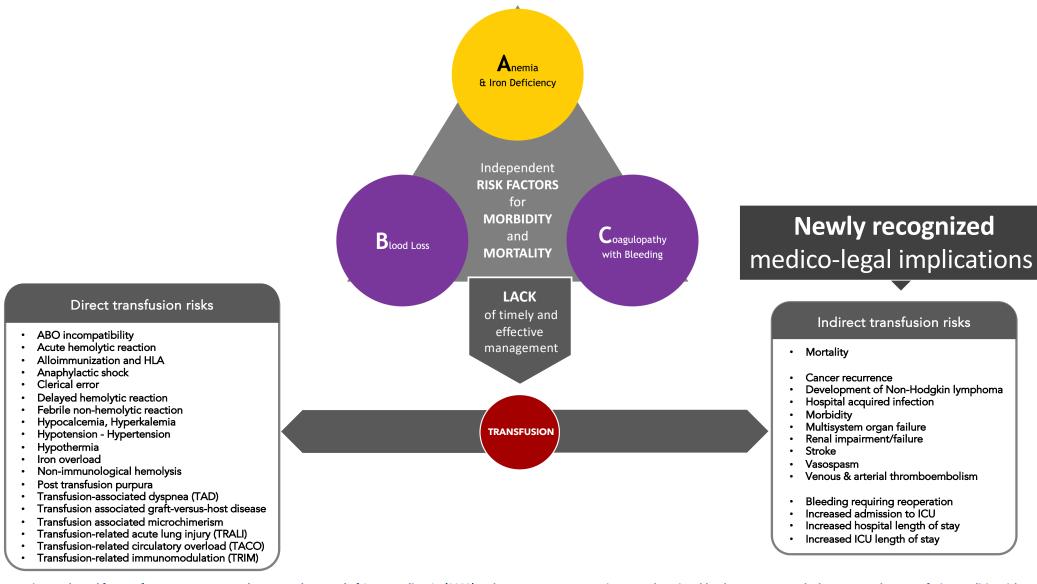
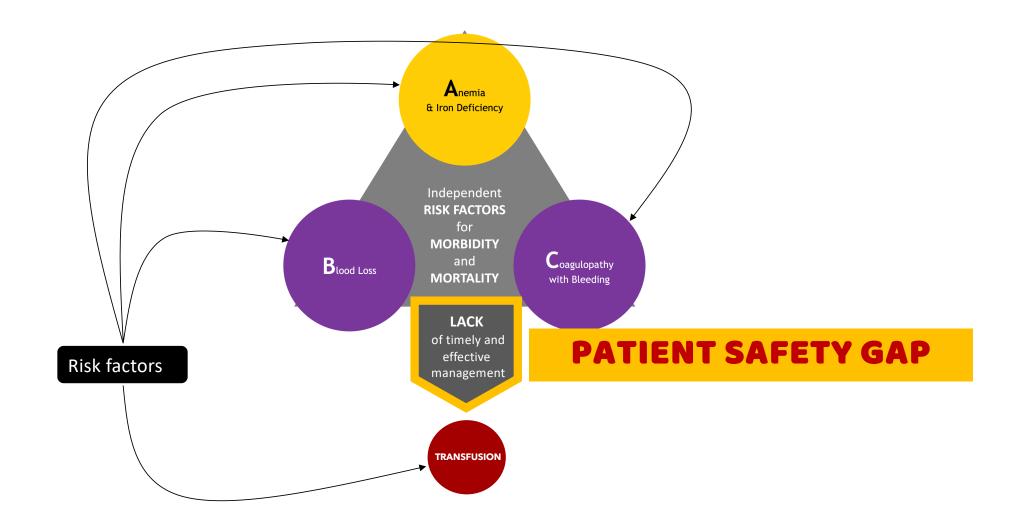
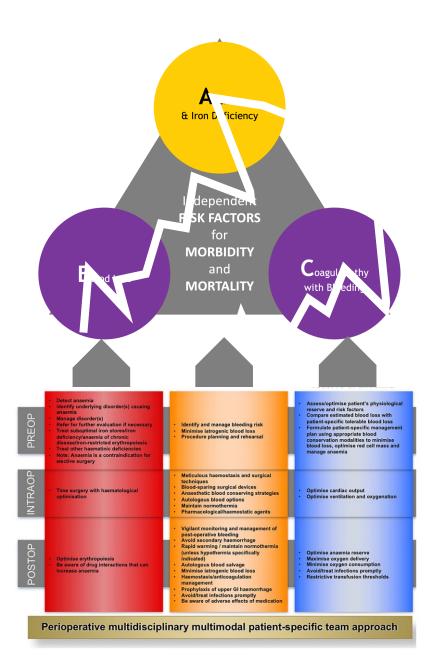


Figure adapted from Hofmann A, Aapro M, Fedorova et al. Journal of Cancer Policy, 31 (2022); Bolcato M, Russo M, Trentino K, et al. Patient blood management: The best approach to transfusion medicine risk management. Transfus Apher Sci 2020:102779; Oehlschläger M. Patient blood management as a medical standard – in the light of legislation and jurisdiction. Anästh Intensivmed 2019;60:572–476





Reformatted from Hofmann A, Friedman D, Farmer S.
Western Australia Patient Blood Management Project 20082012: Analysis, Strategy, Implementation and Financial
Projections. Perth, Western Australia: Medicine and
Economics; 2007:1-215 in: Leahy MF, Hofmann A, Towler S,
Trentino KM, Burrows SA, Swain SG et al. Improved outcomes
and reduced costs associated with a health-system-wide
patient blood management program: a retrospective
observational study in four major adult tertiary care
hospitals. Transfusion. 2017;57:1347-58.



POLICY BRIEF

THE URGENT NEED TO IMPLEMENT PATIENT BLOOD MANAGEMENT

The unmet need to manage and preserve the patients' own blood





2.9+ BILLION

individuals with anaemia (2-4,195) and/or micronutrient deficiencies (4-7)

600+ MILLION

individuals with chronic or acute blood loss and/or bleeding disorders (32-44)

Major surgery

bleeding

Medical and surgical ICU

Obstetric/peripartum

· Heavy menstrual

- Iron deficiency and other micronutrient deficiencies
- Pre-operative anaemia in surgical patients (IDA, AI)
- Anaemia following surgical interventions
- Anaemia in patients with common noncommunicable diseases
 - Anaemia in patients with oncological and haematological malignancies
 - Anaemia in patients with infectious diseases (including viral and parasitic infections)
 - Hospital-acquired anaemia in patients without haemorrhage or surgery

Gastrointestinal bleeding

- HaemoglobinopathiesCoagulopathies
- Phlebotomy/ venipunctures
- Trauma

Taken together, they represent one of the world's biggest, largely preventable, yet greatly underestimated public health and health-economic burdens.

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- Iron deficiency and other micronutrient deficiencies
- Pre-operative anaemia in surgical patients (IDA, AI)
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- Major surgery
- Medical and surgical ICU
- Obstetric/peripartum bleeding
 - Heavy menstrual bleeding
- Gastrointestinal bleeding
- Haemoglobinopathies
- CoagulopathiesPhlebotomy/
- venipunctures
- Trauma

Medicine's
Biggest
Safety and
Quality
Problem?

Patient Blood Management

SPECIAL ARTICLE

A Global Definition of Patient Blood Management

Aryeh Shander, MD,*† Jean-Francois Hardy, MD,‡§ Sherri Ozawa, RN,†|| Shannon L. Farmer, DHSc,¶#**†† Axel Hofmann, Dr.rer.medic,¶**‡‡ Steven M. Frank, MD,§§ Daryl J. Kor, MD,|||¶¶ David Faraoni, MD,§## and John Freedman, MD,***††† Collaborators

Patient Blood Management is a patient-centered, systematic, evidence-based approach to <u>improve patient outcomes</u> by managing and preserving a patient's own blood, while promoting <u>patient safety</u> and empowerment.

Shander A, Hardy JF, Ozawa S, et al. A Global Definition of Patient Blood Management. Anesth Analg. Feb 10 2022





www.ifpbm.org



www.sabm.org





Definition endorsed by

American Society of Anesthesiologists (ASA)
American Society of Extracorporeal Technology (AmSECT)
Anemia Working Group Espana (AWGE)
Asia-Pacific Society for Patient Blood Management (ASPBM)
Chinese Society for Patient Blood Management (CSPBM)
Korean Society for Patient Blood Management (KPBM)
Korean Society of Anesthesiologists (KSA)

Malaysian Society of Haematology (MSH)
National Association of Specialists in Patient Blood Management (NASPBM)
Ontario Nurse Transfusion Coordinators Program, Canada (ONTRraC)
Sociedad IberoAmericano de Patient Blood Management (SIAPBM)
Society of Cardiovascular Anesthesiologists (SCA)
South African National Blood Service (SANBS)

World Health Organization (WHO)



THE URGENT NEED TO IMPLEMENT PATIENT BLOOD MANAGEMENT



Characteristics of patient blood management

Patient blood management addresses the problems of anaemia, blood loss and coagulopathy. It is a patient-centred, systematic, evidence-based approach to improve patient outcomes by managing a patient's own blood through diagnosis and etiology-specific treatment of anaemia and preserving the patient's own blood by minimizing blood loss and bleeding, while promoting patient safety and empowerment (142). It reduces the utilization of health care resources as well as expenditures, transfusion dependency, and the risks and complications of transfusion.

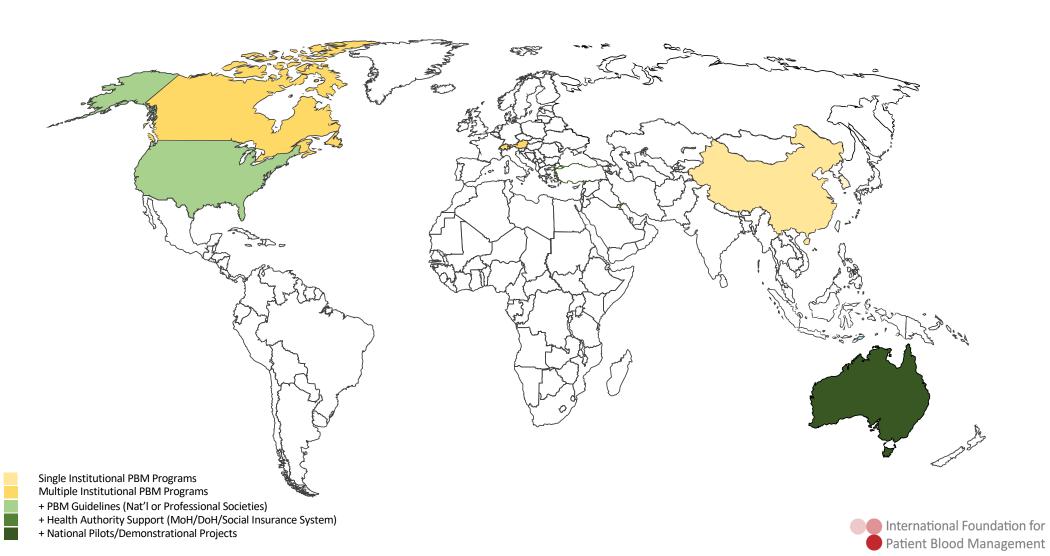
Patient Blood Management

SPECIAL ARTICLE

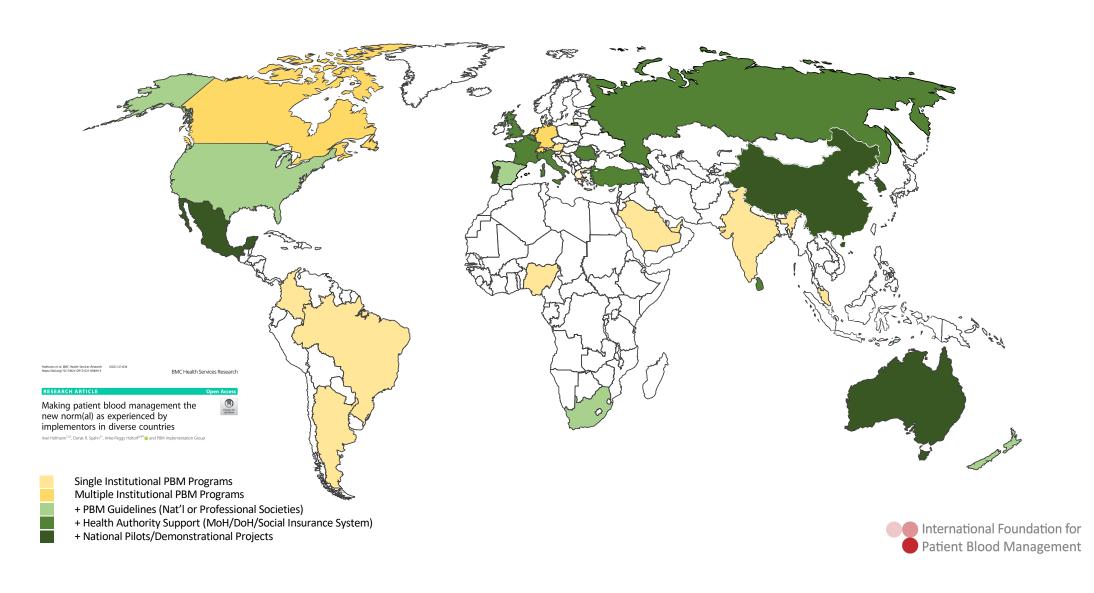
A Global Definition of Patient Blood Management

Aryeh Shander, MD,*† Jean-Francois Hardy, MD,‡§ Sherri Ozawa, RN,† $\|$ Shannon L. Farmer, DHSc,¶***†† Axel Hofmann, Dr.rer.medic,¶***‡‡ Steven M. Frank, MD,§§ Daryl J. Kor, MD, $\|\|\|\|\|$ David Faraoni, MD,§## and John Freedman, MD,***††† Collaborators

PBM Penetration 2012



PBM Penetration 2023







促进实施患者血液管理的专家倡议

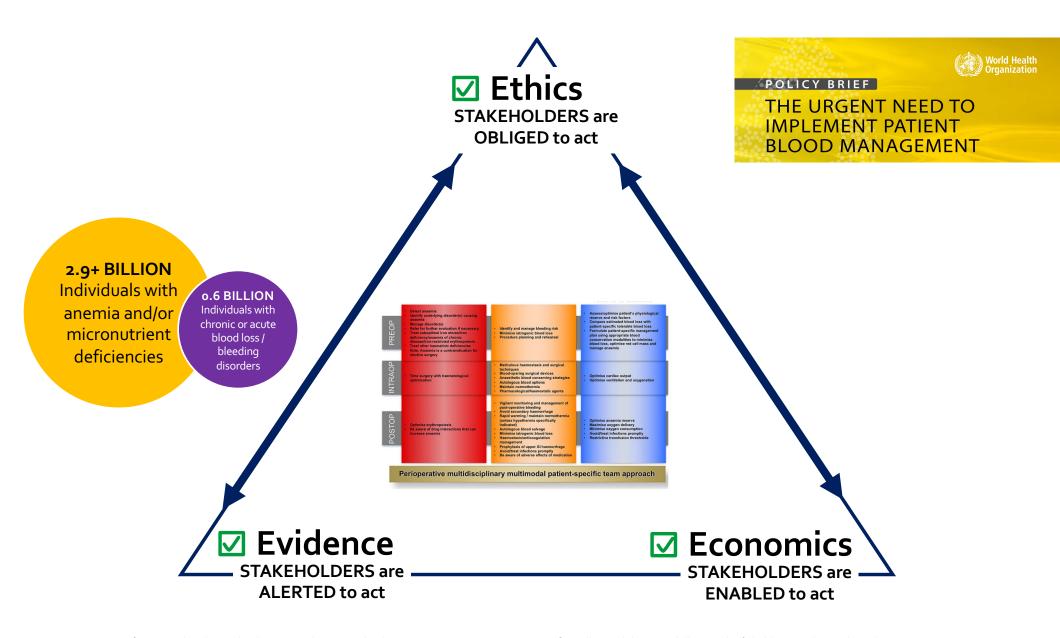
—— 张宗久¹ 胡 豫² Axel Hofmann³ 刘远立⁴ 纪宏文⁵*

Abstract Anemia, blood loss and coagulopathy with bleeding are affecting billions of individuals every year. Each of these conditions represents an independent risk factor for adverse patient outcomes including mortality and morbidity. Patient blood management is a new medical paradigm that can significantly reduce or avoid such risks. Based on the multiple benefit results of patient blood management and relevant policy background in China, this expert initiative was launched to facilitate the implementation of patient blood management for medical institutions. It is believed that this model requires the policy promotion of the competent health authorities, the implementation of education and training, the active participation of all medical institutions and supplementation by innovative diagnosis and treatment paths, reasonable reimbursement plans of medical insurance and evaluation tools based on data.

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Key words Patient Blood Management; Anemia; Blood Loss; Coagulopathy; Bleeding Disorder; Blood Transfusion; Multi-disciplinary Collaboration

Summary and the Way Forward





MoH's TOP-DOWN implementation



POLICY BRIEF

THE URGENT NEED TO IMPLEMENT PATIENT BLOOD MANAGEMENT

1. Introduction

In the past four decades, increased awareness of the inherent risks of transfusion has resulted in major initiatives to mitigate those risks through improvements in blood component safety. The realization that the intense focus on product safety had not been matched with a similar focus on improving transfusion decisions at the bedside led to the concept of "optimal blood use". The practice of transfusion medicine now emphasizes the judicious use of transfusion, only when clinically indicated. The concept that "our own blood is still the best thing to have in our veins" (1) has given rise to various surgical "blood conservation" techniques (for example, minimization of blood loss, blood salvage and acute isovolaemic haemodilution). Underlying these efforts

is the broader concept of "patient blood mana, (PBM). This is a patient-centred approach that ar iron deficiency, anaemia, coagulopathy and bk in both surgical and nonsurgical patients, as risl for adverse medical outcomes. Under PBM, anae iron deficiency are recognized as serious globa issues in their own right, affecting billions of worldwide. Yet, globally, there is still a gap in aw

worldwide. Yet, globally, there is still a gap in awareness and implementation of PBM as an overall framework to address the risks of iron deficiency, anaemia, blood loss and coagulopathy. This policy brief focuses on the urgent need to close that gap and the steps needed to achieve that goal.

2. Purpose of this policy brief

This policy brief aims to:

- create awareness about the enormous, but greatly under-appreciated global disease burden of iron deficiency, anaemia, blood loss and bleeding disorders:
- create a sense of urgency for health care entities to implement PBM, a systematic, multidisciplinary, multiprofessional concept to routinely minimize these risk factors, and, in so doing, significantly and cost-effectively improve health and clinical outcomes for hundreds of millions of medical and surgical patients, pregnant women, neonates, children, adolescents, elderly people, and the population as a whole;
- announce the upcoming World Health Organization (WHO) initiative to develop PBM Implementation Guidelines that will serve as a framework for health care leaders of all Member States;
 - foster the rapid dissemination and implementation of PBM in their jurisdiction;
 - coordinate these efforts with existing initiatives pertaining to improved patient-centred care, patient safety and quality of care, including maternal, prenatal and child care, and nutritional supplementation programmes;
 - act as an accelerant for change by educating the readers about what PBM is and is not, why PBM implementation is critical, and calling attention to the barriers to implementation.







POLICY BRIEF

THE URGENT NEED TO IMPLEMENT PATIENT BLOOD MANAGEMENT

12. Call to action

All Member States should act quickly through their ministry or department of health to adopt their national PBM policy, install the necessary governance, and reallocate resources to improve the population health status and individual patient outcomes while reducing overall health care expenditures.

Thank you for your attention!