CSL Behring

Shaping the future of PBM: Global guidance and innovation

Moderators: Sigismond Lasocki and Patrick Meybohm

Friday, April 25, 2025

1. FUTURE OF TRANSFUSION MEDICINE

Markus Mueller

Dr. Müller approached the future of transfusion medicine from an integrating perspective, combining scientific breakthroughs, digital transformations, and bioethical challenges.

He started his presentation by analyzing the limitations of the classic transfusion model:

- Late reaction: transfusion is applied once anemia has developed, not as a preventive measure.
- Lack of personalization: transfusion thresholds are only based on hemoglobin, regardless of the blood volume, inflammatory profile, or organic function.
- Poor traceability of clinical justification and subsequent effects.

He reckoned that the future of transfusion medicine should include:

- **Precision medicine:** algorithms integrating biomarkers, clinical data, and predictive tools in order to decide when and how to transfuse.
- **Intelligent automation:** blood bank platforms connected to the patient's clinical and surgical history, to suggest specific components or prevent selection errors.
- **Rational preservation:** inventory management strategies to minimize expirations, waste, and costs, particularly in platelet or irradiated components.

He also spent some time discussing **transfusion ethics**, including:

- The need for a real non-routine informed consent.
- The impact of overtransfusion as an unregistered iatrogenesis.
- The importance of hospital policies limiting unjustified variability between professionals and services.

He concluded arguing that transfusion medicine must transcend its logistic model and take on a proactive role within the healthcare process, integrating artificial intelligence, outcome-based medicine and value-focused institutional policies.

The TRICC clinical trial was the first one to determine that a restrictive red blood cell transfusion strategy was, at least, as effective as the liberal strategy[1], although there can actually be significant differences between the highly-selected population in the study and real-life patients[2].

When making decisions, it is important not to extrapolate the results of clinical trials to any type of patient.

A correlation between both events or observations does not involve causation. In the field of transfusion, results from retrospective observational studies are often published concluding there is a causal relationship between received transfusions and certain clinical outcomes, but such conclusions cannot actually be drawn from this type of studies.

In the FOCUS randomized controlled study, that included patients with a history or risk of cardiovascular disease and low concentrations of postoperative hemoglobin, no statistically significant differences were observed in mortality after 3 years of follow-up (secondary variable in the study) or in the causes of death between patients transfused following restrictive or liberal strategies[3].

To draft evidence-based recommendations in the Frankfurt consensus document on *patient blood management* (PBM), a thorough literature search was carried out, but eventually under 1% of the studies found were analyzed, which is a very low ratio[4]. Moreover, many of the recommendations were strong but backed by a moderate to low evidence level.

The demographic changes occurred in the last few years and the ones ahead will have an impact on the blood supply. In Germany, *babyboomers* (50-65), who currently account for most blood donors, will move on to the highest-receiving group in the next few years[5].

The number of donations per year in Germany is close to 2, which is relatively higher than other European countries. However, the donor ratio is low (3%), considering that 30% of the population could be donors. The average age of German donors is high (46.5), as well as that of new donors (32.9), and the donor return ratio after the first donation is only 25%.

B*lood farming* is proposed as a potential solution to the future blood shortage, but many unsolved issues lay still ahead.

Drawbacks of *blood farming*	Immortalization of direct reticulocyte precursors
• Long expensive differentiation process • Inefficient enucleation • Fragile reticulocytes	• Reduction of differentiation • Culture needed for terminal differentiation

These are the current challenges to ensure supply:

- Young donor motivation and commitment
- Donor mobilization in urban areas
- Yearly supply of all products
- Suppress perception of risk from blood

KEY MESSAGES:

- **Transfusion medicine must evolve into a more proactive, intelligent, ethical model.**
- **Automation and the use of artificial intelligence may increase transfusion safety.**
- **Unjustified transfusion variability should be considered a threat to healthcare equity.**

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2. WHO GUIDANCE ON IMPLEMENTING PBM TO IMPROVE GLOBAL BLOOD HEALTH

Axel Hofmann

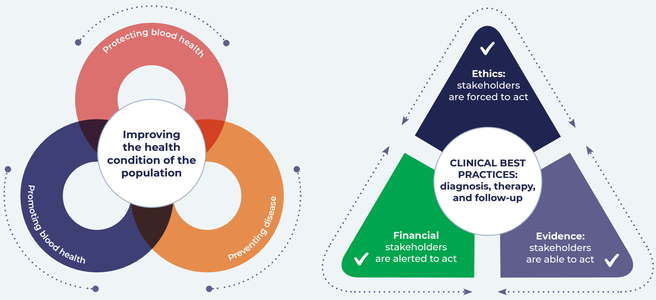
The World Health Organization (WHO) declared that PBM should be urgently implemented worldwide to improve patient clinical outcomes, promote safety, and cut costs, particularly in the inverted pyramid demographic context of the next few decades.

The recent publication of the document *Guidance on implementing patient blood management to improve global blood health status*[6] is a tool to include PBM in the public health agenda of all member states, and thus reduce the costly dependence of transfusions and reassign the limited funds to where they are most needed.

IMPROVING BLOOD HEALTH IS A GLOBAL PUBLIC HEALTH PRIORITY.

The document uses «model 8», a structured way for the implementation of complex integrated systems in large sectors. The model also integrates the «3Ps» and «3Es».

3P83E



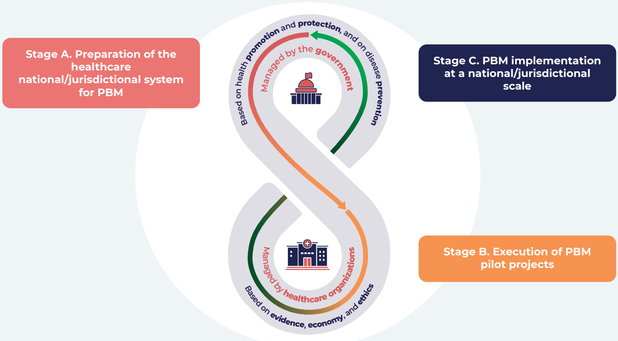
Human blood is also defined as an organ, since it meets all the criteria to be considered as such, although it is often dealt with as a connective tissue, a merchandise, a medication, or a replacement fluid.

HOW CAN THE DOCUMENT HELP OVERCOME CHALLENGES TO GLOBAL IMPLEMENTATION OF PBM

The document provides two essential tools:

- Path for national/jurisdictional implementation.
- PBM toolkits for specific patient populations and diverse resource levels.

PATH FOR NATIONAL/JURISDICTIONAL IMPLEMENTATION BASED ON MODEL 8



Stage A. Preparation of the healthcare national/jurisdictional system for PBM

1. Adopting a PBM policy.
2. Setting up governance for the implementation of PBM.
3. Anchoring the PBM in the WHO quality and safety framework.
4. Training professionals and students on the PBM.
5. Educating the public in matters of blood health.
6. Ensuring access to essential drugs and devices for PBM.
7. Allocating resources to PBM.
8. Selecting PBM pilot projects.

Stage B. Execution of PBM pilot projects

9. Having "champions" promote PBM in healthcare organizations.

> **"Champions" are individuals who support, advocate, and spearhead an implementation initiative, and who overcome resistance so that it can reach the whole organization. They have an inherent interest in implementing change, and they use their position to motivate others. They have good communication and tutoring skills to facilitate the acceptance of the initiative[7].**

10. Preparing the implementation of PBM in healthcare organizations by "champion" teams.
11. Authorizing the pilot project by the direction of healthcare organizations.
12. Creating a specific PBM structure for healthcare organizations.
13. Implementing specific PBM processes for each healthcare organization.
14. Setting up a PBM data and report collection system.

Stage C. PBM implementation at a national/jurisdictional scale

15. Selecting pilot sites as national references.
16. Collecting data, reporting, and *benchmark* the PBM results.
17. Fostering the certification of multidisciplinary physicians in PBM.
18. Fostering the certification and auditing of PBM programs.
19. Facilitating and funding PBM research and development.

PBM TOOLKITS FOR SPECIFIC PATIENT POPULATIONS AND DIVERSE RESOURCE LEVELS.

- Toolkits are a collection of resources, guidelines, strategies, and interventions designed to deal with specific health issues, improving patient care, and expanding the knowledge and skills of healthcare professionals.
- They are included in Appendixes 6-11 of the document. They are organized as tables to facilitate care to the following patients:
  - Anemia/iron deficiency
  - Hemorrhages and blood loss
  - Coagulation and hemostasis disorders
- They cover a wide array of issues and they are meant to be practical tools to implement PBM as a standard of care.
- They are organized based on the resource level:
  - Low-income countries
  - Medium-low and medium-high income countries
  - High-income countries
- They are targeted at specific populations:
  - Neonatology and pediatrics
  - Obstetrics
  - Traumas
- They are designed to reduce the difficulties when implementing PBM, increase the understanding and commitment of patients and healthcare professionals, and improve healthcare outcomes.
- They supplement steps 3 to 6 of the implementation managed by governments, but particularly step 13, aimed at organizations.

KEY MESSAGES:

- **La 2024 WHO guide legitimizes PBM as a healthcare policy.**
- **PBM is no longer a clinical initiative, but a global strategy against anemia and inappropriate transfusion.**
- **The "hospital" approach needs to shift to sustainable and auditable population models.**

LITERATURE

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