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Evaluating the impact of patient blood management implementation: a protocol for a quasiexperimental study in a Portuguese tertiary care setting

Diana Castro Paupério ,[1,2] Henrique Coelho,[3,4] Sandrine Jorge,[5] Guilherme Rabello,[6] Donat R Sphan,[7] João Firmino-Machado[8,9]

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For numbered affiliations see end of article.

Correspondence to
Dr Diana Castro Paupério; diana.pauperio@ulsge.min-saude.pt

ABSTRACT

Introduction Patient blood management (PBM), an evidence-based, patient-centred approach for optimising blood health, faces significant implementation challenges despite regulatory support, and this study explores its adoption within a Portuguese hospital to enhance education, develop tailored protocols and address healthcare system complexities, thereby contributing a unique perspective to the global discourse on PBM in Portuguese-speaking countries. This study will evaluate the clinical outcomes and cost-effectiveness of implementing a PBM programme in elective surgical patients at a tertiary Portuguese hospital, with secondary objectives focusing on preoperative anaemia prevalence and aetiology, PBM protocol adherence, transfusion practices guided by viscoelastic tests and the impact of cell salvage techniques.

Methods A baseline evaluation will be conducted in 2018, and postintervention assessments will follow from 2019 to 2024. The control group comprised patients who underwent selected elective surgeries—including cardiac, general, orthopaedic, urological and gynaecological procedures—during 2018 without exposure to targeted PBM interventions. The intervention group consisted of patients scheduled for the same elective surgeries, who were referred for preanaesthesia evaluation to identify the need for PBM interventions. These interventions, where indicated, were implemented during the preoperative phase and extended to the intraoperative and postoperative periods to ensure a comprehensive and standardised approach to PBM application. Data will be extracted from pseudoanonymised medical records, ensuring full compliance with ethical standards and data protection regulations. Statistical analyses will be performed using robust methods suitable for categorical and continuous variables, enabling the evaluation of temporal trends and the overall effectiveness of PBM interventions in improving clinical outcomes.

Ethics and dissemination Our research has been ethically approved by the Vila Nova de Gaia/Espinho Hospital Centre's Ethical Health Committee (approval number 196/2023–1). We plan to disseminate our findings through posters, lectures at conferences and in scientific journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Employs a quasiexperimental before-and-after design to evaluate the implementation of patient blood management (PBM).
⇒ Incorporates both retrospective and prospective data collection to ensure a comprehensive analysis.
⇒ Engages an interdisciplinary team to enhance adherence to protocols and implementation fidelity.
⇒ Implements standardised PBM protocols that are aligned with national and international guidelines.
⇒ The single-centre design may limit the generalisability of findings to other healthcare settings.

INTRODUCTION

Patient blood management (PBM) addresses key issues such as anaemia, bleeding and thrombosis.[1] The global definition of PBM describes PBM as a patient-centred, evidence-based and systematic approach to improve clinical outcomes by preserving and optimising patients' blood while prioritising safety and patient empowerment.[2] Among the critical drivers of RBC transfusions are anaemia, perioperative blood loss and low haemoglobin thresholds—factors often overlooked in blood health management.[3] In response, PBM has evolved into a strategic framework founded on three core principles: optimising erythropoiesis, minimising blood loss and improving tolerance to anaemia.[4–6]

The global impact of anaemia and blood management inefficiencies is profound. An estimated 2.36 billion individuals worldwide are affected by anaemia, with over 50% attributable to iron deficiency anaemia. Implementing PBM has demonstrated the potential to reduce mortality rates by 28%, infection rates by 21%, myocardial infarction incidences by 31% and hospital stays by 15%.[7] Furthermore, PBM has achieved a 41% reduction in RBC transfusions and a 47% decrease in fresh frozen plasma (FFP)

utilisation, underscoring its economic and clinical benefits.[6–13] The diagnosis and treatment of preoperative anaemia are essential elements of any PBM programme. Addressing anaemia is crucial because it is a leading cause of perioperative red blood cell (RBC) transfusions, directly impacting patient outcomes.[14 15]

The WHO has emphasised the importance of PBM, endorsing it in 2010 and reiterating its urgency in a 2021 policy brief, which calls for accelerated adoption globally.[7] Despite this endorsement, implementation rates vary significantly across regions due to cultural, logistical and interdisciplinary barriers.[11 16–19]

In Portugal, while PBM is supported at the regulatory level, practical implementation remains challenging. These challenges include variability in clinical practices, the need for interdisciplinary collaboration, cultural resistance and improvements in health information systems.[20–25]

Our institution's PBM programme began in 2018 with a baseline assessment of perioperative blood management practices. This assessment identified key gaps and informed the development of a customised implementation plan tailored to our institution's needs. Recognising that similar challenges existed across regional hospitals, the PBM-Tailoring the Implementation in the Portuguese health System initiative brought together six northern Portuguese institutions into a collaborative network. This partnership established a unified protocol based on national and international guidelines, defined key performance indicators and fostered mutual support to drive cultural change and standardise PBM practices.[25] This study represents a preplanned evaluation of the PBM programme at our institution, designed to assess its clinical and economic impact following its implementation.

Objectives

The primary objective of this study is to assess the impact of PBM implementation on the preoperative anaemia rate in elective surgical patients at a tertiary-level Portuguese hospital.

Secondary objectives

The study aims to:

1. Determine the prevalence of preoperative anaemia in elective surgical patients.
2. Determine the severity and underlying causes of preoperative anaemia among elective surgical patients.
3. Quantify the adherence to PBM protocols within the hospital setting.
4. Evaluate the prophylactic utilisation of tranexamic acid in elective surgical patients.
5. Characterise transfusion practices within the institution, focusing on RBCs, FFP and platelets before and after PBM implementation.
6. Determine the proportion of patients receiving transfusions involving FFP, platelets, 4-factor prothrombin complex concentrate or fibrinogen, with viscoelastic test (VET) guidance during the overall length of stay.
7. Assess the impact of cell salvage techniques on RBC transfusion.
8. Assess the specific contributions of preoperative versus intraoperative and postoperative PBM measures using a subgroup analysis of PBM Group 1 and PBM Group 2, evaluating their respective outcomes separately.
9. Explore the effect of the COVID-19 pandemic on the above-mentioned objectives, using a subgroup analysis that includes on the intervention group: (1) patients submitted to surgery in the prepandemic period (17 January 2019–17 March 2020); (2) patients submitted to surgery during the COVID-19 pandemic period (18 March 2020–30 September 2022); (3) patients submitted to surgery in the postpandemic period (1 October 2022–31 December 2024).
10. Assess the effect of time on PBM implementation: to assess how PBM implementation has changed over time by comparing different postimplementation periods.
11. Assess the cost-effectiveness of adopting a PBM framework.

METHODS AND ANALYSIS

Setting

This study will be conducted at Unidade Local de Saúde Gaia e Espinho (ULSGE), a Portuguese non-academic tertiary hospital.

Following the guidance provided by national and international recommendations, we have formulated a comprehensive PBM programme tailored initially for cardiac surgery but then disseminated and extended to encompass other surgical and medical specialties within our institution—online supplemental appendix 1.[20 21 23 24 26–31]

Participants

This study will focus on patients referred by surgeons for preoperative assessment and optimisation, specifically targeting individuals diagnosed with anaemia, micronutrient deficiencies or coagulopathy. Eligible participants are all candidates for the selected elective surgeries, including cardiac, general, orthopaedic, urological and gynaecological procedures, as outlined in figure 1 (surgical procedures selected for PBM pilot programme implementation). These surgical categories were chosen

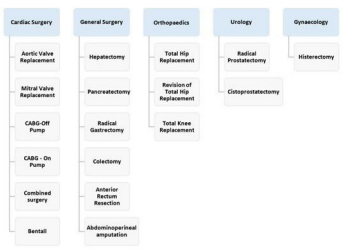

Figure 1 Surgical procedures selected for PBM pilot programme implementation. PBM, patient blood management; CABG, Coronary Artery Bypass Graft Surgery.

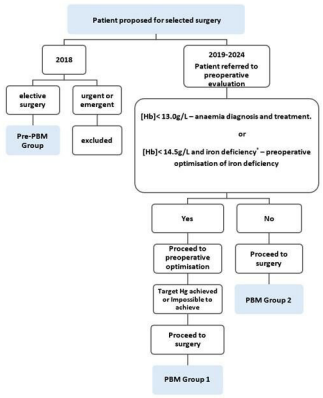

Figure 2 Patients included in pre-PBM, PBM Group 1 and PBM Group 2. *Iron Deficiency is defined as a ferritin level below 100 ug/L or transferrin saturation below 20%.[14] PBM, patient blood management.

based on their strong association with opportunities for short-term improvements in patient outcomes through the implementation of PBM strategies.[30]

Inclusion criteria

This study will include male and female adults aged 18 years or older who are followed in the departments of cardiac surgery, general surgery, orthopaedics, urology or gynaecology and are scheduled for one of the surgical interventions outlined in figure 1.

- *Pre-PBM group (2018)*: this group comprises all elective patients who underwent the specified surgical procedures in 2018 before implementing PBM strategies.
- *PBM group (2019–2024)*: this group includes all patients referred for a preanaesthesia evaluation who subsequently underwent the designated surgeries between 2019 and 2024, during which specific PBM interventions were applied (figure 2).

Patients will be identified for inclusion based on referrals made by surgeons for preoperative anaesthetic evaluation. Their data will be accessed through digital records of these referrals within the hospital's electronic medical records system.

Exclusion criteria

Pregnant or lactating patients will be excluded, as supported by the study of Chau *et al*.[32]

Design

This is a quasiexperimental study (before-after study). Baseline assessment was conducted in 2018 (before the implementation of PBM—historical control group), followed by a postintervention (ie, after PBM implementation—prospective data collection) evaluation that will take place between 2019 and 2024.

Control

The control group, defined here as the pre-PBM group, consisted of individuals who underwent the surgeries listed in figure 1 (figure 1, surgical procedures selected for PBM pilot programme implementation) conducted in 2018.

Intervention

The PBM programme is structured around three critical phases, designed to optimise patient outcomes by preserving the patient's blood (online supplemental appendix 1—PBM interventions selected for the initial implementation process at ULSGE)[4–6]:

1. Optimising the patient's endogenous red cell mass.
2. Minimising bleeding and blood loss.
3. Harnessing and optimising the patient's tolerance of anaemia.

During the preoperative phase (online supplemental appendix 2—preoperative PBM journey), haematological parameters and bleeding history are comprehensively evaluated by the designated physician. This phase includes proactive strategies for enhancing haemoglobin levels and identifying the causes of anaemia (online supplemental appendix 3—diagnostic and therapeutic algorithm for preoperative anaemia), carefully managing anticoagulant and antiplatelet medications and addressing any coagulation abnormalities or bleeding history.[27–29 33 34]

The intraoperative phase is focused on implementing precise surgical techniques that minimise blood loss. This includes prophylactic administration of tranexamic acid, prudent use of a topical haemostatic, advanced management of extracorporeal circulation and judicious use of cell salvage. It also involves detailed anticoagulation and transfusion protocols guided by VETs, critical for real-time coagulation monitoring, and a theragnostic approach to a patient's coagulation status.[24 27–29] In our current implementation phase, we chose to defer autologous predonation of blood to a later stage of the PBM programme.

In the postoperative period, the focus shifts to meticulously managing coagulation dynamics through the ongoing use of VETs. Strategies are refined for blood transfusion and the treatment of postsurgical anaemia and iron deficiencies (online supplemental appendix 4—diagnostic and therapeutic algorithm for postoperative anaemia), ensuring a targeted and efficient approach to patient recovery.[27–29 31]

Outcomes

Primary outcomes

- Proportion of patients with anaemia on the day of surgery. Preoperative anaemia will be defined as a haemoglobin level <13 g/dL for both men and women.[14 33]

Secondary outcomes

- Proportion of patients transfused with RBCs during the overall length of stay.
- Overall length of stay—the total duration of time a patient spends in a hospital from the day of surgery to the day of discharge to home.

- Variation of haemoglobin between baseline (ie, preoperative anaesthesia evaluation) and hospital admission to surgery.
- Intensive care unit (ICU) length of stay—the total duration of time a patient spends in the ICU from the day of surgery to the day of discharge to the ward.
- Ward length of stay—defined as the total duration of time a patient spends in the ward, from the day of discharge from the ICU to the day of hospital discharge.
- Overall prophylactic tranexamic acid administration.
- Overall transfusion proportion regarding FFP and platelets.
- Variation of haemoglobin between preoperative and hospital discharge.
- Number of RBC units transfused during hospital stay.
- Number of FFP units transfused during hospital stay.
- Number of platelet units transfused during hospital stay.
- Variation of creatinine between preoperative assessment and surgery (from preoperative assessment to hospital admission for surgery).
- Variation of creatinine between preoperative assessment and hospital discharge (from preoperative assessment to hospital discharge).
- Complications[35]: cardiac, respiratory, neurological, renal, infectious, haematological and vascular complications will be analysed as described in online supplemental appendix 5—complications after surgery.
- Proportion of in-hospital death.
- 12-month survival rate
- 12-month readmission rate.
- Cost-effectiveness of patient treatment before and after PBM implementation.

Confounders

The potential confounders, described in online supplemental appendix 6—potential confounders, include patients' baseline characteristics, socioeconomic status, type of surgery, preoperative medications, intraoperative management and variation in transfusion practices.[36]

Sample size

The sample size was calculated considering the use of two-sided tests, an alpha level of 5% and a statistical power of 80%, aiming to compare the intervention and control periods (before-and-after comparison) regarding the primary outcome, with a 1:1 ratio between intervention and control groups. We assumed that the proportion of patients with anaemia in the control group was 35%, based on clinical records of eligible patients in 2018. Additionally, we anticipated a reduction in the proportion of patients with anaemia on the day of surgery to 25% during the intervention period. Therefore, the minimum total sample size required was determined to be 656 eligible patients (a minimum of 328 participants in each study group—preintervention and postintervention). All the secondary objectives listed are considered by the research team as exploratory; therefore, the sample size was calculated to address the primary objective.

Data collection

Study variables were collected retrospectively for the pre-PBM group and prospectively for PBM Group 1, comprising patients with anaemia or iron deficiency who required preoperative optimisation, and PBM Group 2, consisting of patients without anaemia or iron deficiency who benefited from all other PBM strategies (figure 2). This was conducted by trained anaesthesiologists through consultation of electronic health records. A multiple imputation methodology for missing data will be applied if the proportion of missing data exceeds 5% overall or in each variable.

Statistical analysis

In this study, categorical variables are represented using frequencies and percentages, while continuous variables are presented as means along with their corresponding SD. For variables with skewed distributions, medians and IQRs are provided.

Proportions will be compared between before and after PBM implementation using the χ^2 test or Fisher's exact test, along with the calculation of proportion differences and corresponding 95% CIs. Continuous variables will be compared before and after PBM implementation using independent samples T-test or Mann-Whitney Test, along with the calculation of mean differences and the corresponding 95% CI.

Correction for potential confounders will be conducted using multivariable binary logistic regression. The presence of anaemia on hospital admission for surgery will be considered as the outcome and pre-PBM group versus post-PBM group will be considered as the independent variable and as confounders, according to the list described in online supplemental appendix 6.

Additionally, to assess the impact of time and the COVID-19 pandemic on PBM implementation and outcomes, a subgroup analysis within the intervention group will be performed across three distinct time periods: prepandemic (17 January 2019–17 March 2020), pandemic (18 March 2020–30 September 2022) and postpandemic (1 October 2022–31 December 2024).

The Kaplan-Meier method will be used to plot the 12-month survival curves, and the Log-Rank test will be used to compare pre-PBM and post-PBM groups.

All reported p values are two-tailed, and statistical significance is determined at the 0.05 level. All statistical analyses were conducted using SPSS Software V.29.

Patient and public involvement

The research questions, study design and outcome measures were tailored by existing clinical guidelines, institutional priorities and the research team's expertise in PBM, although with no direct involvement of patients. The research team will also meet with relevant patient communities and healthcare stakeholders to share

the results using educational materials. This approach ensures the results are accessible while contributing to patient-centred care practices.

Ethics and dissemination

This research study has been granted ethical approval by the Ethical Health Committee of Vila Nova de Gaia/Espinho Hospital Centre and is registered under approval number 196/2023–1. The study complies with ethical standards to ensure participant data's integrity and confidentiality throughout all research phases. The Standards for Quality Improvement Reporting Excellence 2.0 guidelines were followed to ensure transparent and structured reporting.[37]

The dissemination of findings will be achieved through various platforms, including posters, lectures at national and international conferences and publications in scientific journals. These efforts aim to effectively share the knowledge generated by this study with both the scientific community and the public.

DISCUSSION

Translation of guidelines into practice

This protocol, built collaboratively with healthcare workers from five other Portuguese hospitals and tailored to the unique realities of our hospital, also incorporates contributions from national and international experts. It aims to bridge the gap between PBM guidelines and clinical practice within a tertiary Portuguese hospital. By operationalising evidence-based strategies such as preoperative anaemia management, intraoperative blood conservation and postoperative monitoring, the study seeks to create standardised workflows adapted to local contexts. The interdisciplinary approach involving anaesthesiologists, haematologists and other healthcare workers is designed to foster collaboration, which is central to overcoming anticipated barriers, including resistance to embrace change.

Generating real-world evidence

The study is structured to provide robust evidence of PBM's clinical and economic impact. A longitudinal, before-and-after design will evaluate outcomes such as transfusion rates, anaemia management and cost-effectiveness. By including diverse surgical specialities, the protocol aims to demonstrate the scalability and adaptability of PBM. Additionally, the documentation of challenges and solutions will inform strategies for broader implementation across healthcare systems.

Anticipated limitations

This study's single-centre design may limit generalisability to other settings. However, this limitation is expected to be mitigated as partner hospitals are expected to publish their data, providing a more comprehensive and representative perspective on PBM implementation. Retrospective data collection for the preintervention phase may introduce biases, and differences in data quality between phases could affect comparisons. The exclusion of emergency cases narrows the study's scope, and variability in team adherence to protocols may influence outcomes.

Future directions

The results of this study will contribute to the global evidence base on PBM, providing insights into its feasibility, impact and scalability in real-world settings. By addressing implementation barriers and demonstrating cost-effectiveness, the findings will support the integration of PBM into routine practice, improving patient outcomes and resource utilisation.

Author affiliations
[1]Anesthesiology, Unidade Local de Saude de Vila Nova de Gaia/Espinho, Vila Nova de Gaia, Portugal
[2]Medical Sciences Department, University of Aveiro, Aveiro, Portugal
[3]Hemathology, Unidade Local de Saude de Vila Nova de Gaia/Espinho, Vila Nova de Gaia, Portugal
[4]School of Biothecnology, Oporto Catholic University, Porto, Portugal
[5]Perfusion, Unidade Local de Saude de Vila Nova de Gaia/Espinho, Vila Nova de Gaia, Portugal
[6]Head of Innovation of Instituto do Coração HCFMUSP, Universidade de São Paulo Instituto do Coração, Sao Paulo, São Paulo, Brazil
[7]University of Zurich, Zurich, Switzerland
[8]Head of Planning, Innovation and Population Health Department, Unidade Local de Saúde Gaia/Espinho, Vila Nova de Gaia, Portugal
[9]Aveiro University Associate Professor, University of Aveiro, Aveiro, Portugal

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Contributors Each author contributed significantly to developing and writing the protocol. DCP conceptualised the study design, formulated the research questions and drafted the initial version of the protocol. HC contributed significantly to the design of the anaemia treatment protocol, explicitly focusing on the aetiology of anaemia and haemoglobin optimisation. SJ contributed significantly to the cell saver protocol and the refinement of perfusion techniques for cardiac surgery. GR provided critical revisions to the study design, contributed to the methodological framework and enhanced the literature review section. DRS provided critical revisions to the study design and contributed to the methodological framework. JFM assisted in refining the data collection procedures and statistical analysis plan, reviewed the manuscript for important intellectual content, ensured compliance with ethical standards and supervised the writing process, providing final approval for the version to be published. DCP is the guarantor of this work. AI was used to correct grammar and spelling issues.

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Competing interests None declared.

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ORCID iD

Diana Castro Paupério http://orcid.org/0000-0003-0060-4253

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