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STUDY PROTOCOL

A Theoretically Informed Approach to Support the Implementation of Pre-Operative Anemia and Iron Deficiency Screening, Evaluation, and Management Pathways: Protocol for a Type Two Hybrid-Effectiveness Study

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Introduction: Blood transfusions are a risk factor for increased morbidity, mortality, and length of hospital stay. Patient blood management guidelines provide guidance to reduce risk and improve patient outcomes. They outline steps to help prevent transfusions and considerations for when deciding to transfuse. One recommendation to prevent unnecessary transfusion is to optimize patients using Pre-operative Anemia and Iron Deficiency Screening, Evaluation and Management Pathways (PAIDSEM-P). The uptake of these recommendations is highly variable, and an effective approach to implementing them in a tailored and context-specific manner remains elusive.

Method and Design: A mixed-methods, interventional study, using a type two-hybrid effectiveness-implementation design, will evaluate the impact of a change package to improve the uptake of PAIDSEM-P. The change package consists of the intervention (PAIDSEM-P) supported by theoretically informed implementation strategies. Pre- and post-implementation, retrospective health record reviews will determine the effect of the change package on provider outcomes, including compliance with guideline recommendations as measured by the proportion of patients who have the appropriate tests performed, and, if required, appropriate treatment and/or referrals. Patient outcomes will be measured by checking for any difference in the proportion of patients with anemia on the day of surgery and the proportion of patients who receive a blood transfusion during the peri-operative period. An economic evaluation will be conducted to compare health outcomes and costs. The feasibility, acceptability and appropriateness of the PAIDSEM-P will be assessed using a quantitative, validated survey to measure implementation outcomes.

Discussion: Testing of implementation theory is required to advance understanding of what works, in what context, and the impact on implementation success. This study aims to evaluate the impact of a theoretically informed change package on improving the uptake of PAIDSEM-P. If successful, it will also provide a framework for health care facilities to follow when addressing other evidence-practice gaps.

Keywords: patient blood management, implementation, anemia, iron deficiency, surgery

Introduction

Blood transfusions present an increased risk of mortality, infection and coagulopathy, and should be avoided where possible.[1–3] Patient Blood Management (PBM) guidelines provide support to clinicians when considering treatment options for

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preserving and managing a patient's own blood and guidance when transfusion is a treatment option.[4–7] The guidelines consider three fundamental principles, or "pillars": the maximization of a patient's red cell mass before invasive procedures, the minimization of iatrogenic and coagulopathic blood losses, and that patients are supported to tolerate anemia in the short term rather than automatically resorting to red blood cell transfusion.[8,9] When implemented effectively, the guidelines can significantly improve patient care, health outcomes and reduce costs.[8,10–12]

Pillar one, which focuses on the maximization of a patient's red cell mass recommends that elective surgical patients at risk of losing >500 mL of blood are screened and treated according to Preoperative Anemia and Iron Deficiency Screening, Evaluation and Management Pathways (PAIDSEM-P).[7] Multiple models are used to deliver PAIDSEM-P in Australia and internationally. Some examples include the minimal staffing model (whereby anesthetists take carriage of the screening and treatment),[13] the introduction of staff whose role is specifically to screen and refer anemic or iron deficient patients for treatment,[14] the inclusion of the screening and treatment into the existing preadmission team responsibilities,[15] and finally, creation of a hybrid model where a nurse oversees and manages the preoperative anemia and iron deficiency screening and treatment.[16] The success of these models remains highly variable, and it is unclear how facilities can best support this intervention.

Implementation strategies that support the uptake of PADISEM-P are reported in the literature. However, it is unclear how and why they are selected, and the language describing them is highly variable.[8] Implementation strategies previously used to improve uptake of PAIDSEM-P include local consensus processes, audit and feedback, providing education, and identifying and preparing champions.[17,18] A systematic review found that behavioral implementation strategies reduced blood product utilization, but due to heterogeneity across studies, no specific recommendations as to which are more effective than others could be made.[19] Another review noted that many studies inadequately report the process of implementation.[20] These difficulties are not unique to PAIDSEM-P implementation. Much research has been undertaken to improve evidence translation into clinical practice through the development of theoretical frameworks to support implementation strategy selection.[21,22]

This study uses a theoretically informed change package that consists of an intervention and supporting implementation strategies.[23] The intervention is the implementation of a Preoperative Anemia and Iron Deficiency Screening, Evaluation and Management Pathway (PAIDSEM-P), delivered by a Pre-operative Anemia Care Coordinator (PACC). This intervention will be supported by implementation strategies that were selected in a previously reported study. The study identified barriers using the Consolidated Framework for Implementation Research (CFIR), which were then mapped to the Expert Recommendations for Implementing Change (ERIC) framework.[23–25]

Method and Design

Aim

To test the effectiveness, feasibility, appropriateness, and acceptability of a change package (consisting of the intervention (PAIDSEM-P) supported by theoretically informed implementation strategies).

Design

A mixed-methods, interventional study, using a type two-hybrid effectiveness-implementation design.[26] Type two-hybrid effectiveness designs evaluate both the effect of an intervention and the implementation strategies that support it.[26] They are appropriate when utilizing interventions that have been proven to be effective but require further investigation regarding the context and implementation strategies that best support delivery.[26] A pre- and post-implementation retrospective health record review will be undertaken to determine effectiveness and a validated survey will be used to measure acceptability, appropriateness and feasibility.[27]

Setting: The study will be undertaken in a large, metropolitan, tertiary referral hospital that provides services for public and privately insured patients over a wide range of specialties. For this study, the focus is on public patients only. Approximately 1400 major surgeries (eligible for the PAIDSEM-P) are undertaken annually in this public facility. A Pre-operative Anemia Care Coordinator (PACC) will deliver the intervention, overseen by an implementation facilitator.

Ethics: Ethical approval was granted by the Mater Misericordiae Ltd Human Research Ethics Committee (HREC), and administrative approval from the University of Newcastle HREC (reference: AM/MML/47826) in accordance with the Declaration of Helsinki. The screening tests outlined in the PAIDSEM-P occur in the scope of hospital

policy. Any treatment that arises as a consequence will be provided in the setting of fully informed consent – eg, where intravenous iron is required.[28] A waiver of consent has been granted for the collection of deidentified data to be obtained from retrospective medical chart reviews. All survey participants will be provided with a participant information and consent form prior to entering the survey.

Funding: Funding for this study has been provided by the Mater Research Foundation.

Change Package

The Intervention

The intervention is a Preoperative Anemia and Iron Deficiency Screening, Evaluation and Management Pathway (PAIDSEM-P) delivered by a Pre-operative Anemia Care Coordinator (PACC) (Figure 1). The intervention is described in Table 1 using the Template for Intervention Description and Replication (TIDieR) checklist.[29] The checklist enables standardized reporting of intervention components to enhance replicability.[29] Detailed information about the intervention delivery is outlined in Table 2.

Implementation Strategies

The intervention delivery will be further supported using theoretically informed implementation strategies selected based on results from a previously described qualitative investigation.[23] The summarised results and delivery of the implementation strategies are outlined in Table 2, below:

Outcomes

The impact of this study will be measured at the provider, patient and health service levels.

- Provider outcomes are compliance with the National Blood Authority Patient Blood Management Guidelines[7] which will be measured by the proportion of patients that receive recommended care including the performance of appropriate tests and provision of appropriate treatment and/or referral.

- Patient outcomes include the proportion of patients who are anemic on the day of surgery defined by World Health Organization haemoglobin levels (males <130g/L, females <120g/L);[30–35] and, the proportion of patients who receive a blood transfusion during the peri-operative period.[7,20,36]

- An economic evaluation will be conducted to compare the costs and effects of the program to the health service.

- Implementation outcomes will measure the acceptability, appropriateness and feasibility of the PAIDSEM-P.[27]

Data Collection and Analysis

Retrospective Health Record Review

Using the pilot tested data collection tool in Supplementary File 1, a before and after implementation health record review will be conducted using hospital administrative data to identify a random sample of patients eligible for inclusion. Patients eligible for inclusion must be aged 18 years or older, and have undergone elective, major surgery where there was a risk of blood loss >500mL (see Supplementary File 1 for list of surgeries). Revision surgeries are excluded. Assuming a baseline (pre-implementation) level of compliance of 5% during sample size calculations, 400 patients (200 pre and 200 post implementation) are needed to detect a 20% absolute improvement in compliance (ie, Post-stage compliance of 25%).[31,32] Data will be described using means and standard deviations, for continuous variables, and counts and percentages, for categorical data. Statistical analysis for the patient outcomes (proportion of patients anemic on the day of surgery, and proportion of patients who receive a blood transfusion during the peri-operative period) will involve using binary logistic regression. We will investigate whether there may be other differences in the pre-and post-populations, which will be controlled for using stratified propensity score analysis. General linear modelling will be utilized for the other continuous outcomes and logistic regression methods for categorical outcomes. All analysis will be conducted using the R statistical package, and propensity score analysis will be performed using the R library Matching.

Economic Analysis

A cost-effectiveness analysis will be undertaken from a health payer perspective using data from the retrospective health record reviews. We will also access general hospital administrative data through a formal request to quantify and value health resources consumed including medications, pathology tests, transfusions and other resources required to manage complications. We will also include the cost of delivering the project using this method (costs associated with a project coordinator) using the

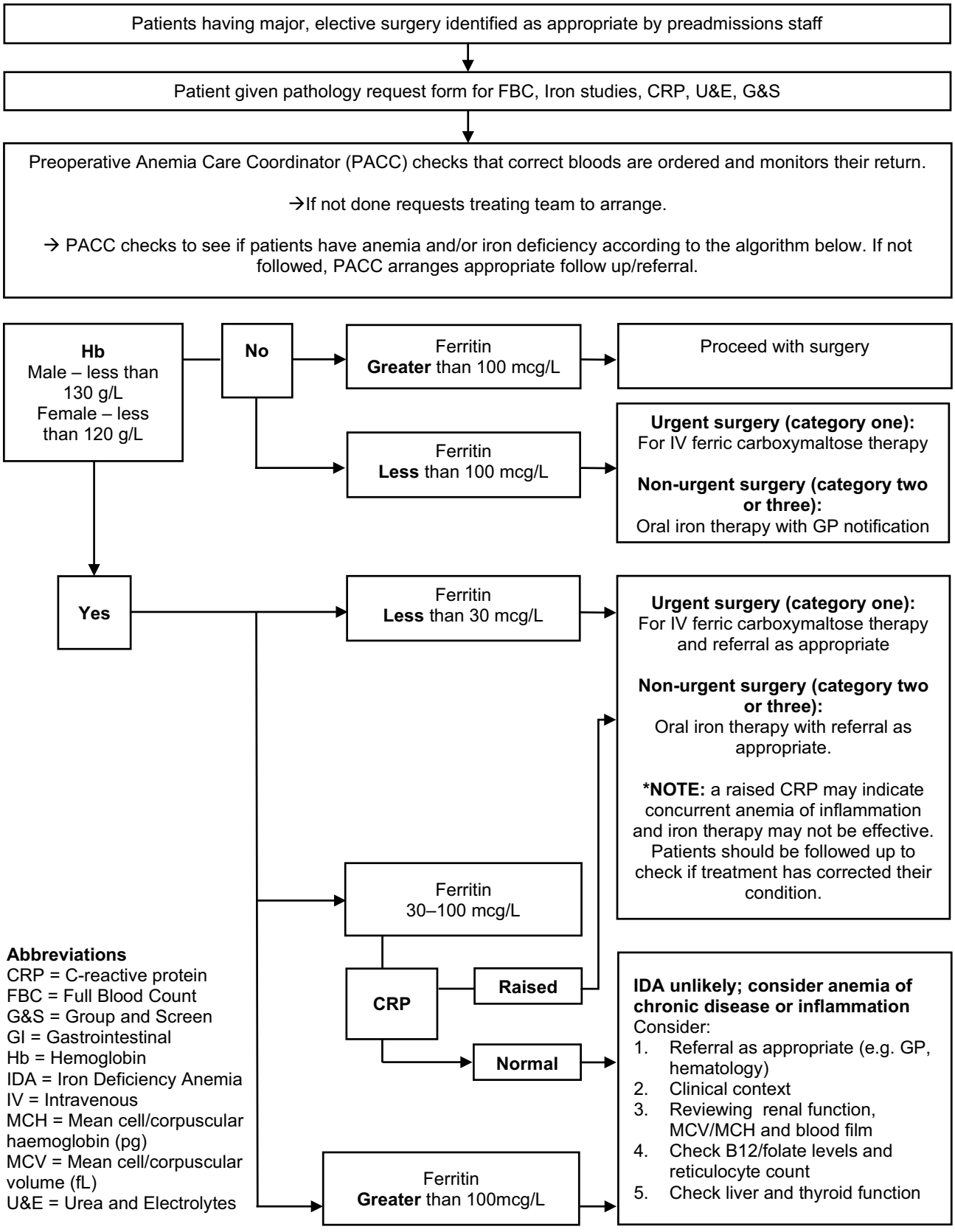

Figure 1 Pre-operative Anemia and Iron Deficiency Screening, Evaluation and Management Pathway (PAIDSEM-P) and Preoperative Anemia Care Coordinator (PACC) steps.

Table 1 Detailed Intervention Description

Template for Intervention Description and Replication (TIDieR) Checklist Item[29]	Explanation
Brief name	Preoperative Anemia and Iron Deficiency Screening, Evaluation and Management Pathway (PAIDSEM-P).
Why - rationale	To ensure haemoglobin and iron levels of surgical patients are optimized prior to surgery according to evidence-based recommendations.
What – materials	All preadmissions staff and surgical teams will be informed of the procedure via a printed and intranet version of the pathway and a list of eligible procedures. The pre-admissions team will be responsible for ordering the relevant tests.
What – procedures	The steps outlined in the PAIDSEM-P (Figure 1).
Who will provide the intervention	A Preoperative Anemia Care Coordinator (PACC) with appropriate knowledge, skills, and training.
How will the intervention be delivered	The PACC will extract a report of all patients who had a preadmission appointment the week prior and filter the results to identify patients having major surgery. They will then check to ensure that the correct blood tests have been ordered and actioned appropriately. If not, they will contact the treating team via email or phone to ensure appropriate referrals are in place. The blood tests will be performed at a pathology collection center. Any treatment required as a result of the tests will be undertaken at a purpose-built infusion center located on the study site.
Where will the intervention be delivered	The intervention is being delivered at a large, tertiary metropolitan hospital that delivers care to approximately 1400 patients eligible for the PAIDSEM-P annually.
When will the intervention be delivered and over what period of time	The intervention is being delivered over an initial trial period of six months, after which time the effectiveness, feasibility, appropriateness, and acceptability will be measured.
Will the intervention be tailored?	There are multiple specialties that see patients having major surgery with varying degrees of urgency of care, and it is expected that the intervention will need to be modified based on the characteristics and processes of individual surgical specialties.
Will modifications be made	If required, the intervention will be modified to enhance the fidelity of the intervention. Any modifications made will be reported.
How will adherence and fidelity be assessed?	Adherence will be monitored by the PACC on a weekly basis and measured through retrospective health record reviews undertaken by an implementation facilitator.
How will changes be made?	Where changes are required, the implementation facilitator will liaise with relevant stakeholders to ensure these are executed.

incremental cost effectiveness ratio, which is the difference in cost divided by the difference in effects with and without the PADISEM-P. A health economist (HT) will oversee the analysis process.

Survey

A range of multidisciplinary, peri-operative team members will be invited to participate in a survey measuring acceptability, appropriateness, and feasibility of the change package. Invitations will be made verbally or through individual email after the study has been running for six months. The online survey will be administered through REDCap[R] and is based on an existing validated tool[27] (see Supplementary File 2), with additional space for qualitative responses. The survey form has been pilot tested for content and face validity by three research team members. All participants will be presented with a participant information sheet and informed that completion of the survey confirms consent. Following agreement to participate reminder emails will be sent at one, two, and four-week intervals unless sufficient responses are received prior. Analysis of categorical data will use a descriptive statistical analysis, including counts and percentages. For qualitative data, a thematic analysis will be conducted using

Table 2 Barriers, Implementation Strategies and Method of Delivery

Barriers	Implementation Strategies	How Will These Be Delivered?
• Access to knowledge and information	• Conduct educational meetings • Develop educational materials • Distribute educational materials	• The implementation facilitator will attend specialty group meetings and undertake educational consultations with members of the treating team. • Education and training will be provided to the preadmissions nursing team to ensure adequate preparation to inform patients of the reason for screening and optimization. • A range of key stakeholders were consulted during the development of educational resources. • Patient information sheets will be distributed as appropriate.
• Patient needs and resources	• Obtain and use patients/consumers family feedback • Involve patients/consumers/family members • Conduct a local needs assessment	• Patients were consulted during the development of educational resources. • Patients will also be provided with education during their preadmission appointment by nurses. • Complete – earlier phases of this research completed the execution of this strategy.[23]
• Knowledge and beliefs about the intervention	• Conduct educational meetings	• The implementation facilitator will ensure all the perioperative medicine team and preoperative admissions team are educated on the intervention during a launch week, and as needed where compliance issues arise.
• Available resources	• Access new funding	• Funding has been obtained for a preoperative anaemia care coordinator to ensure the pathway is being followed.
• Networks and communications	• Promote network weaving • Organize clinician implementation team meetings	• The implementation facilitator will ensure ongoing contact and encourage socialization between groups at appropriate meetings. • A perioperative patient blood management working party was established and met regularly during the pathway's formative stages. They now meet ad-hoc when decisions or consultation are required.

an iterative approach, as described by Braun and Clarke.[37] Free text data will be analyzed and coded with recurring themes. All coded data will be sent to at least two other authors to check for agreement. Where disagreement occurs, it will be resolved by consensus.

Discussion

Consensus among experts that pre-operative anemia should be identified and addressed before elective surgery has been in existence since 2005.[38] Since that time, multiple studies have shown that pre-operative anemia and/or iron deficiency is an independent risk factor for blood transfusion, increased length of stay and increased risk of blood transfusion.[7,39,40] Based on the results of these studies, patient blood management guidelines have been developed that recommend the implementation of PAIDSEM-P.[5,7,41] Despite evidence to support the implementation, there remains high variability in the uptake of PAIDSEM-P.[20] A systematic review previously undertaken by the study authors revealed that there is high variability in the approaches used for the implementation of PAIDSEM-P, which are also poorly described and do not appear to leverage available theoretical frameworks.[20]

Thorough reporting of theoretical frameworks may help improve the uptake of PAIDSEM-P and assist in addressing other evidence-practice gaps. A cluster randomized controlled trial that sought to evaluate the use of the Capability, Opportunity, Motivation, Behavior (COM-B) and the behavior change wheel, on reducing sitting time in the workplace demonstrated a significant result when using this approach (−83.28 min/workday, 95% CI −116.57 to −49.98 (in favor of the intervention group).[41] Studies such as this demonstrate the impact of theoretically informed approaches on achieving change. This

study will be the first (to the author's knowledge) to use an approach informed by the CFIR and ERIC frameworks, and apply a theoretical approach in the context of PAIDSEM-P implementation.

Implications for Practice

If this study is successful, there is potential for replication of the model, which includes barrier identification, strategy mapping and utilization of tailored implementation strategies.[24,42] The package has the potential to assist health facilities with decision-making regarding suitable approaches to embed PAIDSEM-P in addition to other evidence-based problems.

Conclusion

Pre-operative anaemia and iron deficiency screening evaluation and management pathways should be the standard of care adopted in hospitals. Developing context-specific change packages using theoretically informed frameworks to select tailored implementation strategies may help improve uptake. This study aims to evaluate if a theoretically informed change package can help improve the utilization of evidence-based practice.

What this paper adds:

- This protocol outlines a theoretically informed approach to addressing healthcare problems which can be generalized to other implementation challenges.

Disclosure

The authors JD, JH, KM, LG, NG, GA, HT report no conflicts of interest in this work.

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JM attended a meeting with other health care professionals organised by the company 3M.

SF reports personal fees for travel, accommodation and meeting support as member of Working Group and Clinical Reference Group developing National Patient Blood Management Guidelines from National Blood Authority (Australia), personal fees from Ethicon Biosurgery, personal fees from Baxter, honorarium for book chapter from Thieme (Stuttgart), non-financial support from Health Round Table (Australia), and Member of WHO Working Group developing Guidance for PBM Implementation into Health Care (non-renumerated) for World Health Organization, outside the submitted work.

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