Supporting Patient Blood Management (PBM) in the EU

A Practical Implementation Guide for Hospitals

March 2017
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doi:10.2818/533179

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**Expert reviews**

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**Acknowledgements**

The board of the European Society of Anaesthesiology (ESA) has officially endorsed this Practical Implementation Guide for Hospitals to support Patient Blood Management (PBM) in the EU. The authors want to express their gratitude to the ESA board and ESA guidelines committee for all their efforts and time dedicated to this project.

The authors are also grateful to experts from the European Blood Alliance and the EU Member State Competent Authorities for Blood and Blood Components, for their critical reading and constructive comments on this document.
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### Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>ACD</td>
<td>Anaemia of chronic disease</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<td>ALOS</td>
<td>Average length of stay</td>
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<td>AR</td>
<td>Adverse reactions</td>
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<tr>
<td>CKD</td>
<td>Chronic kidney disease</td>
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<tr>
<td>CPOE</td>
<td>Computerised physician order entry</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>ESA</td>
<td>Erythropoiesis-stimulating agent</td>
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<tr>
<td>FFP</td>
<td>Fresh frozen plasma</td>
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<tr>
<td>Hb</td>
<td>Haemoglobin</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B virus</td>
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<tr>
<td>HCV</td>
<td>Hepatitis C virus</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>ICU</td>
<td>Intensive care unit</td>
</tr>
<tr>
<td>ICU-ALOS</td>
<td>Average length of stay in intensive care unit</td>
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<tr>
<td>IDA</td>
<td>Iron-deficiency anaemia</td>
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<tr>
<td>INR</td>
<td>International normal ratio</td>
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<tr>
<td>PACU</td>
<td>Post anaesthesia care unit</td>
</tr>
<tr>
<td>PBM</td>
<td>Patient Blood Management</td>
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<tr>
<td>POC</td>
<td>Point-of-Care</td>
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<tr>
<td>RBC</td>
<td>Red Blood Cells</td>
</tr>
<tr>
<td>TI</td>
<td>Transfusion index</td>
</tr>
<tr>
<td>TR</td>
<td>Transfusion rate</td>
</tr>
<tr>
<td>TRIM</td>
<td>Transfusion related immunomodulation</td>
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<tr>
<td>WA</td>
<td>Western Australia</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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1 Introduction

1.1 Background

For many physicians and clinicians and across many different specialties, blood transfusion is still considered the first line treatment when facing anaemia and/or blood loss. In the European Union (EU), more than 5 million patients are receiving around 24 million units of blood or blood components each year (Annual Summary of the Reporting of Serious Adverse Reactions and Events, 2015, European Commission1). However, a large body of clinical evidence shows that in many clinical scenarios both anaemia and blood loss can be effectively treated with a series of evidence-based measures to better manage and preserve a patient’s own blood, rather than resorting to a donor’s blood, thus leading to a significant overall reduction of blood transfusions.

This is why over the last decade the focus in the EU, and elsewhere, has shifted from ensuring safety and quality of blood and blood components (product focused) towards a broader concept that takes a holistic, multi-disciplinary approach to caring for each patient’s haematopoietic system in a manner that aims to ensure the best possible outcome (patient-focused). This widely accepted approach is referred to as Patient Blood Management (PBM).

According to the WHO, patient blood management (PBM) is a “patient-focused, evidence based and systematic approach for optimising the management of patients and transfusion of blood products to ensure high quality and effective patient care” (1). In 2010 the World Health Assembly Resolution WHA63.12 endorsed PBM specifically referring to the three-pillar concept “bearing in mind that patient blood management means that before surgery every reasonable measure should be taken to optimise the patient’s own blood volume, to minimise the patient’s blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia” (2). The resolution urges WHO Member States to promote PBM where appropriate. It also requests the Director General of the WHO to provide guidance, training and support to Member States on safe and rational use of blood products and to support the introduction of transfusion alternatives and PBM.

In March 2011 the WHO organised the “Global Forum for Blood Safety: Patient Blood Management” in Dubai, stating in its Concept Paper that “Patient blood management (PBM) is designed to improve patient outcomes through the safe and rational use of blood and blood products and by minimizing unnecessary exposure to blood products. Essential elements of patient blood management include: the prevention of conditions that might otherwise result in the need for transfusion (through health promotion and screening for early detection), appropriate diagnosis and optimal treatment, including the use of alternatives to transfusion, good surgical and anaesthetic techniques and blood conservation.” The attendees also sought to assess the current challenges in implementing PBM programmes and to identify mechanisms for improving the impact of PBM programmes (3).

The modern patient blood management (PBM) concept is an evidence-based, multidisciplinary, multi-modal therapeutic approach to individually manage and preserve the patient’s own blood in surgical and non-surgical settings (4–6). Contrary to the traditional product-focused approach of Optimal Blood Use programmes, PBM takes a patient-focused approach. This is achieved by sustainably preventing and
correcting anaemia, preventing blood loss and harnessing and optimising the physiological tolerance of anaemia. Thus, unnecessary transfusions are reduced or avoided and patient safety and outcome are improved.

The high prevalence of untreated pre-operative anaemia, the unmet need for improved bleeding management and a liberal transfusion practice, point towards huge potential to improve outcome and avoid millions of transfusions each year (7). This is driven by ongoing patient safety issues such as new and re-emerging risks from infected donor blood, inventory pressures/product shortage leading to delays in surgeries, and above all, the mounting evidence on adverse outcome due to anaemia, blood loss and transfusion (8-10). The findings from a growing number of large observational studies and randomised controlled trials strongly suggest avoiding each unnecessary transfusion to reduce morbidity and mortality (11-16). Thus, in recent years, a growing number of publications support the benefits and cost-effectiveness of PBM. In addition, these issues are increasingly addressed in postgraduate educational and training programmes (17-29).

In the EU, the change in approach from ‘product focused’ to ‘patient focused’ first led to an EU Public Health funded project entitled EU Optimal Blood Use (30) which explored blood transfusion processes, making recommendations to ensure the safety, clinical effectiveness and efficiency of blood transfusions. A Manual of Optimal Blood Use was developed by transfusion experts from 18 EU countries and is available in 9 languages. Subsequently, several national PBM programmes were developed including Better Blood Transfusion in Scotland (31), PBM by NHS Blood and Transplant (NHSBT) in England (32), initiatives in Italy (33, 34) and in four University hospitals in Germany (35).

In other parts of the World also, an increasing number of leading organisations and transfusion medicine specialists support the PBM concept, including the American Association of Blood Banks (36). Experience in Australia and New Zealand has shown that, although PBM was first developed in elective surgery, the principles can also be applied to emergency surgery, trauma, medical settings and obstetrics (27, 29, 37-43). Furthermore, the effect of PBM on transfusion utilisation is not confined to red blood cells. Its principles can be extended to pre-empt the transfusion of platelets, fresh frozen plasma and other blood products that also carry risk.

In recognition of the important role of PBM in promoting patient safety and improving clinical outcomes, the European Union (EU) Public Health Programme called for tenders in 2013 for a service contract that would support the progress of PBM in the EU. The contract was awarded to a team led by the AIT Austrian Institute of Technology GmbH.

This PBM Implementation Guide for hospitals was delivered to the European Commission under that contract. An equivalent guide for authorities on developing national PBM programmes was also developed under the contract. These guides have no regulatory or legally-binding status but are intended as tools to support hospitals and authorities in EU Member States in establishing PBM as a standard to improve quality and safety of patient care. In order to ensure appropriate and optimal use of blood and blood components (5, 6), transfusion decisions should always adhere to current evidence-based guidelines, and be taken after careful evaluation of a variety of patient-specific and patient-group-specific factors.
1.2 The purpose of this guide

This PBM implementation guide was developed as a supporting tool for hospitals in the implementation of PBM at the operational level. It has taken inspiration from successfully implemented programmes in different parts of the world, recommending a well-recognised model for introducing change. It is acknowledged that alternative change management models could also be applied successfully.

The guide focuses on how to implement the PBM concept in hospitals in a practical way, building on already recognised best practices (44-47). It does not aim to review the clinical evidence for PBM or to provide clinical PBM guidelines. A substantial list of publications that provide the rationale for PBM and that define good clinical practice supporting PBM is included at the end of this document.

This guide is the result of the combined expertise of an international, multidisciplinary team of clinicians and PBM professionals and the collective experience gathered from a 30 month pilot programme for the implementation of PBM in five European teaching hospitals. The final goal is to support PBM as a sustainable standard of care across the EU.

Given the multi-disciplinary and holistic approach required for PBM implementation, the guide is relevant for all medical professionals and organisations involved in caring for patients suffering from anaemia, blood loss and medical conditions that might require transfusion. It should stimulate hospital management to invest greater efforts in the evaluation and treatment of patients with low iron status prior to admission or surgery and should encourage transfusion stakeholders to take a fresh look at their professional fields and discover new opportunities for safely reducing the transfusion rate in their hospitals.

1.3 Utilization of allogeneic blood products in European countries

The utilization of allogeneic blood products in European countries has been analysed and reported in a study conducted as part of the EU-PBM service contract. Overall, a remarkable variability between countries in issuance figures per 1,000 population has been observed. As an example, Figure 1 shows the inter-country variability of RBC units issued per 1,000 population from 2011 and 2012. The median for all countries in 2012 (ES and NO with 2011 data) was 38.8 RBC units issued per 1,000 population with a standard deviation of ±11.9 units. The relative variability of platelet units and fresh frozen plasma units issued lies in the same range.

In many countries (AT, BE, CZ, DK, IE, LU, NL and UK) a continuous reduction in RBC usage can be observed over the past five to ten years. Notably, the Netherlands, although already having the lowest per capita use of all three major allogeneic blood products, still shows a reduction in issuance figures. This may be the result of a successful cultural change towards PBM. According to a survey article published in 2012, the Netherlands has PBM strategies in place, at least for major elective surgery (48); it represents a good example of a country where PBM related measures have been successfully implemented. Ireland has also shown remarkable reductions in terms of RBC issuance resulting from initiatives to improve blood stock management and increased monitoring of usage indicators.
The large inter-country transfusion variability per 1,000 population across Europe may be partly explained by different characteristics of national health care systems. However, numerous studies have also shown that significant national and international inter-centre transfusion variability for standard procedures in matched patients is highly prevalent. This variability has been shown also in other parts of the world (49-53). In addition the percentage of RBC units that are transfused to surgical patients is now much lower than for medical patients and suggest that PBM initiatives should increasingly focus on medical patients and in particular on haematology patients (41, 42).

Overall data collected on utilisation show that the implementation of PBM across Europe has the potential to remarkably reduce the usage of allogeneic blood products (29, 54, 55). Based on the international literature, a targeted and careful administration of blood and blood components can be expected to lead to a significant reduction in the usage of allogeneic blood products, and at the same time significantly improve patient safety and outcomes.
2 Stakeholders, their roles and responsibilities in the implementation of PBM at the hospital level

A stakeholder is "one who is involved in or affected by a course of action" (56), "a person, group or organisation that has interest or concern in an organisation" (57) or "a person with an interest or concern in something, especially a business" (58). Stakeholders can be categorised as key, primary and/or secondary stakeholders:

- **Key stakeholders** are individuals or groups who can significantly influence the course of action. They are also described as key players or champions. They develop or have a high level of power and interest in the course of action.

- **Primary stakeholders** are those ultimately involved in or affected by a course of action.

- **Secondary stakeholders** are individuals or groups that have a role in the decision-making in the course of action without being directly impacted or being impacted to a lesser degree.

In general, active stakeholder involvement can have a positive (supportive) or negative (obstructive) impact. Likewise, passive stakeholders can be affected positively or negatively by the course of action.

In a broader sense, a PBM stakeholder is an individual or group involved or affected by establishing PBM as a new paradigm in the field of medicine. When confined to a regional health system or a hospital, a PBM stakeholder is an individual or group involved or affected by establishing PBM as a new standard of care in this particular health system or hospital. For instance, the newly appointed head of the department of anaesthesiology and intensive care has identified sufficient support from some of his team members to introduce PBM as the new standard of care. As programme champions, they embark on their change management mission, recruiting more clinical staff members. In understanding the need for change and the potential benefits, some orthopaedic or cardio-thoracic surgeons might join as primary stakeholders while others might oppose for various reasons. Whether opposition will be successfully overcome and the new standard will be anchored in the hospital's culture heavily depends on the level of adherence to the change management principles discussed hereafter.

The following section solely relates to stakeholder roles and responsibilities in the implementation of PBM in clinical institutions.

2.1 Key stakeholders in the implementation of PBM at the hospital level

2.1.1 Demanding patients and responding clinicians – key stakeholders of the first blood conservation initiatives

Many of the early Blood Conservation programmes, the predecessors of PBM programmes, were initiated through patients who declined blood transfusions for personal reasons. These patients pro-actively looked for individual physicians offering surgical and/or medical treatment options without the use of allogeneic blood components. Numerous physicians around the world responded favourably to this request and, in some clinical centres, were joined by their colleagues. These small groups began offering their
professional services on a regular basis, thereby establishing the first blood conservation centres (59, 60). Over time, some of these developed further and became large, internationally recognised PBM centres (61–64).

The key stakeholders driving these developments were a specific group of patients with a particular need and individual clinicians that agreed to help them. The approach they developed in the early 1990s is now considered by many professionals to be a standard of care that should be available to all patients facing a medical or surgical intervention with a potentially significant blood loss or being profoundly anaemic (65).

### 2.1.2 Current and future roles of patients, patient organisations and physicians as key PBM stakeholders

In order to make PBM the new standard of care, it is necessary to build on the early successes of the blood conservation programmes outlined above. The key stakeholders to achieve this goal are primarily clinicians, such as department heads, who both have a professional interest to implement this new method of care and sufficient power to do so (see Table 1). The current evidence on anaemia, blood loss and transfusion as independent predictors for adverse outcomes (19, 20, 66–73), the precautionary principle, and the principle of non-maleficence (‘primum non nocere’) are compelling reasons to take action to sustainably implement PBM, and to formally and informally disseminate and support the concept within their other spheres of influence. Their primary role is to lead the practice change within their own clinical departments.

Table 1. Roles and responsibilities of key PBM stakeholders

<table>
<thead>
<tr>
<th>Key PBM stakeholders</th>
<th>Roles and responsibilities</th>
</tr>
</thead>
</table>
| Clinical department heads | • Taking the clinical lead to implement PBM as the hospital’s standard of care  
• Educating peers about PBM  
• Disseminating PBM guidance based on peer-reviewed evidence  
• Recruiting more champions  
• Networking active primary stakeholders  
• Ensuring continuity and sustainability of PBM |
| Patient organisations | • Giving patients a "voice"  
• Publicly formulating the need for PBM to improve patient safety and outcome |
| Transfusion medicine departments/hospital blood bank heads, blood services | • Taking the clinical lead to implement PBM as the hospital’s standard of care  
• Educating peers about PBM  
• Disseminating PBM guidance based on peer-reviewed evidence,  
• Taking the lead in restructuring of hospital blood bank to meet changing transfusion needs  
• Expanding from transfusion consultation to PBM consultation with appropriate training where necessary |
As the evidence for the benefit of PBM and the risk of transfusion are more broadly communicated through secondary PBM stakeholders (e.g. government agencies, media doctors and medical journalists), an increasing number of patients/consumers are likely to seek treatment options without transfusion. Factual (evidence-based) and targeted public communication on transfusion and PBM is required. Once this kind of public information and education reaches critical mass, patients are able to make an informed treatment choice and patient advocacies/organisations can become key stakeholders and push for a rapid clinical implementation of PBM. Patients should be supported and educated in a way that they might be enabled to become key PBM stakeholders. As an example, a fact sheet of the Western Australia Department of Health informs the public about the state’s PBM Programme (74).

### Actions to be taken

PBM fact sheets and patient information should be issued by public health authorities to help patients get educated on PBM. They should encourage patients facing a medical or surgical intervention to ask their general practitioner questions like:

- Am I anaemic or are my iron levels low? If so, how can it be treated before my procedure?
- Are there any medications, herbal or vitamin supplements I should stop taking before my procedure?

When meeting a specialist, patients should be encouraged to ask:

- Is there a possibility of blood transfusion in my planned procedure?
- Besides the risk of infection, are there other complications from transfusion that I should be aware of?
- What options are available to help me to avoid a transfusion in my procedure?
- If a blood transfusion becomes necessary, can you limit the amount of blood you give me?

#### 2.1.3 Transfusion medicine specialists as key stakeholders at a crossroads

Transfusion medicine specialists and/or laboratory physicians are often the heads or chief administrators of hospital blood banks. The implementation of PBM programmes can lead to significant reductions in the hospitals’ blood utilisation. This may have economic consequences for hospital blood banks and regional blood services. Finding themselves at a crossroads, they must either downscale the transfusion medicine department, by adjusting the infrastructure and personnel, or align the department’s activities to new activities/services, for instance within the scope of PBM. Blood centres might also choose to consolidate and merge with other centres within certain geographical areas.

As an example the department of anaesthesiology and intensive care at the General Hospital Linz, one of Austria’s largest public hospitals, initiated a PBM programme in 2005. Over a period of six years clinicians reduced blood utilisation by 60 - 70% (75) (see 4.3.1 page 45).
2.2 Primary PBM Stakeholders

**Actions to be taken**
All primary stakeholders – including patient representatives, physicians, nurses, perfusionists, clinical pharmacists, hospital administrators, IT administrators) should be addressed and actively integrated into the multidisciplinary PBM team as further elaborated in Step 2 – “Form a powerful PBM Group” (see 3.2.2 page 31)

![Figure 2. Primary PBM Stakeholders](image)

2.2.1 Patients

Although most patients do not yet have the awareness to take on a role as key PBM stakeholders, they are clearly primary PBM stakeholders because they are personally affected by PBM as a new standard of care. The most affected patient groups are:

- Bleeding patients
- Anaemic patients
- Iron deficient patients
- Patients at a high risk of major blood loss
- Patients with bleeding disorders

These patients receive the vast majority of RBCs, platelets and FFP. Blood transfusion was the most common procedure performed during hospitalisations in 2011 in the United States; with 2.93 million counts or 94 per 10,000 population (12% of stays with a procedure) (76). Assuming that a similar rate can be applied for the European Union, an estimated 4.8 million acute-care inpatients receive blood
component transfusions. Once educated on why PBM is beneficial for them, a large proportion of patients could become primary PBM stakeholders and pro-actively discuss their PBM options and treatment plan with their general practitioner and clinicians.

2.2.2 Physicians

Physicians are clearly primary PBM stakeholders. They are intimately involved in the course of action because they have to change practice and sometimes behaviour (77). Managing the patient's blood or circulatory system, according to the three-pillar-principle of PBM, requires them to understand and follow peer-reviewed PBM guidelines, and apply related algorithms1. This might also necessitate structural changes and additional workflows, i.e. instituting a pre-operative anaemia clinic, a well-established point-of-care coagulation management, routine use of cell-salvage when indicated, etc.

All physicians at an institution should be aware of the PBM implementation process. Physicians who regularly treat patients at risk of or with major blood loss and/or anaemia (and with empirically high blood product prescriptions) are very important stakeholders. Each has the potential of becoming a PBM champion. Department heads have the means and power to make PBM a new standard of care. Those in senior positions can influence and network in favour of PBM.

The following professions regularly deal with patient populations as described under 2.2.1:

- Anaesthesiologists
- Intensive care specialists
- Transfusion medicine specialists/laboratory physicians
- Surgeons
  - cardio-thoracic
  - orthopaedic
  - vascular
  - visceral/abdominal
  - transplant
  - general
  - trauma/emergency
- Internists
  - Haematologists
  - Gastroenterologists
  - Cardiologists
  - Oncologists
- Obstetricians and gynaecologists

Although not always the case, anaesthesiologists are often responsible for transfusion decisions in the operating theatre and, over a period of ≤ 4hrs, in the post anaesthesia care unit (PACU). In tertiary hospitals, most blood components are transfused in intensive care units [up to 40% of the total units transfused; unpublished data, Western Australia PBM Project]. Therefore, anaesthesiologists and intensive care specialists are primary stakeholders in the implementation of PBM (in some countries,

1 see 5 “Identification of good practices in PBM” in deliverable 2 EU-PBM Project – Study and Survey report
anaesthesiologists are also intensive care specialists). Their departments have a central role in implementing PBM across their entire institution. Often a PBM programme’s champions/key stakeholders are working in these departments. Pre- and peri-operative anaemia management, (systemic) bleeding management, and measures to optimise oxygenation while reducing metabolic demand are usually in the professional domain of these experts. These treatment modalities represent major elements of the three pillars of PBM. Therefore, these two groups of professionals are strong primary PBM stakeholders.

PBM strongly impacts the role of transfusion medicine specialists and/or laboratory physicians in the hospital blood bank (see 2.1.3). In some hospitals they may even represent the key PBM stakeholders. This has the advantage that they can restructure their department in the most controlled way. They can also support PBM by promoting and scrutinising strict adherence to transfusion guidelines and a single-unit transfusion policy. They can further support post- and under-graduate PBM education programmes with emphasis on transfusion risks and outcomes. They can also support basic PBM benchmarking of transfusion rates and indices (often hospital information systems and hospital blood bank information systems are not or only partly interfaced; in the early implementation phase of hospital PBM programmes, the electronic hospital blood bank system is sometimes the only available source for: total transfusion numbers, transfusion per ordering physician, pre-transfusion haemoglobin measures, and other important baseline data to measure and monitor the progress of the PBM programme). With the implementation of PBM the hospital blood bank will most likely encounter significant reductions in pre-transfusion testing (cross matching, antibody search, etc.). This decrease in activity might be partly compensated by regularly measuring other laboratory parameters, i.e. iron status of anaemic patients.

Cardio-thoracic, orthopaedic, vascular, visceral/abdominal, general, transplant and trauma/emergency surgery are often associated with high blood loss and high transfusion variability\(^2\). Surgeons in these fields are primary PBM stakeholders. Many still need education on transfusion no longer being the default position, and that the circulatory system/patient's own blood volume should be treated with the same care and diligence as every other body system. Their course of action change is ultimately affected by putting more emphasis on surgical bleeding control that includes a number of modalities from the second pillar of the PBM concept. They might also have to learn that anaemia in many of their elective patients is a contraindication for surgery.

Gastroenterologists are often dealing with anaemic patients due to chronic bleeding. Cardiologists sometimes encounter unintended bleeding events/haemorrhage in the course of percutaneous coronary interventions (PCI). Haematologists and oncologists are regularly dealing with chemotherapy and cancer induced anaemia; oncology patients are often undergoing major surgeries with potentially high blood loss. The course of action of these specialists is ultimately affected by PBM, urging them to apply the precautionary principle and the principle of non-maleficence - primum non nocere -, and not transfusing their patients by default.

2 \(^{see 2.1.5} “Transfusions by specific operations or procedures” in deliverable 2 EU-PBM Project – Study and Survey report
2.2.3 Other health professionals

Due to their close daily working relationship with physicians who are primary stakeholders in PBM, a number of other health professionals are also ultimately involved in or affected by the course of action.

- Perfusionists
- Intensive care nurses
- Theatre nurses
- Ward nurses
- Transfusion nurses.

Perfusionists are ultimately affected by facilitating/enabling low-prime perfusion to reduce RBC utilisation. Intensive care nurses and theatre nurses are affected by the protocols for minimisation of iatrogenic blood loss (restricted phlebotomy through smaller samples and reduced sampling frequency). They have to closely monitor and quickly report bleeding events, particularly in coagulopathic patients and patients with increased bleeding tendency. They may also need to get used to the concept of transfusion decision points, looking at symptoms rather than numbers (haemoglobin, haematocrit) (78).

Ward nurses might be affected by new and more restrictive blood ordering schedules. Transfusion nurses are affected by the reduction of transfusion rates, but might monitor intravenous iron infusions instead.

2.2.4 Clinical pharmacists

Clinical pharmacists interact directly with physicians to ensure that the medications prescribed contribute to optimal health outcomes (79). The implementation of PBM ultimately impacts on the clinical pharmacist’s portfolio of products, mainly drugs and medications. Purchasing volumes for haematinics, hyperfibrinolytics, and factor concentrates are likely to increase; whereas volumes for RBCs, platelets, FFP and pre-transfusion test assays are likely to drop. As long as all these products are under the same hospital pharmacist’s budget control, the overall impact of PBM is expected to be favourable and change management will easily be supported by the pharmacy.

2.2.5 Hospital administrators: Reallocation of resources to improve effectiveness

Hospital administrators and executives are primary PBM stakeholders because they are ultimately affected by the course of action. They include the:

- Administrative director
- Chief financial officer (CFO)
- Medical director / Clinical governance
- Medical director
- Nursing director
- Risk and Quality Assurance Manager
- IT Manager

Mastering financial challenges and reaching satisfactory quality and safety levels are top priorities for health executives and hospital administrators. From their perspective, the five most important parameters to control are:

- Cost
• Mortality rates
• Complication rates
• Readmissions
• Average length of stay (ALOS)

An increasing number of studies show significant reductions in mortality, complications, readmissions, ALOS and cost with PBM and blood conservation programmes (19, 28, 35, 80-88). Once hospital administrators have understood the positive impact PBM can have on their institutions’ financial results (in addition to improved patient outcomes) – regardless of whether the organisation follows a cost minimisation or a profit maximisation model – they are expected to fully support the change management process (89), and facilitate the following four tasks:

• Providing PBM infrastructure
• Establishing continuous PBM benchmarking and reporting systems
• Instituting PBM related educational programmes
• Proactively offering PBM to medical and surgical patients

Actions to be taken
Based on expected savings of direct and indirect costs from sustainable implementation of PBM the hospital administration should support the PBM guiding coalition with necessary resources.

2.3 Implementation tasks to enable PBM

2.3.1 Providing PBM infrastructure

The PBM infrastructure for a hospital is the basic organisational framework needed to develop and maintain PBM as a standard of care. It includes human resources, equipment and technology, third party services and workspace. This involves decisions and support from all hospital directors and the CFO in their roles as primary stakeholders. It requires establishing a:

• PBM organisation with (77, 86)
  o Formal structure (organisational chart)
  o Duties and responsibilities (job descriptions)
  o Multidisciplinary PBM committee (this could be established by reorganising and extending the role of the existing hospital transfusion committee, along with the haemovigilance committee/contacts if they are separate)
  o Full time equivalents (FTEs) and salaries
• Pre-operative anaemia clinic (75, 90, 91)
• Point-of-care bleeding management system (92-94)
• PBM information system (see 2.3.2 ) (95)
• Computerised physician order entry (CPOE) system for blood components (96-98)
• Microsampling systems (99)
• PBM and transfusion audits (77)
Given the short to mid-term returns on investment, most investments should be made available through reallocation of resources or departmental budgets.

2.3.2 Establishing continuous PBM benchmarking and reporting systems

One of the most important structural PBM measures chief hospital administrators are responsible for is the introduction and implementation of a continuous benchmarking and reporting system. Systematic measurement is essential for improvement (“If you cannot measure it, you cannot improve it”, Lord Kelvin). The multidisciplinary PBM committee (see 2.3.1 above) would use the data generated by such a system on an ongoing and continuous basis. During the implementation period, comprehensive support from the IT department is necessary. Depending on the size of the organisation and the PBM programme, the support needed may reach one or even two FTEs over a 12-month period and coordination with the human resources department may be indicated.

In a fully developed PBM benchmarking and reporting system, transfusion data are routinely linked to data from a variety of other domains like: demographic data, patient outcomes data, departmental performance data and sometimes physicians’ performance data.

Since most of these data are typically subject to data protection regulations, proper pseudo- or anonymisation is required. From the start, governance and legal requirements as well as aspects of data collection and privacy protection measures must be taken into account. These need to be communicated to and documented for all stakeholders of the benchmarking process. This issue usually requires input and clearance from the legal department, the ethics committee/internal review board and, as far as physician performance data are concerned, support from the human resources department.

Actions to be taken
1. Establishing a continuous reporting system for internal benchmarking.
2. Once the internal information system has reached its operational stage, a subset of the data collected for internal benchmarking should be sent to a cross-institutional benchmarking site to assess the performance as compared to peer programmes in other healthcare organisations.

Stage 1: Measuring transfusion rate (TR) and transfusion index (TI) as an inverse function of PBM
Stage 2: Collecting patient-level data on anaemia and its treatment
Stage 3: Collecting patient-level data on calculated perioperative blood loss
Stage 4: Measuring outcome data comparing patients with transfusion and with PBM

(details see below)

Stage 1: Measuring transfusion rate and index as an inverse function of PBM

The key performance indicators (KPIs) are:

- **Transfusion rate (TR):** the percentage of transfused patients with a defined patient cohort of patients
Transfusion index (TI): the mean number of units per transfused patient within a defined cohort of patients

Figure 3. A fictitious example of a dynamic bubble diagram with transfusion rates (TR), transfusion indices (TI) and number of patients in observed cohort. Bubble size represents the number of cases (100, 101).

The literature suggests using bubble diagrams with the relative bubble sizes representing the number of procedure-specific inpatient admissions or patients of a pre-defined cohort; the position of the bubble representing the transfusion rate (TR) on the x-axis and the mean transfusion index (TI) on the y-axis. The different colours help to identify the developmental path over time. The graph can be used per:

- Surgeon
- Prescribing clinician
- Department
- Hospital/hospital system
- State

These KPIs can be monitored for RBCs, platelets, FFP and also for cryoprecipitate (where in use). The reduction of TR and TI can be used as inverse PBM performance indicators.

Stage 2: Collecting patient-level data on anaemia and its treatment

It is also recommended to monitor the incidence and treatment of anaemia prior to surgery, particularly in patients undergoing high risk procedures. Even mild anaemia is an independent predictor of adverse
outcomes (102-106) that should be corrected by treatment modalities of the 1st pillar of PBM. Thus, it is necessary to collect (anonymised) patient-level data on:

- Haemoglobin concentration at the patient’s first visit of the pre-op anaemia clinic
- Pre-operative haemoglobin concentration (after anaemia correction)
- Post-operative haemoglobin concentration, preferably between post-op days 3, 4 or 5 (107, 108)

In transfused patients, it is important to capture data on:

- Pre-transfusion haemoglobin concentration
- Post-transfusion haemoglobin concentration

When linked with stage 1 data, over-transfusion and non-compliance with single-unit transfusion policies of clinicians, departments etc. may become apparent. Analogous to this, platelet counts pre- and post-platelet transfusions, and international normal ratios (INR) pre- and post-FFP transfusions should be collected.

In benchmarking these performance indicators, the risk of under-transfusion, as with all risks associated with the implementation of a significant change in practice, should not be ignored and should be monitored. It is acknowledged, however, that the risk of undertransfusion is reportedly significantly less than the risk of overtransfusion (109-119).

Stage 3: Collecting patient-level data on calculated perioperative blood loss

Monitoring the incidence and volume of perioperative blood loss, particularly in procedures with empirically devised high blood volume losses is also recommended. Blood loss is another independent predictor for adverse outcomes (120-126) and should be corrected by treatment modalities of the 2nd PBM pillar. Using the Mercuriali-algorithm (107), perioperative blood loss can be calculated using the following variables:

- Pre-operative circulatory volume derived from body weight and height (127)
- Pre-operative haemoglobin concentration, and
- Post-operative haemoglobin concentration

In transfused patients the result can be corrected for units transfused (from linking with stage 1 data) and in cell-salvaged patients it can be corrected for salvaged volumes. Change of mean calculated blood loss in specific surgical populations over time is an important quality indicator for PBM.

Stage 4: Measuring outcome data comparing patients with transfusion and with PBM

In the final stage of implementing PBM benchmarking and reporting systems, all available data on blood utilisation, anaemia and calculated blood loss should be linked with patient outcome data. Capturing the following outcome parameters is recommended:

- Hospital mortality
- 30-day mortality
- 90-day mortality
• 5-year mortality
• Infection rate
• Pulmonary complication rate
• Hospital acquired anaemia rate
• Readmission rate
• Reoperations
• Composite morbidity
• ALOS
• ICU-ALOS
• Cost

Standardised electronic reporting, regular reviewing and internal auditing of transfusion and PBM benchmark results, helps the key and primary stakeholders to direct the change management process effectively. Such standardised information systems must of course comply with all legal requirements (e.g. data protection). The following points should be clearly defined:

• Who the different recipients are (key PBM stakeholders/champions and on aggregated levels, representatives of clinical departments, hospitals, etc.)
• What the information contents and formats are for each group of recipients
• What the reporting cycles are (for instance monthly or quarterly)
• What the cycles for internal auditing are (e.g. departmental auditing might sometimes be necessary on an ad-hoc basis, otherwise one audit per year might be sufficient).

2.3.3 Supporting PBM related education programmes

Multiple ongoing education strategies are pivotal to bring about practice change and sustained realignment of the hospital’s culture. The knowledge base on the impact of anaemia, blood loss and bleeding, transfusion, and PBM is comprehensive and rapidly growing. This is well reflected by the tens of thousands of related PubMed listed articles. It is challenging for PBM stakeholders to keep up with the abundant flow of new information, and to select what might be clinically relevant and important to support the PBM change management process. Therefore, hospital administrators and executives should support continuous educational programmes and initiatives with a PBM focus. These might include:

• Multidisciplinary PBM post- and under-graduate training courses and education/curricula (77).
• Workshops on specific PBM topics (e.g. how to manage different forms of anaemia in pre-operative clinics, point-of-care coagulation management, surgical bleeding management and others)
• Enrolment in PBM e-learning systems (128)
• Development of lectures for nursing schools
• Regularly organising lectures with national and international PBM key opinion leaders

Well-coordinated PBM programmes have education programmes for all stakeholders within the hospital, including physicians, nurses, transfusion medicine specialists, pharmacists, medical controllers, hospital administrators and other non-clinical staff. Some hospitals expand their educational activities even further by annually inviting patients and their families to learn about PBM programmes and the patient benefits.
2.3.4 Proactively offering PBM training to medical and surgical patients

Hospitals should communicate their PBM programmes. Hospital administrators and executives should involve the institution’s public relations or communications department to develop a communication strategy with a focus on the patient centeredness and the outcomes of PBM.

Actions to be taken
Communication of the PBM programme requires appropriate media channels such as:
- Hospital websites
- Annual report of the hospital with a PBM section
- Press releases
- Downloadable and/or printed materials
- Posters
- Patient information brochures
- PBM newsletters
3 How to implement PBM as a new standard of care

3.1 Introduction
Change in organisations can be of utmost importance, but a high percentage of change projects fail. Various change management models have been developed. Some of them are more general, while others are customised for specific types of organisations including the clinical sector (29, 47, 129-139). John Kotter’s eight-step model (140) integrates important elements that are common in change management processes and has been successfully applied to implement the PBM concept at the Western Australia Patient Blood Management Program [2]. Overall, the Kotter model serves as a framework rather than a step-by-step action plan. Kotter’s organisational change principles are also incorporated in the IHI improvement model (141), which may be used to take the implementation further into everyday practice within the hospital department by establishing local improvement teams, larger hospital networks, and using the plan-do-study-act (PDSA) cycle of quality improvement and local data. The eight-step model serves as a template for the implementation of PBM in this EU-PBM guide. The model is based on the avoidance of eight common errors, which usually account for failure of change efforts. Each error has a specific solution, and together these represent the eight-step change model.

These eight errors are (130):
1) allowing too much complacency,
2) failing to create a sufficiently powerful guiding coalition,
3) underestimating the power of vision,
4) under-communicating the vision,
5) permitting obstacles to block the new vision,
6) failing to create short-term wins,
7) declaring victory too soon, and
8) neglecting to anchor changes firmly in the corporate culture.

In this implementation guide, Kotter’s eight steps have been adapted to the implementation of the PBM concept with the ultimate goal to alter physicians’ behaviour and to improve transfusion culture in the medical setting (Figure 4). This overarching concept determines all the clinical and organisational measures to be taken by and adapted to the particular institution. Since this is a step-by-step strategy, skipping or not completing one step leads to a halt or even regression of the process. On the other hand, moving too quickly to the further steps involves the risk of failure.
3.2 Managing change from the default transfusion position to PBM

3.2.1 Step 1 - Create urgency for PBM

1) Help others see the need for change and they will be convinced of the importance of acting immediately (J. Kotter).

A failure to develop a sense of urgency leads, almost with certainty, to a failure of the entire change management process. Kotter suggests for a change to be successful that about 75% of the people involved need to “buy into” that change. “Buy in” from frontline staff is especially essential (142). Therefore, devoting a significant amount of time and energy to the first step is an absolute must. The PBM concept, which must be modelled and adapted in accordance with institutional needs by the respective institutional leaders, has to be communicated to all stakeholders concerned. This includes, but is not limited to, nurses, physicians, patient advocates and hospital managers. Tailored to the different needs of the audiences, communication has to be simple, repetitive and bi-directional (from leaders to team members and back).

Striking PBM arguments that may be put forward are: harming patients due to the prevalence of untreated preoperative anaemia (108, 143-147), a lack of attention to proactive bleeding management (148), the often behaviour-based blood ordering schedules (149-152), and the frequent to high
transfusion rates of individual institutions (obtained by benchmarking or comparison to recent literature) (108).

According to the three pillar PBM concept, a minimal set of parameters (Table 2) should be assessed on individual case levels, ideally by directly linking the main data sources (transfusion database, hospital information system, patient data management system) in order to capture and evaluate intra-institutional baseline data such as anaemia prevalence, surgical blood loss, transfusion rate and index. Whenever possible, baseline data should also be compared inter-institutionally. This could help to identify differences in practice and knowledge. This would further lay the foundations for a regular (e.g. monthly) reporting process.

**Table 2. Recommended transfusion parameters for internal assessment**

<table>
<thead>
<tr>
<th>Parameters to be included in the monthly generated internal PBM report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of blood and blood components issued</td>
</tr>
<tr>
<td>- Red blood cells (RBC)</td>
</tr>
<tr>
<td>- Fresh frozen plasma (FFP)</td>
</tr>
<tr>
<td>- Factor concentrates</td>
</tr>
<tr>
<td>- Platelets</td>
</tr>
<tr>
<td>- Cryoprecipitate</td>
</tr>
<tr>
<td>Blood and blood component data per patient (patient level and mean values per indication)</td>
</tr>
<tr>
<td>- Number of units ordered</td>
</tr>
<tr>
<td>- Number of units transfused</td>
</tr>
<tr>
<td>Transfusion indicators (patient level and mean values per indication)</td>
</tr>
<tr>
<td>- Anaemia prevalence at hospital admission</td>
</tr>
<tr>
<td>- Pre- and postoperative haemoglobin.</td>
</tr>
<tr>
<td>- Pretransfusion haemoglobin.</td>
</tr>
<tr>
<td>- Perioperative blood loss calculated using the Mercuriali algorithm [161, 378]</td>
</tr>
<tr>
<td>- Bleeding assessment - actively bleeding (yes/no).</td>
</tr>
<tr>
<td>Parameters to be included in the monthly generated internal PBM report</td>
</tr>
<tr>
<td>- Transfusion rate for blood and blood components</td>
</tr>
<tr>
<td>- Transfusion index for RBC and FFP</td>
</tr>
<tr>
<td>- Total transfusion index for RBC and FFP</td>
</tr>
<tr>
<td>- Number of components transfused per transfusion episode to monitor single-unit transfusion policies</td>
</tr>
<tr>
<td>- Responsible person for transfusion.</td>
</tr>
</tbody>
</table>

Additional classical drivers for an urgent change are: increasing transfusion related costs, newly and re-emerging pathogens in the blood pool, remaining disease transmission, increased morbidity and mortality and limited efficacy often associated with transfusion and the objective to reduce risk for potential blood donors (69). Inversely, the definition of expected results and their positive impact on patient outcome underlines the urgent need to implement a PBM concept. Table 3 shows a list of recommended minimal data set for follow-up of patients.
Table 3. Recommended mid- to long-term follow-up of outcome data from all patients (transfused and non-transfused)

<table>
<thead>
<tr>
<th>Length of stay</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>in hospital</td>
<td></td>
</tr>
<tr>
<td>in intensive care unit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rate of complications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmission rate</td>
<td></td>
</tr>
<tr>
<td>Reoperation rate</td>
<td></td>
</tr>
<tr>
<td>Infection rate</td>
<td></td>
</tr>
<tr>
<td>Others like Transfusion-related acute lung injury (TRALI), acute respiratory distress syndrome (ARDS), etc.</td>
<td></td>
</tr>
<tr>
<td>Postoperative iron deficiency rate</td>
<td></td>
</tr>
<tr>
<td>Anaemia rate at discharge</td>
<td></td>
</tr>
<tr>
<td>Anaemia rate at out-patient follow-up</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mortality rate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>in hospital</td>
<td></td>
</tr>
<tr>
<td>30 days / 90 days / 1-year / 5-year</td>
<td></td>
</tr>
</tbody>
</table>

Additional financing might be required at least at the initiation of the PBM programme. However, the full implementation of PBM substantially reduces hospital treatment costs (19, 153, 154). The following data should be considered for cost effectiveness reasoning:

- Product costs of transfused blood and blood components
- Product costs of discarded and expired blood and blood components
- Product costs for PBM treatment modalities (e.g. erythropoietin, iron)
- Costs for lab tests and diagnostic processes
- Costs of logistics and delivery process

Cost impacts should be calculated following well established methodologies such as those recommended by the National Institute for Clinical Excellence in the UK (Methods guide assessing cost impact) (155).

Introducing an informed consent process for anaemia management including PBM related questions into the pre-operative checklist for surgeons and anaesthesiologists, and PBM curricula for post- and undergraduates also help to create a sense of urgency.
Key points – Step 1

- Communication of the PBM programme through appropriate media channels such as:
- Implementing PBM requires management, but above all, leadership is a key requirement.
- Devoting a significant amount of energy and time to create a sense of urgency is a must.
- Communicating the arguments for the PBM concept and its beneficial effects on patient safety and outcome to all stakeholders - from leadership to frontline staff is critical.
- An immediate sense of urgency should be established by pointing out the main problem (1-3 problems), which are obvious and easy to understand for all major stakeholders. This overall headline message should be strong, clear and short (30 seconds to explain). Beyond this, a differential communication plan is necessary.
- Initially, additional financing might be necessary. However, the full implementation of PBM substantially reduces hospital treatment costs.
- Moving onto the further steps too fast involves the risk of failure.

Table 4. Checklist for step 1: Create urgency for PBM

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Main arguments for the implementation of PBM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Communication strategy including strong arguments (e.g. lower mortality,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>lower complication rate, shorter length of stay etc. as shown in relevant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>publications)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Compelling and logical arguments tailored to the audience and the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>department’s specific needs (“heart &amp; brain arguments”).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Communicating current evidence</td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Specially tailored educational information to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- clinical directors and co-workers in surgery, nursing and finance...</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- hospital managers (and health care providers)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- primary care physicians</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- patients and patient advocates</td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Capture and evaluate intra-institutional PBM related baseline data such as</td>
<td></td>
</tr>
<tr>
<td></td>
<td>prevalence of anaemia, blood loss, transfusion trigger, transfusion rate and index</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Report results to departmental teams and key stakeholders.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Communicate PBM as “gold standard”</td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Compare inter-institutional baseline data such as anaemia prevalence, blood loss,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>transfusion threshold, transfusion rate and index</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Report (anonymised) results to departmental teams and key stakeholders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Evaluate differences and try to identify practice and knowledge gaps.</td>
<td></td>
</tr>
</tbody>
</table>
1.5 Informed patient consent for anaemia treatment \(^3\) (39)

1.6 Adding relevant PBM questions to the preoperative checklists (SOP) of the surgeons and anaesthesiologists

1.7 Developing and introducing mandatory post- and undergraduate PBM curricula

(*) +++ strong, ++ moderate, + weak, - none

### 3.2.2 Step 2 - Form a powerful PBM group as guiding coalition

2) Assemble a group with enough power to lead the change effort, and encourage the group to work as a team (J. Kotter).

A clinical reference group acting as a **guiding coalition**, hereafter called the **PBM group**, with commitment and a heavy influence that is able to work as a team **outside** the hierarchy has to be established (the PBM group requires many more members than the PBM committee, however some members of the group might later on also serve in the PBM committee). Support from the hospital managers and directors is also essential for successful teamwork. Above all, simply managing the change is not enough. Teamwork and leadership are preconditions for success. To lead the change, a coalition of influential people whose power is derived from a variety of sources including job title, expertise, reputation and political importance, has to be formed (156, 157). In order to secure inclusion of all relevant specialties and professions, and reduce built-in resistance from major stakeholders, the PBM group should include several clinical specialties where patients are at risk, organisational quality managers, and transfusion medicine specialists, if available, from the in-hospital blood centre. Also, managerial representation should be present (hospital directors, or managers with direct connections to the hospital directors). Such leaders can be found throughout their hospital. A PBM group without strong leadership will not have the power required to overcome inertia and resistance against PBM implementation.

The leaders should communicate the special PBM aspects regarding expected results (157), modify their language ("building up" and "breaking down"(158)), support improvisation (159), sell solutions for encompassing change, and engage co-workers through purpose and challenge (160).

As PBM is a multidisciplinary and multi-professional concept, leaders and team members have to be recruited from different departments, professional groups and hierarchical levels. For example, implementation of perioperative PBM without support from leading nurses and surgeons can barely be successful. The impact of multidisciplinary teams is often limited by suboptimal intra-team communication. Perception of the current PBM team climate and teamwork may reveal room for improvement (161, 162). Perioperative PBM scenarios can be managed by a team of PBM trained

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\(^3\) "If patients suffer from anaemia, they shall be informed that their surgery related risks can be reduced by treating their anaemia first. Surgery related risks might be an increased transfusion rate, infection risk and anaemic infarct rate and therefore a longer hospital stay. For all elective surgeries a previous anaemia clarification and treatment is highly recommended" (Informed consent, General Hospital Linz, 2016).
anaesthesiologists, surgeons and, if necessary, by intensive care specialists. Other scenarios will benefit from support from haematologists, gastroenterologists, radiologists or specialists from trauma surgery, oncology or diagnostic labs. Also, transfusion medicine specialists may play an important role, particularly if there is a hospital based blood centre, especially since some PBM programmes have been initiated by transfusion specialists. In others, nurses play a key role in establishing and maintaining the PBM project (163, 164).

Once formed, the PBM group should continue to build a sense of urgency within their environment (step 1) and generate their own momentum for change. Potential weaknesses of the PBM coalition should be identified and corrected as soon as possible. All relevant data about utilisation of blood and blood components should be accessible to the PBM team; technical support from the IT-department for professional data management is necessary.

The PBM group should be founded by, merged with or as a minimum supported by the hospitals’ transfusion committee.

**Key points – Step 2**

- Teamwork and leadership are essential for successful and sustainable change management.
- The PBM group should be constituted as a multi-professional and multidisciplinary team.
- The PBM members need to be committed and have enough power and sense of responsibility to lead the change.
- The PBM group should continue to build a sense of urgency and generate the momentum needed for change.
- The PBM group should eventually be merged with the hospitals’ transfusion committee.

**Table 5. Checklist for step 2: Form a powerful PBM group as guiding coalition**

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Main disciplines included (anaesthesia, surgery, transfusion medicine, laboratory, haematology, gastroenterology, pharmacology, quality management)</td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Sufficient number of professionals included (physicians, nurses, perfusionists, hospital management, networkers, quality managers)</td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Leading professionals (key leaders), officially assigned by the hospital providers, included</td>
<td></td>
</tr>
<tr>
<td>2.4</td>
<td>Support from hospital management (including budget for PBM)</td>
<td></td>
</tr>
<tr>
<td>2.5</td>
<td>Support from clinical directors</td>
<td></td>
</tr>
<tr>
<td>2.6</td>
<td>Support from patient advocacy</td>
<td></td>
</tr>
<tr>
<td>2.7</td>
<td>Support from IT-department for data management</td>
<td></td>
</tr>
</tbody>
</table>
2.8 Use of tools to facilitate the team
2.9 Emphasis on networking and cross communication within the hospital teams

(*) +++ strong, ++ moderate, + weak, - none

3.2.3 Step 3 - Create a vision for PBM

3) Create a vision to help direct the change effort, and develop strategies for achieving that vision (J. Kotter).

Vision (mission statement) plays a key role in producing the necessary change. The vision should emphasise the importance of PBM implementation and should motivate team members through empathy, envisioning and empowerment. Without vision-guided decision-making, the implementation effort can easily dissolve into a number of confusing and incompatible projects, which are time consuming and may go in the wrong direction or nowhere at all.

Without a clear direction in mind, a suggestion for change has no context. Mission statements should create a link between the vision and the more specific recommendations. To be more precise, the vision of PBM implementation should be the result of group discussions based on recent literature and the current hospital circumstances. The obligatory use of scientific evidence represents a continuous basis to continuously evolve PBM. All proposed ideas and solutions should be linked to an overall vision that is easy to understand and remember (158). Eventually, the entire PBM staff should be able to describe this vision within five minutes or less.

The vision of PBM implementation is: improved patient safety and optimal clinical outcome can be achieved when the optimisation and preservation of a patient’s own blood takes priority over the transfusion of donor blood.

Exemplary vision statements in favour of PBM:

- “We prevent and treat anaemia to improve outcome and safe lives!”
- “PBM is the gold standard to improve patient safety and outcome”

In addition, strategies to execute the vision should be defined and include timelines as well as milestones. These strategies should closely follow the PBM concept and should be based on the personnel and medical resources of the institution.

Key points - Step 3

- PBM implementation should follow a vision that is clear, easy to understand, communicate and remember.
- The vision should serve as an umbrella for the different PBM modalities.
- Principles to create a vision
  - encompass all staff members and all patients
- be positive
- do not provoke fear

- Vision plays a key role in producing useful change and may inspire large numbers of people.
- PBM vision should be executed in a way that is based on the current scientific evidence and the current and future resources of the hospital and of the regional health care system.

**Table 6. Checklist for step 3: Create a vision for PBM**

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Vision of the PBM Group formulated and consented</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Vision in line with the current evidence and the available resources of the hospital</td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>Vision supported by relevant stakeholders</td>
<td></td>
</tr>
<tr>
<td>3.4</td>
<td>Strategies for executing the PBM (vision) developed</td>
<td></td>
</tr>
<tr>
<td>3.5</td>
<td>Each strategy should have milestones defined and be executed within a given time frame (road map and timelines)</td>
<td></td>
</tr>
<tr>
<td>3.6</td>
<td>Strategies should include a stakeholder mapping for the environment (level of interest/power level)</td>
<td></td>
</tr>
</tbody>
</table>

(*) +++ strong, ++ moderate, + weak, - none

### 3.2.4 Step 4 - Communicating the PBM vision

Implementing PBM requires that all people involved are willing to co-operate. Once people see the potential benefits of the PBM concept and believe that expected results are really possible they will support it (157). For that reason the PBM leading group and hospital directors should use continuous and multi-channel communication to capture the team’s hearts and minds. Each opportunity for communication should be used. However, communication must be tailored to the special needs of the team members and come in both words and actions. “The talk has to be walked”, i.e. what is done is more important than what is said. Behaviour inconsistent with verbal communication undermines change efforts significantly. Also, all stakeholders’ concerns and anxieties must be addressed and discussed.

Expected strategies, results and how their performance is measured should be communicated. For example, if a baseline evaluation shows a significantly higher perioperative blood loss compared to other institutions, the goal to reduce perioperative blood loss by PBM must be unmistakeably formulated. Also, evidence-based modalities of how to achieve it, like with the use of antifibrinolytics (165-170), minimal invasive surgery (171, 172) etc., must be clearly communicated to the target audience.
As a result of this "communication campaign" each member of the departments involved should be motivated by the benefits of PBM implementation, thus leading to a positive attitude towards this concept. Measures of intervention should be deliberately chosen to reach maximum effectiveness and sustainability (see Appendix 1 – Methods of intervention).

Key points – Step 4
- Lead by example.
- Talk often and credibly about the vision of PBM implementation.
- Use every occasion to launch reminders, such as portal, screen saver, tweets, social media, and posters.
- Communicate PBM within different channels.
- Address key members’ concerns and anxieties openly and honestly.
- Announce well-defined goals and monitor their accomplishment.
- Anchor PBM to the education programme.
- Include health authorities.

Table 7. Checklist for step 4: Communicate the PBM vision

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Meetings, lectures and workshops are held</td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>PBM is communicated through the hospitals’ homepage, intranet and other suitable channels</td>
<td></td>
</tr>
<tr>
<td>4.3</td>
<td>Guidelines, literature and other information material are provided in print and electronically (apps etc.)</td>
<td></td>
</tr>
<tr>
<td>4.4</td>
<td>Target audiences are familiar with PBM concept</td>
<td></td>
</tr>
<tr>
<td>4.5</td>
<td>Lead by example (with sufficient number of leaders)</td>
<td></td>
</tr>
</tbody>
</table>

(*) +++ strong, ++ moderate, + weak, - none

3.2.5 Step 5 - Empower the PBM group and remove obstacles

5) Remove obstacles to change, change systems or structures that seriously undermine the vision, and encourage risk-taking and non-traditional ideas, activities, and actions (J. Kotter).

The driving forces behind the project need to be strengthened while the resisting forces need to be weakened. The team leaders should have their jobs and responsibilities clearly defined. Also, they should have the competence and resources necessary to make the expected changes possible. As a consequence,
to empower the team, signal involvement including support of change and deployment of resources by (senior) leaders is recommended (157). Innovation, risk-taking, and improvisation should be encouraged, since they provide new ways for enabling the change, especially when resources (time, material, staffing) are limited. Benchmarking comparing not only institutions but also physicians may highlight specific problems and provide solutions.

In many cases the obstacles may be very real and change cannot happen without addressing barriers, since one well-placed blocker can stop the entire change effort. Therefore, time and strategies to remove obstacles are necessary. Do not waste time (“death by delay”) In the first place, obstacles have to be identified continuously and be quickly bypassed or removed to get the organisation in line with the PBM concept. Barriers are mostly intertwined and may be structural, cultural and psychological. According to Kotter, “occasionally, the roadblocks are only in people’s heads and the challenge is to convince them that no external barriers exist” (4). For example, long-standing traditional transfusion habits, which have seldom been evaluated, are still frequently discussed. Whereas, the quick and positive results yielded by PBM with regard to the degree of anaemia and transfusion are rarely discussed. To couple information and clinical experience is a powerful way to get the attention of busy physicians (“see, feel, change” approach) (131). Implementing and continuously using electronic intra- and inter-institutional benchmarking and reporting systems between physicians and between departments are strongly recommended (“data is power”). A mentoring programme could also be helpful. It is advisable to concentrate on the supporters and not waste too much time with those who are resistant to change (“don’t waste time and energy!”) (173).

Organisational obstacles, amongst others, are lack of resources and interdisciplinary communication, absence of incentives, and insufficient periods between referral to the anaesthesia department for preoperative assessment and the operation date. If structural barriers relate to functions that impact behaviour, trying to influence behaviour won’t work unless the structure is changed. For example, a functioning preoperative clinic needs sufficient staff and work space.

**Key points - Step 5**
- Define clear roles and responsibilities for leaders.
- Encourage innovation and improvisation.
- Encourage leadership power and competence.
- Recognise and reward people for making change happen (incentives).
- Identify and quickly remove or bypass obstacles (human or otherwise).
- Concentrate on supporters and do not waste too much time and energy with “no nos” (174).

---

Table 8. Checklist for step 5: Empower the PBM group and remove obstacles

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Identify behavioural and organisational obstacles (human or otherwise)</td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>Implement electronic benchmarking and reporting systems to continuously measure transfusion and patient level outcome data. Have a first version of the database including minimal dataset ready as early as possible</td>
<td></td>
</tr>
<tr>
<td>5.3</td>
<td>Establish ongoing PBM training for all relevant staff</td>
<td></td>
</tr>
<tr>
<td>5.4</td>
<td>Duties and responsibilities of leaders clearly defined</td>
<td></td>
</tr>
<tr>
<td>5.5</td>
<td>Personnel and technical support recruited</td>
<td></td>
</tr>
<tr>
<td>5.6</td>
<td>Team members incentivised (e.g. publications)</td>
<td></td>
</tr>
<tr>
<td>5.7</td>
<td>Official empowerment from hospital administration / management obtained</td>
<td></td>
</tr>
</tbody>
</table>

(*) +++ strong, ++ moderate, + weak, − none

3.2.6 Step 6 - Create short-term wins of PBM

6) Plan for achievements that can easily be made visible, follow-through with those achievements and recognise and reward employees who were involved (J. Kotter).

Nothing motivates more than success. However, real change takes time and complex projects, like PBM implementation, are at risk of losing momentum if there are no short-term goals to meet and celebrate. Generating short-term wins increases the chance that PBM implementation will not only be continued, but also completed by the staff (130, 174). Short-term wins mean short-term targets (“low hanging fruits”), which should be implemented within a reasonable time frame (three to 12 months depending on the type of modality). Short-term modalities are effective when they are inexpensive, easy to understand, and visible to many with little room for failure. They should be part of the PBM concept and be implemented without the help from any critics of PBM and results should be unambiguous. It is advisable to start with the easiest one and employees who help to meet the targets should be rewarded (public acknowledgment, participation in meetings etc.). In short, failure of implementing easy goals can hurt the entire PBM initiative.

Characteristics of effective short-term win strategies (175)

- **Measurable** - Select short-term with convincing improvements (not vague and fuzzy).
- **Visible** - People need to see real evidence of the progress to validate the change effort.
- **Timely** - Ideally first results should appear within three months (partial or progressive results are also valid).
- **Relevant to stakeholders** - Ensure the improvements are valuable to the majority of the stakeholders.
• **Relevant to the situation** - Wins should provide a test of the vision and change plan against real conditions so they provide useful information to learn from.

Proposed PBM modalities for easy wins are the following:

- optimising blood-ordering schedules to avoid unnecessary logistics, lab tests, control measures and blood samples (176),
- reducing amount of phlebotomies (micro sampling, reduced number of lab tests) (177, 178),
- reducing transfusion index by using a single unit strategy (179),
- checking for blood count and iron status to detect preoperative anaemia on time (146, 180, 181),
- calculating blood loss for benchmarking (182),
- starting a transfusion database for continuous monitoring of blood use (183),
- irradiating washed blood to increase utilisation of autologous blood (184),
- using restrictive/symptomatic transfusion thresholds/triggers to avoid unnecessary transfusions (84),
- using antifibrinolytics to reduce perioperative blood loss (170),
- maintaining perioperative normothermia (185),
- using other modalities appropriate for the individual institution (e.g. patient questionnaire) (100)

### Key points – Step 6

- Take some time to work through the various needs of your stakeholders and categorise these needs by ‘importance to the stakeholder’ and ‘ease of implementation’.
- Select only one or two easily achievable short term measures.
- Select short-term goals carefully, because failure to reach them compromises the PBM initiative as a whole.
- Define short-term targets and clear results (e.g. reduction of RBC usage).
- Include an implementation timeline (do not waste time).
- Complete selected short-term measures in less than 12 months.
- Reward people who help to meet the targets.

### Table 9. Checklist for step 6: Create short-term wins of PBM

<table>
<thead>
<tr>
<th>Proposed assessment of short-term winning measures</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1 Revised blood ordering schedules</td>
<td></td>
</tr>
<tr>
<td>6.2 Micro sampling (smaller volumes, less frequent)</td>
<td></td>
</tr>
<tr>
<td>6.3 Implementation of a single unit ordering and transfusion strategy</td>
<td></td>
</tr>
<tr>
<td>6.4 Preoperative anaemia management</td>
<td></td>
</tr>
<tr>
<td>• Introduction of patient information about options for preoperative anaemia treatment (where appropriate), web-based and/or paper form (39)</td>
<td></td>
</tr>
<tr>
<td>• Preoperative screening for anaemia and iron status</td>
<td></td>
</tr>
</tbody>
</table>
6.5 Preoperative check for coagulation and expected blood loss (e.g. Mercuriali algorithm to calculate expected blood loss and post-operative haematocrit)

6.6 Standard use of antifibrinolytics

6.7 Irradiation of salvaged blood in surgical cancer patients

6.8 Applying restrictive/symptomatic transfusion thresholds/triggers

6.9 Other hospital specific easy wins (patient questionnaire)

(*) +++ strong, ++ moderate, + weak, - none

3.2.7 **Step 7 - Build on the change**

7) Use increased credibility to change systems, structures, and policies that don’t fit the vision, also hire, promote, and develop employees who can implement the vision, and finally reinvigorate the process with new projects, themes, and change agents (J. Kotter).

The complex efforts of PBM implementation risk losing momentum if there are no short-term goals to meet and celebrate. Without short-term wins, too many team members will give up or even actively resist. However, easy wins are only the beginning of what has to be done to achieve sustainable PBM implementation. Each success is a chance to build on what went right and to set further goals for PBM implementation (by removing barriers, by getting more resources, etc.).

To suggest after an easy win the project is mostly done would be a severe mistake, because new approaches are fragile and have a tendency towards regression until they sink deep into the culture. Therefore, it is mandatory to analyse not only the objectives achieved, but also which further improvements need to be accomplished.

PBM team members must continue to focus on new PBM implementation modalities to keep momentum going. This means, with the idea of continuous improvement and adaptation in mind, they should consolidate the gains achieved and produce even more change along the three pillars of PBM (186). The PBM team should find workarounds and solutions to overcome still existing behavioural, structural and organisational obstacles. It is important to gradually expand the PBM concept across the entire hospital.

**Key points - Step 7**

- Consolidate and celebrate successful short-term wins.
- Continue to focus on PBM parameters and set further goals (continuous improvement).
- Regular workarounds.
- Expand PBM across the entire hospital.
- Continuously monitor key parameters via a database and communicate the results to all clinicians.
Table 10. Checklist for step 7: Build on the change (Never let up)

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
<td>Consolidate and complete the implementation of the three-pillar strategy (e.g. preoperative anaemia treatment if Hb &lt; WHO threshold or if expected blood loss is likely to make patient anaemic)</td>
<td></td>
</tr>
<tr>
<td>7.2</td>
<td>Continue with workarounds and solutions to overcome behavioural, structural and organisational obstacles</td>
<td></td>
</tr>
<tr>
<td>7.3</td>
<td>Implement a database for the continuous monitoring of parameters</td>
<td></td>
</tr>
<tr>
<td>7.4</td>
<td>Internal auditing of transfusion practice on a regular basis</td>
<td></td>
</tr>
<tr>
<td>7.5</td>
<td>Reporting and evaluating results and achievements with hospital staff and management</td>
<td></td>
</tr>
<tr>
<td>7.6</td>
<td>Motivate hospital staff to attend lectures and study publications</td>
<td></td>
</tr>
<tr>
<td>7.7</td>
<td>Continuous improvement, rethinking strategies and goals</td>
<td></td>
</tr>
<tr>
<td>7.8</td>
<td>Rewards and incentives for successful PBM team members</td>
<td></td>
</tr>
<tr>
<td>7.9</td>
<td>Include project management / timeline / milestones / benchmark cycles</td>
<td></td>
</tr>
<tr>
<td>7.10</td>
<td>Set up a framework using stepwise indicator systems to follow changes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Structure indicators (examples)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ establishing the PBM team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ patient flow for cardiac surgery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Process indicators (examples)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ using more tranexamic acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ higher rate of single unit ordering</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Outcome indicators (examples)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ lower transfusion rate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ lower transfusion index</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ lower rate of complications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ lower rate of patients with anaemia</td>
<td></td>
</tr>
</tbody>
</table>

(*) +++ strong, ++ moderate, + weak, - none

3.2.8 Step 8 - Anchor PBM in culture

8) Articulate the connections between the new behaviours and organisational success, and develop the means to ensure leadership development and succession (J. Kotter).

The PBM concept should become an integral part of and be deeply anchored in the hospital’s culture. Otherwise, it might become the subject of degradation as soon the pressure associated with the change
efforts is removed. Therefore, success stories showing the positive results of PBM implementation have to be frequently communicated to the entire hospital staff and at scientific meetings. For example, significant reduction of the transfusion rate in combination with better outcome and increased patient safety. Success stories should also be published. Moreover, not only should the key members’ contributions to the change process be publicly recognised, but also the frustrations they experienced acknowledged and discussed.

To give PBM a solid place in hospital culture, PBM leaders and hospital directors should continue to support PBM implementation. This includes the existing PBM team as well as new staff. One bad succession decision (for example not considering PBM in the training of new staff members or not providing necessary resources) can undermine a decade of hard work. Anchoring PBM also requires that sufficient time be taken to ensure the next generation of PBM team members really do internalise this new approach. Therefore, the PBM concept must be part of the staff’s training and education programme.

Key points – Step 8
- PBM should be part of the hospital’s culture.
- The PBM team has clear competences and responsibilities.
- PBM is an intrinsic part of the staff’s training and education programme.
- Internal reporting on outcome indicators is supported by direct data access to transfusion database, hospital information system and patient data management system.

Including specific criteria related to PBM to a national hospital accreditation programme:
- Level 1 - Start of PBM implementation based on the EU-PBM Guide (Step 1)
- Level 2 - First results based on easy win measures (Step 1 to 6)
- Level 3 - Full implementation of PBM (Step 1 to 8) → EU-PBM Excellence centres

Table 11. Checklist for step 8: Anchor PBM in culture

<table>
<thead>
<tr>
<th>#</th>
<th>Proposed assessment topics</th>
<th>Result(※)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1</td>
<td>Three pillar strategy anchored as part of the hospital’s culture</td>
<td></td>
</tr>
<tr>
<td>8.2</td>
<td>PBM patient level benchmarking and reporting processes by procedure, clinician and department are in place and fully automated</td>
<td></td>
</tr>
<tr>
<td>8.3</td>
<td>Routine reporting of key parameters to clinical directors and the hospital management in place (mortality, complications, readmissions, length of stay and cost)</td>
<td></td>
</tr>
<tr>
<td>8.4</td>
<td>Conducting clinical studies and producing (multidisciplinary) publications</td>
<td></td>
</tr>
<tr>
<td>8.5</td>
<td>PBM certification from national hospital accreditation programme</td>
<td></td>
</tr>
</tbody>
</table>

(※) +++ strong, ++ moderate, + weak, - none
### 3.3 PBM Implementation steps (Matrix)

The matrix summarises actions supporting each step according the Kotter model and could be used to build a customised action plan or checklist for a hospital.

**Table 12. Summary of actions supporting each implementation step according to the Kotter model**

<table>
<thead>
<tr>
<th>Step</th>
<th>(1) Establish urgency for PBM</th>
<th>(2) Form a powerful PBM group</th>
<th>(3) Create a vision for PBM</th>
<th>(4) Communicate the PBM Vision within the hospital</th>
<th>(5) Empower the team and remove obstacles</th>
<th>(6) Generate short-term wins</th>
<th>(7) Build on the change</th>
<th>(8) Anchor PBM in culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Putting together main arguments for the implementation of PBM</td>
<td>Formulating and consenting the vision of the PBM Group</td>
<td>Organizing and conducting meetings, lectures, and workshops</td>
<td>Identifying behavioural, organisational, financial and infrastructural obstacles</td>
<td>Revising blood ordering schedules</td>
<td>Consolidating and completing the implementation of the three-pillar strategy (e.g. Preoperative anaemia treatment if Hb &lt; WHO threshold or if expected blood loss is likely)</td>
<td>Anchoring three pillar strategy as part of the hospital’s culture</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Specially tailoring educational contents to • clinical directors and department heads in surgery, internal medicine, nursing, pharmacy, controlling, finance, and IT • hospital managers and health care providers • primary care physicians • patients and patient advocates</td>
<td>Including sufficient number of professionals from multiple disciplines (physicians, nurses, perfusionists, hospital managers, networkers, quality managers)</td>
<td>Ensuring vision is in line with the current evidence and the available resources of the hospital</td>
<td>Communicating PBM through the hospitals’ homepage, intranet and other suitable channels</td>
<td>Implementing electronic benchmarking and reporting systems to continuously measure transfusion and patient level outcome data. Having a first version of the database including minimal dataset ready as early as possible</td>
<td>Introducing microsampling (smaller volumes, less frequent)</td>
<td>Continuing with workarounds and solutions to overcome behavioural, structural and organisational obstacles</td>
<td>Having fully automating benchmarking and reporting processes by procedure, clinician and department in place</td>
</tr>
<tr>
<td>3</td>
<td>Capturing and evaluating intra-institutional PBM related baseline data such as prevalence of anaemia, blood loss, transfusion trigger, transfusion rate and index • Reporting results to departmental teams and key stakeholders • Communicate PBM as “gold standard”</td>
<td>Officially assigning leading professionals by the hospital executives (key leaders)</td>
<td>Ensuring stakeholders support of PBM vision</td>
<td>Providing guidelines, literature and other suitable information materials in print and electronically</td>
<td>Establishing ongoing PBM training for all relevant staff</td>
<td>Implementing a single unit ordering and transfusion policy</td>
<td>Expanding the database for the continuous monitoring of key parameters.</td>
<td>Routinely reporting of key parameters to clinical directors and the hospital management</td>
</tr>
</tbody>
</table>
## Establish urgency for PBM

Comparing inter-institutional baseline data such as anaemia prevalence, blood loss, transfusion threshold, transfusion rate and index.
- Reporting results to departmental teams and key stakeholders
- Evaluating differences and trying to identify practice and knowledge gaps.

## Form a powerful PBM group

Ensuring support from hospital management (including budget for PBM)
- Reporting results to departmental teams and key stakeholders
- Evaluating differences and trying to identify practice and knowledge gaps.

## Create a vision for PBM

Developing strategies to communicate and execute the PBM vision
- Reporting results to departmental teams and key stakeholders
- Evaluating differences and trying to identify practice and knowledge gaps.

## Communicate the PBM Vision within the hospital

Ensuring target audiences are familiar with PBM concept
- Reporting results to departmental teams and key stakeholders
- Evaluating differences and trying to identify practice and knowledge gaps.

## Empower the team and remove obstacles

Clearly defining duties and responsibilities of leaders
- Installing preoperative anaemia management
  - Patient information about options for preoperative anaemia treatment
  - Preoperative screening for anaemia and iron status

## Generate short-term wins

Installing preoperative anaemia management
- Patient information about options for preoperative anaemia treatment
- Preoperative screening for anaemia and iron status

## Build on the change

Regularly conducting internal audits of transfusion/PBM practice
- Attaining PBM certification from national hospital accreditation programme

## Anchor PBM in culture

Conducting clinical studies and producing (multidisciplinary) publications
- Attaining PBM certification from national hospital accreditation programme

---

### Comparing institutional baseline data

- Anaemia prevalence
- Blood loss
- Transfusion threshold
- Transfusion rate
- Index

### Reporting results and discussing achievements

- To departmental teams and key stakeholders
- Evaluation through identifying practice and knowledge gaps.

### Ensuring support from hospital management

- Budget allocation for PBM

### Developing strategies

- Communication and execution of the PBM vision
  - Reporting results to departmental teams and key stakeholders
  - Evaluation of differences and practice

### Communicating the PBM vision

- To target audiences in the hospital
  - Ensuring familiarity with PBM concept

### Empowering the team

- Clear definition of duties and responsibilities

### Generating short-term wins

- Preoperative anaemia management
  - Patient information
  - Preoperative screening

### Building on the change

- Internal audits of transfusion/PBM practice

### Anchoring PBM in culture

- Clinical studies and publications
- PBM certification

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### Additional Strategies

- Preoperative check for coagulation and expected blood loss
- Patient information on options for preoperative anaemia treatment
- Preoperative screening

### Continuous Improvement

- Revisions in strategies and goals
- Monitoring and evaluation of improvements

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### Setting up a framework for monitoring changes

- Structure indicators
- Process indicators
- Outcome indicators
- Lower rate of patients with anaemia
4 Examples of successful PBM initiatives

4.1 Western Australia Department of Health: The world’s first state-wide PBM programme

In 2008, the Western Australia Department of Health initiated a 5-year project to implement a sustainable health-system-wide PBM programme with the aim to improve patient outcomes while reducing costs (187). Clinically, the programme was structured on the three pillar/nine-field matrix of PBM (40, 75, 188). Kotter’s eight step model was applied and multiple strategies were employed to bring about a cultural change from a blood-product focus to a patient focus. At the start of the programme, the State of Western Australia (WA) already had one of the lowest red blood cell issuance rates per 1,000 population in the developed world (31.8 RBC per 1,000 population). The programme identified reasons and drivers for practice change (189, 190). From 2008 to 2015, issuance for RBCs in WA progressively decreased to 19.4 units per 1,000 population. During the same years, despite an increasing volume of hospital admissions, total issuance of RBC in the entire state decreased from 70,143 to 50,529. The study is the world’s largest to date in the field of PBM. It included 605,046 patients admitted to Western Australia’s four major adult tertiary-care hospitals over six years, with results showing:

- 28% reduction in hospital mortality
- 15% reduction in average hospital length of stay
- 21% decrease in hospital-acquired infections
- 31% decrease in the incidence of heart attack or stroke.

The use of blood products reduced by 41% during the study period, representing a cost saving of $18.5 million. However, gross savings, which include the cost of administering transfusions in the hospitals, is estimated to be between $80–100 million (188).

4.2 OnTRAC: A provincial PBM programme in Canada

In 2002 the Ministry of Health and Long-term Care of Ontario developed a provincial blood conservation programme (86, 191). A medical director and a project administrator were appointed, along with programme nurse coordinators in 23 hospitals. OnTRAC started with focus on three targeted procedures: knee and hip arthroplasty, and elective coronary artery bypass graft (CABG) surgery. Later on in the project implementation radical prostatectomy was included as an additional procedure. Initial results at 12 months demonstrated an overall 24% reduction in blood use for total knee arthroplasty, 14% reduction for AAA, and 23% reduction for CABG surgery. Additionally, patients who were transfused received fewer units. Non-transfused patients had lower postoperative infection rates (p<0.05) and length of stay (p<0.0001); and a multivariate analysis showed transfusion as an independent predictor of increased length of stay. The investigators concluded: “Implementation of the programme represents important savings in costs associated with blood components, hospital stay and work in transfusion laboratories and nursing units, as well as enhancing patient satisfaction and safety”. In an updated report published in 2007, data at 18 and 24 months showed there was an overall reduction in the number of patients receiving RBC transfusion (192). In 2014 the authors reported overall cost savings for the four targeted procedures of 39.5 million dollar to the health care system by consequently try to lose less and to
save/give back patients’ blood. The cost of the programme itself was $3,257,000 (86, 191). In the context of these high quality and outcomes gains at reduced cost, the authors stated that the slow adoption of the concept is due to “the traditional concept that blood products are an effective and safe therapeutic intervention”, but continue “this needs to be replaced by the new concept that transfusion of blood products represents an undesirable outcome” (86). Changing practice needs data on current transfusion rates and practices. It has been shown that a key component is to treat pre-operative anaemia and this requires seeing patients early. Among others difficulties the following have been encountered in the program: governmental emphasis on shorter wait times for surgery (sometimes precluding the possibility of appropriate anaemia treatment), costs and accessibility to blood conservation measures, and sometimes difficulty in recruiting physician and administrative champions. The OnTRAC team acknowledges the cardinal role of the medical directors when they were able to identify one in each hospital.

4.3 Institutional programmes

4.3.1 General Hospital Linz (Austria)

The 900-bed General Hospital in Linz performs about 27,000 surgical procedures per year. Although it was one of the institutions with the lowest transfusion rate in the Austrian Benchmark Study, a patient blood management project was initiated in 2008. In addition to lectures and workshops in co-operation with all departments, several measures have been taken to reduce allogeneic blood transfusions with the ultimate goal to improve patient outcome and safety. Over a period of six years clinicians reduced blood utilisation by 60 - 70% (75). The General Hospital Linz (Austria) reported a reduction of RBC utilisation of more than 40% after the implementation of PBM (with a reduction of 75% in the department of anaesthesiology and intensive care, 77% in the department of orthopaedics and 57% in the general surgery department (193). By the end of 2014, an overall reduction of almost 70% in red blood cell concentrates has been achieved. Unfortunately, due to limited financial and logistical resources, the effect on patient outcome could not be evaluated.

Pillar I

One of the most important steps for the success was the implementation of a premedication outpatient clinic and the establishment of a diagnostic pathway. The diagnostic pathway was developed in consultation with surgical colleagues and included timely assignment of patients and standardised treatment of preoperative anaemia. At the beginning, this was only possible in some surgical specialities. However, the emerging success of this approach led to the commitment of more and more surgical partners. As a consequence, more than 80% of patients are currently sent to the premedication outpatient clinic before surgery. The introduction of a standardised operating procedure (SOP) for PBM resulted in the award of an Austrian quality management certificate. Furthermore, surgical partners recognised PBM as a trademark and organised PBM meetings to work out instructional material for their professions. By gaining broad acceptance the need for further necessary changes were accepted and PBM implementation became easier.

Moreover, adequate preparation of patients was improved. More and more patients received intravenous iron and erythropoietin after passing through the diagnostic pathway. In 2014, a total of 888 g of intravenous iron was administered. This corresponds to an iron rate of 0.033 g/surgical procedure; whereas, during the same time period, the transfusion rate declined to 0.22 RBC per surgical procedure.
Pillar II
Since surgical partners anticipated blood-free or blood-sparing techniques as a valuable goal, several measures were adopted to minimise perioperative blood loss: increased usage of cell salvage, application of local haemostyptics, usage of small circuits for cardiopulmonary bypass, and modern surgical approaches (minimal invasive) in order to minimise damage to surrounding tissues.

Pillar III
From 2008-2014, the transfusion trigger was reduced from 10 g/dl to 7 g/dl. However, this did not result in a significant decline of the mean haemoglobin concentration during a hospital stay. In the same time period the transfusion rate declined significantly (about 70%).

4.3.2 Implementing PBM at the Landesklinikum Gänserndorf-Mistelbach (Austria)
The Landesklinikum Gänserndorf-Mistelbach (Austria) participated in the first and second Austrian PBM benchmark trial conducted by the Austrian Ministry of Health. At the hospital about 29,400 in-patients are treated in 12 departments per year. After the head of anaesthesia and intensive care unit received the first PBM benchmark report the hospital management decided to disclose the results and to start a PBM programme. Out of 18 participating centres the Landesklinikum Gänserndorf-Mistelbach had the highest RBC transfusion rate with 8,648 transfused RBC in 2004. After an external audit by PBM experts in 2005 a PBM implementation team was installed. Immediate implementation of “short term win” actions resulted in reduced RBC utilisation although the number of in-hospital patients increased. In 2006 the total number of RBC units declined by 35% to 5,694. In a six years follow-up period the overall transfusion rate for RBC was reduced from 6.7% to 4.8% and the transfusion index was reduced from 4.5% to 3.8% (5).
5 References

74. Lamhaut L, Apriotesi E, Combes X, Lejay M, Carli P, Vivien BÆ. Comparison of the Accuracy of Noninvasive Hemoglobin Monitoring by Spectrophotometry (SpHb) and HemoCueÆ with Automated Laboratory Hemoglobin Measurement. Anesthesiology. 2011;115(3).


141. Institute for Healthcare Improvement, Cambridge U.S. Website, Avaliable from: http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx, (last access: 11.07.2016)


6 Appendix 1 – Methods of intervention

Consistently effective interventions

• Reminders (manual or computerised)
• Interventions which are multifaceted (a combination that includes two or more of the following: audit and feedback, reminders, local consensus processes, promotion)
• Education through interactive meetings (participation of healthcare providers in workshops that include discussion or/and practice)

Interventions of variable effectiveness

• Audit and feedback (or any summary of clinical performance)
• Support of local opinion leaders (practitioners identified by their colleagues as influential)
• Local consensus processes (inclusion of participating practitioners to ensure that they are in agreement that the chosen clinical problem is important and the approach to managing the problem is appropriate)
• Patient mediated interventions (any intervention aimed at changing the performance of healthcare providers for which specific information was sought from or given to patients)

Interventions that have limited effect

• Solitary educational materials are not sufficient (distribution of recommendations for clinical care, including clinical practice guidelines, audio-visual materials, and electronic publications)
• Didactic educational meetings when held out of context (such as lectures)

Available protocols and guidelines

Table 13. Available protocols and guidelines

<table>
<thead>
<tr>
<th>Method</th>
<th>Topic of the guideline</th>
<th>Available from</th>
<th>Last access</th>
</tr>
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</table>
### European Commission

**Directorate-General for Health and Food Safety**

**Health Programme**

#### AABB - Advancing Transfusion and Cellular Therapies Worldwide

- [http://www.aabb.org/phmPages/default.aspx](http://www.aabb.org/phmPages/default.aspx)
- 11/08/2016

#### Society for Blood Management (SABM)

- [https://www.sabm.org/](https://www.sabm.org/)
- 11/08/2016

#### Recommendations for the implementation of a Patient Blood Management programme. Application to elective major orthopaedic surgery in adults

- 11/08/2016

### Blood salvage

#### National Institute for Health and Care Excellence (NICE) - Intraoperative blood cell salvage in obstetrics

- [https://www.nice.org.uk/guidance/ipg144](https://www.nice.org.uk/guidance/ipg144)
- 11/07/2016

#### Royal Cornwall Hospital - Clinical Guideline for Intraoperative Cell Salvage

- 11/07/2016

### Maintaining normothermia

#### US Normothermia Guidelines

- [US Normothermia Guidelines](https://www.ncbi.nlm.nih.gov/pmc/article/PMC4828865/)
- 11/07/2016

#### University of Pennsylvania Health System

- [http://www.uphs.upenn.edu/surgery/Education/trauma/SCCS/protocols/Normothermia_Tipsheet.pdf](http://www.uphs.upenn.edu/surgery/Education/trauma/SCCS/protocols/Normothermia_Tipsheet.pdf)
- 11/07/2016

#### ASPAN's Evidence-Based Clinical Practice Guideline for the Promotion of Perioperative Normothermia

- 11/07/2016

### Anaesthesiological techniques

#### Controlled Hypotension – A Guide to Drug Choice

- 11/07/2016

### Management of severe bleeding

#### The European guideline on management of major bleeding and coagulopathy following trauma: fourth edition (194)

- [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4828865/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4828865/)
- 13/09/2016

#### Management of severe perioperative bleeding: Guidelines from the European Society of Anaesthesiology (195)

- [https://www.esahq.org/guidelines/guidelines/published](https://www.esahq.org/guidelines/guidelines/published)
- 13/09/2016
7 Appendix 2 – Further reading


• Estcourt, L. J., et al. 'Restrictive versus liberal red blood cell transfusion strategies for people with haematological malignancies treated with intensive chemotherapy or radiotherapy, or both, with or without haematopoietic stem cell support.' Cochrane Database Syst Rev 1: Cd011305, 2017.
**EUROPEAN COMMISSION**


Trentino, KM, et al., Increased hospital costs associated with red blood cell transfusion. Transfusion, 2014.
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