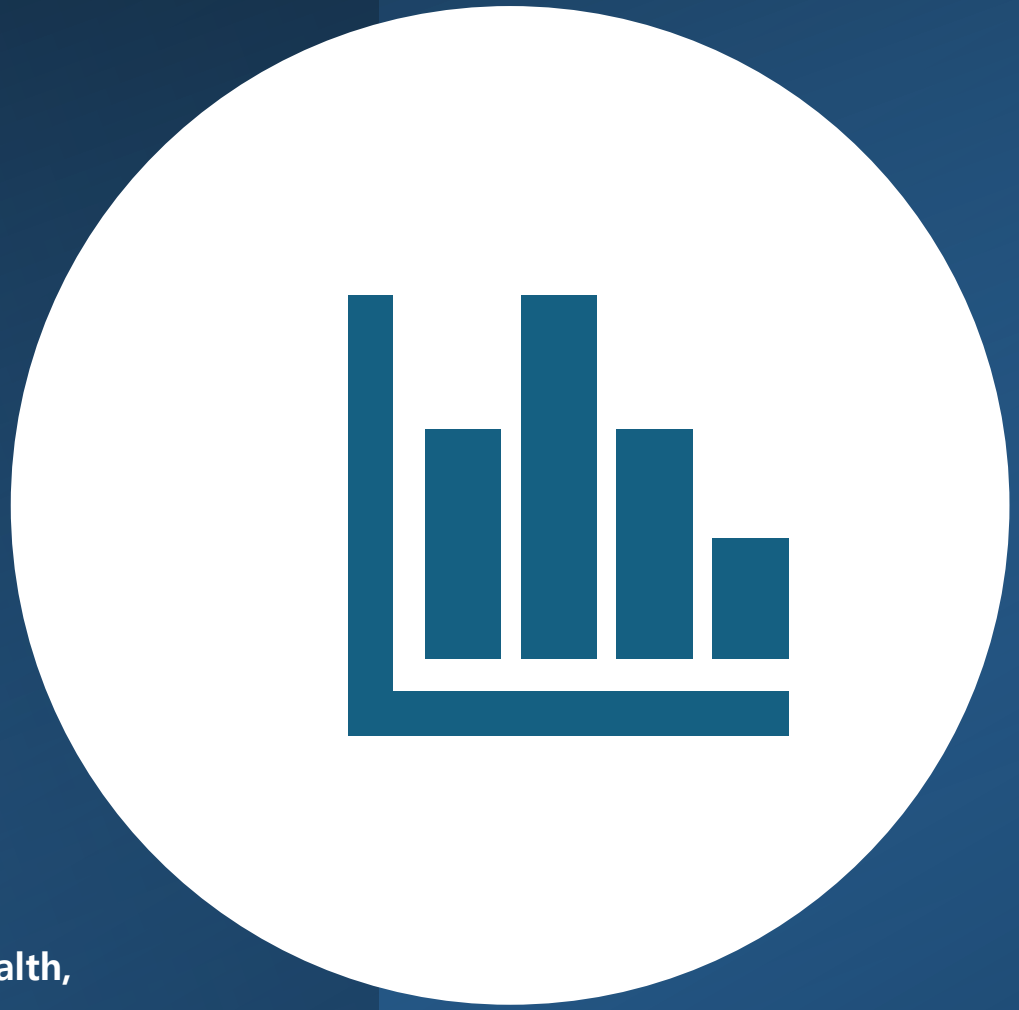
Development of a PBM Index for Evaluation of Performances of PBM



OSSTEM IMPLANT HEADQUARTERS
AUDITORIUM
MAGOK, SEOUL, KOREA
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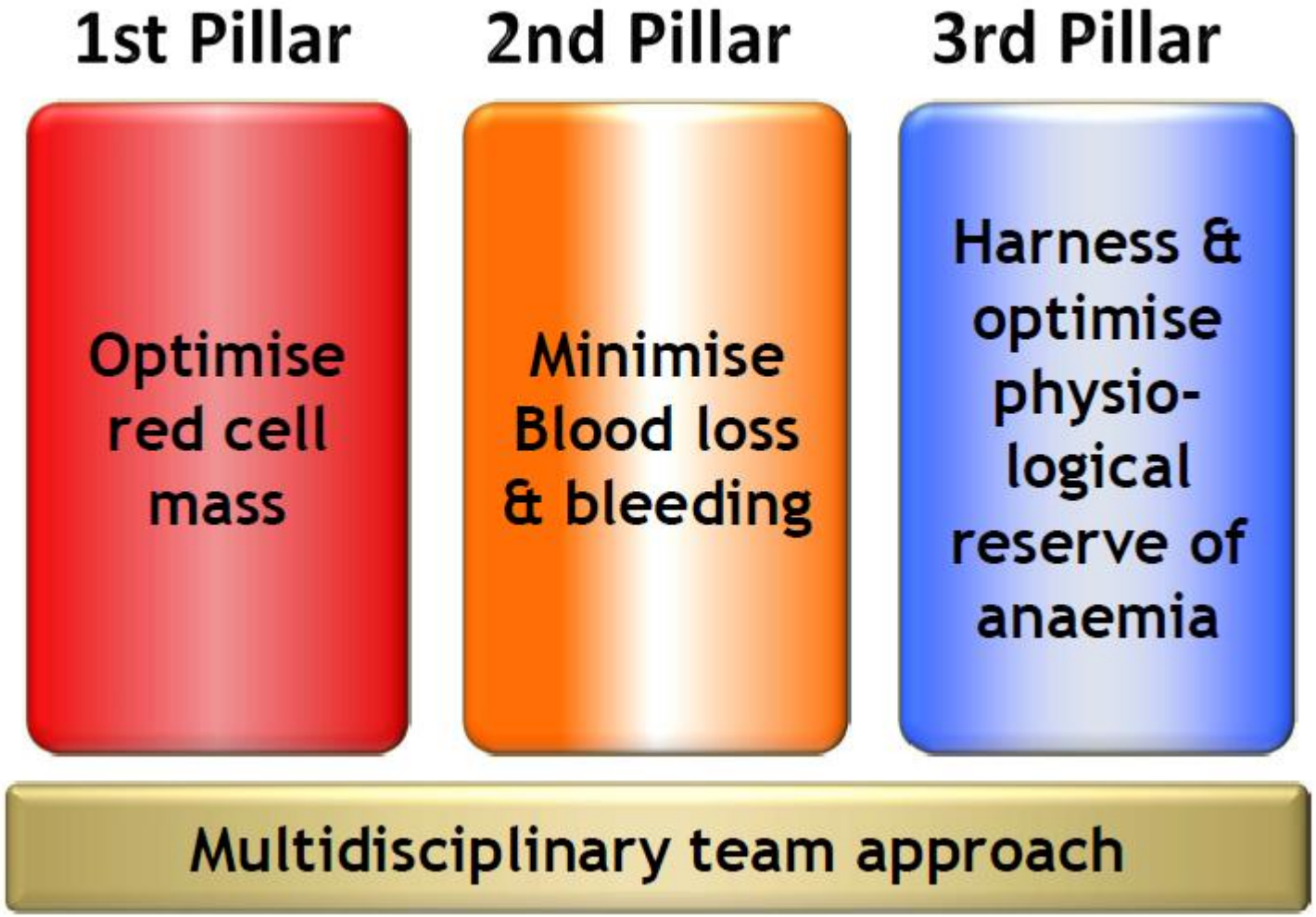
Patient Blood Management



Hofmann A, Farmer S, Shander A. Five drivers shifting the paradigm from product-focused transfusion practice to patient blood management.
Oncologist. 2011;16 Suppl 3:3-11

A Literature Review of **Patient Blood Management (PBM) Outcomes**

- **5 Meta-analyses**, **5 Randomized Controlled Trials (RCTs)**, and **5 Systematic Reviews were included.**

- **Interventions:** PBM multimodal strategies such as p re-operative anemia management, active blood loss minimization (e.g., TXA), and restrictive transfusion t hresholds.

A Summary of Patient Blood Management Outcomes

Outcomes	Main Results
RBC Transfusion Rate	Confirmed PBM programs significantly reduce allogeneic RB C transfusion rates (e.g., by 39% or RR 0.60).
Mortality	Demonstrated PBM is associated with reduced overall morta lity (e.g., RR 0.89), though some complexity was noted (not all studies show significance).
Morbidity (comlications)	Confirmed PBM is associated with a reduced total number o f complications and that TXA reduces bleeding without incre asing the risk of thromboembolic events.
Hospital length of stay (LoS) as cost-effective	Established PBM is associated with reduced hospital length of stay (LoS) and is generally considered cost-effective.

Randomized Controlled Trial (RCT)

Outcomes	Main Results
Avoiding allogeneic blood transfusions	Most frequent primary endpoint. Interventions like IV Iron or EPO were confirmed to be highly effective at avoiding allogeneic blood transfusions (e.g., up to 60% reduction in incidence).
Clinical Efficacy (Hb, Bleeding rate)	Proven successful treatment of the underlying issue: IV Iron leads to significantly higher Hemoglobin (Hb) recovery post-operatively; TXA significantly reduces direct bleeding rates.
Adverse events	Established the safety profile by showing no increase in adverse events (AEs) when comparing the intervention to the control.
Hospital length of stay	Proven to shorten the hospital length of stay and associ

Systematic Review (SR)

Outcomes	Main Results/Conclusions
Policy & Consensus	Affirmed that multimodal PBM programs are a critical patient safety initiative.
Optimal Practice	Established that restrictive transfusion practices (lowe r Hb thresholds) are the evidence-based standard in most patient populations.
Intervention Feasibility	Confirmed that core PBM components like IV iron are effective for anemia management and should be inte grated into clinical pathways.
Quality Assurance	Highlighted gaps in current practice or methodology, such as confirming the accuracy of surgical blood los s measurement tools.

Limitations in Measuring PBM Outcomes

Heterogeneity of PBM Interventions and Patient Population

Challenges with Safety and Morbidity Outcomes

Difficulty in Measuring Appropriateness

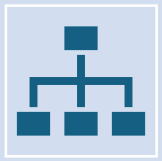
Lagging Indicators for Program Success

The Unmet Need: Current Challenges in PBM Implementation and Evaluation

1. **Lack of Standardized Evaluation Tool**
2. **Variability in Clinical Practice**
3. **Challenges with Safety and Morbidity Outcomes (rare, confounding factors)**
4. **Systemic Complexity and Financial Barriers**

The development process relies on gathering expert consensus on core PBM indicators.

Composite Index



The Power of Aggregation: Translating Complexity into a Single Score

To simplify complex, multidimensional realities into an easily understandable and actionable metric.

Indices in Action: Examples from Other Fields

Simplifying Decisions Across Finance, Health, and Development

S&P 500	**Finance**	Aggregates the performance of 500 leadi ng US public companies.
Apgar Score	**Pediatrics**	Aggregates 5 signs of newborn health (A ppearance, Pulse, Grimace, Activity, Respir ation) into a score (0-10) to assess imme diate health.
Human Development Index (HDI)	**Socio-Economics**	Aggregates health (life expectancy), educ ation (years of schooling), and standard o f living (GNI per capita).

Goal of The PBM Index

To aggregate 3 PBM Pillars across 3 Donabedian domains (S, P, O) into a single, standardized quality score.

Core Function	Why it Matters in Healthcare
Synthesis	Combines hundreds of individual patient data points (Hb, LoS, transfusion) into one comparable score.
Weighting	Allows experts to assign importance (weights) to critical c omponents (e.g., Process is more critical than Structure).
Tracking	Provides a reproducible baseline and a clear target for m easuring progress over time.

Benefits of the PBM Index

From Guideline to Action

The PBM Index transforms the abstract concept of "good PBM" into a measurable, targetable score:

Standardization	**Objective Evaluation**	**Actionable Feedback**

Structure of PBM Index

The PBM Index Structure: Structure (S), Process (P), Outcome (O) (Donabedian Model).

Domain	Weight (Proposed)	Focus	Impact
Structure (S)	**20%**	The resources and infrastructure in place	Essential foundation, but low weight reflects that protocols alone don't guarantee results.
Process (P)	**40%**	The actions taken by clinicians	High weight reflects that **doing the right thing** drives quality.
Outcome (O)	**40%**	The results for the patient	High weight reflects the ultimate goal of PBM: **better, safer patient care.**

Delphi Surv ey Ongoing

Invitation to Participate in a Delphi Survey for PBM Index Indicator Development

Focus group 20

Korean expert 10	oversea exert 10

Index Verification and Future Steps

EVALUATION OF INDICATOR QUALITY

VERIFICATION OF THE WEIGHTING STRUCTURE

IDENTIFYING GAPS (FUTURE REFINEMENT)

PBM Index Validation Study

Validation of PBM Index

The index aggregates multiple structural, process, and outcome metrics (3 Pillars) into a single score.

Need for Proof: We must prove that a high score truly correlates with superior clinical practice and improved patient outcomes

To rigorously validate the new PBM Index as an objective, reliable, and functional tool for quality improvement in Patient Blood Management.

Observational Cohort & Construct Validation

Element	Description	Validation Mechanism
Study Cohort	multicenter hospitals selected to represent a range of PBM maturity (from non-imple menting to highly mature).	Ensure the Index can differentiate between high and low performers .
Data Collection	Collect all necessary data for the Index calc ulation. **Hospitals operate as normal; no i ntervention is announced.**	The Index calculation must be rep roducible and accurate.
Primary Validation Targ et	**Correlation of PBM Index Score vs. Exter nal Metrics**	A higher PBM Index Score must s how a **significant correlation** wit h external metrics.
Expert Review	Present the Index scores and outcome data to the Delphi Expert Panel for qualitative c onfirmation.	Validate that the score meets **Crit erion Validity**—experts agree hig h scores represent high-quality ca re.

Cluster Randomized Trial : PBM Index as the Primary Outcome

Cluster Randomized Trial Protocol: PBM Index as the Primary Outcome

- Primary Objective
  To determine if the implementation of a structured, multimodal Patient Blood Management (PBM) Program in a healt hcare facility leads to a significantly gre ater positive change in the composite P BM Index Score compared to facilities p roviding routine care.

Study Design

Element	Description
Design	**Multicenter, Parallel-group Cluster Randomized Trial (CRT)**
Clusters (Randomization Unit)	Hospitals or major surgical/anesthesia departments that are not currently operating a formal, comprehensive PBM program.
Randomization	Clusters are randomized 1:1 to either the Intervention Group (PBM Program Implementation) or the Control Group (Standard Care).
Duration	**Baseline Period (6 months):** Data is collected from all clusters to establish initial PBM Index scores. **Intervention Period (18 months):** Sufficient time for systemic change and clinical outcome realization.
Study Population	All adult patients undergoing moderate to major elective surgery at the participating hospitals, as this is the group most impacted by PBM initiatives.

Intervention and Control

Arm	Name	The Intervention	Measurement
Intervention	**PBM Program Group**	Clusters receive funding, resources, training, and a mandate to establish a formal PBM p rogram based on the **Three Pillars** (anemia management, blood loss minimization, physiological reserve optimization). Teams are directed to use the PBM Index and its S/P/O breakdown as their internal **QI score card** to guide efforts.	The PBM Index is calculated and provided **monthly** to drive iterative improv ement.
Control	**Standard Care Group**	Clusters continue with their current clinical practice. They are not prohibited from transfusing appropriately but do **not** receive the structured PBM guidelines, PBM team support, or index-based feedback.	The PBM Index is calculated only at **Baseline** and at **18 months** (End-of-Stud y) to prevent contamination of the intervention.

Primary and Secondary Outcomes

Outcomes	Measurement	Interpretation
Primary Outcome	**Absolute Increase in Composite PBM Index Score** (18-month score minus Baseline score).	**PBM Effectiveness:** Demonstrates that the PBM program significantly improved the overall quality and safety of patient blood management practice compared to standard care
Secondary Outcome 1	**TBD (e.g. Allogeneic RBC Transfusion Rate)**	**Clinical Benefit**
Secondary Outcome 2	**TBD (e.g. Post-operative Complication Rate** and **Hospital Length of Stay)**	**Patient Safety & Efficiency**
Secondary Outcome 3	**TBD** (e.g., Iron Treatment Rate)	**Systemic Change**

Thank you for your attention!