A patient blood management (PBM) strategy for SA – highlights of the SAMJ submission

Dr Jackie Thomson
The triad of independent risk factors for adverse patient outcome
Anaemia
A systematic analysis of global anemia burden from 1990 to 2010

Nicholas J. Kassebaum, Rashmi Jasrasaria, Mohsen Naghavi, Sarah K. Wulf, Nicole Johns, Rafael Lozano, Mathilda Regan, David Weatherall, David P. Chou, Thomas P. Eisele, Seth R. Flaxman, Rachel L. Pullan, Simon J. Brooker and Christopher J. L. Murray

68.36m YLD or 8.8% of total for all conditions [globally]

Associated w/
• weakness
• fatigue
• difficulty concentrating
• poor work productivity
• infection
• heart failure
• preterm labor
• low birth weight
• child and maternal mortality
The impairment that affected the greatest number of people in 2015 was anaemia, with 2.36 billion (2.35–2.37 billion) individuals affected.

The prevalence of iron-deficiency anaemia alone was 1.46 billion (1.45-1.46 billion).
Meta-analysis of the association between preoperative anaemia and mortality after surgery

- 949’449 patients of 24 studies analyzed
- 39% of patients were anemic (WHO definition)
- Anemia was associated with
  - Perioperative mortality $\uparrow$ - OR 2.90 (2.30 – 3.68, p< 0.001)
  - Acute kidney injury $\uparrow$ - OR 3.75 (2.95 – 4.76, p< 0.001)
  - Infections $\uparrow$ - OR 1.93 (1.06 – 1.55, p< 0.01)
  - Stroke in cardiac surgery $\uparrow$ - OR 1.28 (1.17 – 3.18, p< 0.01)
  - RBC transfusion $\uparrow$ - OR 5.04 (4.12 – 6.17, p< 0.001)

Preoperative anaemia and postoperative outcomes in non-cardiac surgery: a retrospective cohort study


US Veterans Database (NSQIP) (n=227’425)

Anaemia (n=69’229; 30.4%)

30 day mortality
30 day composite morbidities (9 defined areas)

Multivariate regression analysis (9 defined subgroups) (56 confounders)
• Preoperative anemia: 30.4%

• **Mild** anemia $\Rightarrow$ OR mortality $\uparrow$: 1.4 (1.3 – 1.5)

• **Mild** anemia $\Rightarrow$ OR morbidity $\uparrow$: 1.3 (1.3 – 1.4)

• RBC trans. $\Rightarrow$ OR mortality $\uparrow$: 2.0 (1.8 – 2.2)

• RBC trans. $\Rightarrow$ OR morbidity $\uparrow$: 1.8 (1.7 – 1.9)

Effect of Anemia on Mortality and Composite Morbidity

Targeted anemia surveillance and intervention should be a greater priority in high-risk populations, especially young children and females.\textsuperscript{42} Despite causing so much disability, anemia does not receive its requisite attention in many public health spheres. Such inattention may be partly because anemia is thought of as a by-product of other disease processes rather than as a target for intervention in and of itself. It is somewhat ironic, then, that etiology-specific
PBM has the potential to address several health care related challenges that are specific to South Africa:

- *First*, the population of South Africa totals 57.8 million in 2018 and includes an estimated
- **17.8 million suffering** from anaemia,
- predominantly in neonates and children,
- women in the reproductive age and the elderly.
- also a high prevalence of HIV-related anaemia, anaemia of inflammation, malarial anaemia and anaemia from intestinal parasite infestations.
- In hospitalized patients, the prevalence of anaemia is even higher than in the general population and it is an independent predictor for adverse
- outcomes including morbidity and mortality.
Preoperative anaemia and clinical outcomes in the South African Surgical Outcomes Study

D Marsicano,¹ BComm, MB ChB, DA (SA); N Hauser,²,³ BSc (Physio), MB ChB, DA (SA), FCA (SA), MMed, FANZCA; F Roodt,² MB ChB, FCA (SA); E Cloete,⁴ MB ChB, DA (SA), FCA (SA); W Conradie,⁵ MB ChB, FCS (SA), MMed (Surg); V Morford,⁶ MB BCh, DA (SA), FCA (SA); D Nel,⁷ MB ChB, DA (SA), FCA (SA); D G Bishop,⁸ MB ChB, FCA (SA); T E Madiba,⁹ PhD; B M Biccard,¹¹ PhD; on behalf of the South African Surgical Outcomes Study investigators

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² Department of Anaesthesia and Perioperative Medicine, Groote Schuur Hospital, Red Cross War Memorial Children's Hospital and Faculty of Health Sciences, University of Cape Town, South Africa
³ Department of Anaesthesia and Pain Medicine, Fiona Stanley and Fremantle Hospital Group, Perth, Australia
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⁵ Department of Surgery, Tygerberg Hospital and Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa
⁶ Department of Anaesthesia, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
⁷ Department of Anaesthesia, Chris Hani Baragwanath Academic Hospital and Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
⁸ Perioperative Research Group, Department of Anaesthetics, Critical Care and Pain Management, School of Clinical Medicine, College of Health Sciences, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa
⁹ Department of Surgery, School of Clinical Medicine, College of Health Sciences, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa
Background. In high-income countries, preoperative anaemia has been associated with poor postoperative outcomes. To date, no large study has investigated this association in South Africa (SA). The demographics of SA surgical patients differ from those of surgical patients in the European and Northern American settings from which the preoperative anaemia data were derived. These associations between preoperative anaemia and postoperative outcomes are therefore not necessarily transferable to SA surgical patients.

Objectives. The primary objective was to determine the association between preoperative anaemia and in-hospital mortality in SA adult non-cardiac, non-obstetric patients. The secondary objectives were to describe the association between preoperative anaemia and (i) critical care admission and (ii) length of hospital stay, and the prevalence of preoperative anaemia in adult SA surgical patients.

Methods. We performed a secondary analysis of the South African Surgical Outcomes Study (SASOS), a large prospective observational study of patients undergoing inpatient non-cardiac, non-obstetric surgery at 50 hospitals across SA over a 1-week period. To determine whether preoperative anaemia is independently associated with mortality or admission to critical care following surgery, we conducted a multivariate logistic regression analysis that included all the independent predictors of mortality and admission to critical care identified in the original SASOS model.

Results. The prevalence of preoperative anaemia was 1 727/3 610 (47.8%). Preoperative anaemia was independently associated with in-hospital mortality (odds ratio (OR) 1.657, 95% confidence interval (CI) 1.055 - 2.602; p=0.028) and admission to critical care (OR 1.487, 95% CI 1.081 - 2.046; p=0.015).

Conclusions. Almost 50% of patients undergoing surgery at government-funded hospitals in SA had preoperative anaemia, which was independently associated with postoperative mortality and critical care admission. These numbers indicate a significant perioperative risk, with a clear need for quality improvement programmes that may improve surgical outcomes. Long waiting lists for elective surgery allow time for assessment and correction of anaemia preoperatively. With a high proportion of patients presenting for urgent or emergency surgery, perioperative clinicians in all specialties should educate themselves in the principles of patient blood management.

The iron status of South African blood donors: balancing donor safety and blood demand

Karin van den Berg, Ronel Swanevelder, Charlotte Ingram, Denise Lawrie, Deborah Kim Glencross, Caroline Hilton, and Martin Nieuwoudt
BACKGROUND: Several studies in developed countries have demonstrated high levels of iron deficiency (ID) among blood donors. There is a paucity of data for developing countries where blood shortages remain a major concern.

STUDY DESIGN AND METHODS: A total of 4412 donors were enrolled in the study. Specimens were collected for full blood count, iron, transferrin saturation, and ferritin assessment. Donor demographics were recorded. ID was indicated by a ferritin level of less than 20 ng/mL for men and less than 12 ng/mL for women. Anemia was defined as hemoglobin levels less than 12.5 g/dL. Regression models for predictors of ID were developed.

RESULTS: A total of 17.5% of all donors had ID, with 16.3% prevalence in women and 18.6% in men. Low hemoglobin had the highest association with ID (adjusted odds ratio [AOR], 11.078; 95% confidence interval [CI], 7.915–15.505); male donors had twice the odds of ID compared to female donors (AOR, 2.501; 95% CI, 1.964–3.185), while increasing age was associated with lower odds (AOD, 0.965; 95% CI, 0.956–0.975). Among male donors, an interdonation interval of less than 3 months (AOR, 2.679; 95% CI, 1.929–3.720) was associated with ID. Compared to other females combined, colored female donors (AOR, 2.335; 95% CI, 1.310–4.160) had higher odds and black female donors (AOR, 0.559; 95% CI, 0.369–0.845) lower odds of ID.

CONCLUSION: ID is common among South African donors; low hemoglobin, gender, ethnicity, and past donation history is independently associated with ID. Recommendations aimed at protecting donor health may increase blood shortages in South Africa.
## HB threshold for transfusion

### Red cell patients / HB category, 2018

<table>
<thead>
<tr>
<th>HB Category</th>
<th>Private (n=77,426)</th>
<th>Public (n=236,241)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3</td>
<td>346</td>
<td>6,438</td>
</tr>
<tr>
<td>3-5</td>
<td>3,774</td>
<td>40,614</td>
</tr>
<tr>
<td>5.1-6.9</td>
<td>16,926</td>
<td>83,696</td>
</tr>
<tr>
<td>7-7.9</td>
<td>25,958</td>
<td>42,644</td>
</tr>
<tr>
<td>8-8.9</td>
<td>27,888</td>
<td>30,471</td>
</tr>
<tr>
<td>9-11.9</td>
<td>18,421</td>
<td>26,655</td>
</tr>
<tr>
<td>12+</td>
<td>4,271</td>
<td>5,241</td>
</tr>
<tr>
<td>N/A</td>
<td>17,199</td>
<td>37,496</td>
</tr>
</tbody>
</table>
Figure 2: Usage of hospital wards by age
## Blood demand

Table 1: RBC demand in 2017 under each scenario

<table>
<thead>
<tr>
<th>Scenario</th>
<th>2017</th>
<th>RBC demand per 1K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>765,824</td>
<td>15.06</td>
</tr>
<tr>
<td>Actual need</td>
<td>1,824,756</td>
<td>35.87</td>
</tr>
<tr>
<td>Medium scenario</td>
<td>1,776,307</td>
<td>34.92</td>
</tr>
<tr>
<td>Best case</td>
<td>1,295,617</td>
<td>25.47</td>
</tr>
</tbody>
</table>
there is also an overall economic argument for the implementation of PBM:

• Unmanaged or poorly managed anaemia impairs the cognitive development of children and adolescents, reduces the ability to concentrate and diminishes work productivity with losses in some countries of up to 9% of the gross domestic product.
• Programs promoting oral iron therapy may be effective in specific subpopulations, but in patients with profound iron deficiency and iron deficiency anaemia, who require therapy for immediate correction, an appropriate dose of intravenous iron is the best option, while treatment of the underlying cause produces a cure.
• Improvements in patient outcomes with the concomitant savings as seen in previous studies, could lead to a significant decrease in pressure on bed occupation and a healthcare budget under extreme pressure.
“Uncontrolled hemorrhage is the only defense of the unconscious patient against the incompetent surgeon.”

William Stewart Halsted
1852 – 1922
Johns Hopkins University
Major blood loss associated with increased
• Mortality (3-fold)
• Major morbidity (3-fold)
• ICU and hospital length of stay
• Likelihood of transfusion

Causes
• On average 75 - 90% local surgical interruption or vessel interruption
• 10-25% acquired or congenital coagulopathy

Shander A. Surgery 2007
Vivacqua et al Ann Thorac Surg 2011
Christensen et al J Thorac Cardiovasc Surg 2009
Ye, X., et al BMC Health Serv Res, 2013
Blood transfusion is the most common procedure performed during hospitalizations in 2011 (12% of stays with a procedure); the rate of hospitalizations with blood transfusion more than doubled since 1997.

http://www.hcup-us.ahrq.gov/reports/statbriefs/sb165.pdf
Maternal Mortality

Fig. 4. Trend in iMMR per underlying cause: 2011 - 2016. (iMMR = institutional maternal mortality rate; HT = complication of hypertension in pregnancy; OH = obstetric haemorrhage; EC = ectopic pregnancies; Miscar. = miscarriage; PRS = pregnancy-related sepsis; AR = anaesthetic-related deaths; Emb. = embolism; AC = acute collapse, cause unknown; NPRI = non-pregnancy related infections; MeS = pre-existing medical and surgical conditions, Unk. = unknown.)
Infectious Agents in the Blood Supply

✔ HIV, HCV, HBV

✘ New infectious agents

- Prions (vCJD)
- Dengue (DENV)
- Babesia species
- Chikungunya (CHIKV)
- HBV variants (vl)
- HEV (vl)
- Herpes viruses (other than CMV, EBV, HHV-8) (t)
- HTLV variants (t)
- Influenza A and B viruses (other than H5N1 (t)
- Japanese encephalitis virus (t)
- La Crosse virus (t)
- Lassa virus (t)
- Lymphocytic choriomeningitis virus
- Marburg virus (t)
- Monkeypox virus (t)
- Mumps virus (t)
- Papillomaviruses (t)
- Polyomaviruses (t)
- Porcine endogenous retrovirus (t)
- Porcine parovirus (t)
- Rhabdovirus (a)
- SARS coronavirus (t)
- Tick-borne encephalitis virus complex (vl)
- Torque teno (TTV/TTLV/SEN-V)
- Vaccinia virus (t)
- Variola virus (t)
- Western equine encephalitis virus (t)
- XMRV?
- and what is next?

However, pathogens in the blood pool are just the tip of the iceberg when looking at the problem of adverse transfusion outcomes ...

“[M]ore patients have died in any one year owing to transfusion immunomodulation’s side effects than died in the entire transfusion transmitted AIDS epidemic”

The Multi-Billion Dollar Question:

Does transfusion do what it is intended to do—improve outcome or prevent adverse outcomes?

- There are few if any articles that support transfusion actually improving patient outcomes.
- The majority of database papers show associations between transfusion utilization and with immunosuppression, increased infection, increased renal failure, multisystem organ failure, and death.

RED CELL STORAGE LESIONS

PLASMA
Cleavage/activation of plasma proteins

BUFFY COAT

RED CELLS

PLASMA

CLEAVAGE

OF PLASMA PROTEINS

Acidosis
K+, Na+, NH4+
Hypothermia
Glucose
Plasticisers

Procoagulants

Thrombosis

Other adverse effects of leukocytes

Cytokines

Kinin
Complement
Histamine

Microaggregates

Haemolysis

Bilirubin
LDH
Iron

Jaundice

Hypotension
Flushing
Anxiety
GIT symptoms
Pain
Proinflammatory

Thrombosis
ARDS
RES Blockade
Microvascular Pathology

Acknowledgement: Prof. James Isbister
Perfusion vs. oxygen delivery in transfusion with “fresh” and “old” red blood cells: The experimental evidence

Amy G. Tsai a, Axel Hofmann b, Pedro Cabrales a, Marcos Intaglietta a, *

a Department of Bioengineering, University of California, San Diego, CA, United States
b Society for the Advancement of Blood Management, Milwaukee, WI, United States

Impairment of oxygen transport of stored RBCs was first reported when measurement of the corresponding oxygen dissociation curves showed an immediate and significant increase in the oxygen affinity during the initial week of storage at 4 °C. This resulted in a decrease of oxygen delivery during transfusion of stored RBCs by comparison to normal RBCs, the difference being proportional to the volume transfused and storage time [16].
Posttransfusion Increase of Hematocrit per se Does Not Improve Circulatory Oxygen Delivery due to Increased Blood Viscosity

Robert Zimmerman, MS,* Amy G. Tsai, PhD,† Beatriz Y. Salazar Vázquez, MD, PhD,†‡§ Pedro Cabrales, PhD,† Axel Hofmann, ME, PhD,‖ Jens Meier, MD, PhD,§ Aryeh Shander, MD,** Donat R. Spahn, MD,¶ Joel M. Friedman, MD, PhD,‖ Daniel M. Tartakovsky, PhD,*
and Marcos Intaglia, PhD†

RESULTS: Blood transfusion of up to 3 units of PRBCs increased DO$_2$ when Hct (or hemoglobin) was 60% lower than normal, but did not increase DO$_2$ when administered before this threshold.

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Population</th>
<th>Sample size</th>
<th>Dose-response increased adverse outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaw 2014&lt;sup&gt;19&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>3'516</td>
<td>Mortality</td>
</tr>
<tr>
<td>Horvarth 2013&lt;sup&gt;20&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>5'158</td>
<td>Infection</td>
</tr>
<tr>
<td>Mikkola 2012&lt;sup&gt;21&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>2'226</td>
<td>Stroke</td>
</tr>
<tr>
<td>Stone 2012&lt;sup&gt;22&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>1'491</td>
<td>Mortality</td>
</tr>
<tr>
<td>Van Straten 2010&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>10'425</td>
<td>Mortality</td>
</tr>
<tr>
<td>Hajjar 2010&lt;sup&gt;24&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>512</td>
<td>Morbidity &amp; mortality</td>
</tr>
<tr>
<td>Karkouti 2009&lt;sup&gt;25&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>3'460</td>
<td>Acute kidney injury</td>
</tr>
<tr>
<td>Scott 2008&lt;sup&gt;26&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>1'746</td>
<td>Postoperative LOS</td>
</tr>
<tr>
<td>Murphy 2007&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>8'500</td>
<td>Infection &amp; ischemic events</td>
</tr>
<tr>
<td>Kulier 2007&lt;sup&gt;28&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>5'065</td>
<td>Cardiac and non-cardiac adverse events</td>
</tr>
<tr>
<td>Banbury 2006&lt;sup&gt;29&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>15'592</td>
<td>Septicemia, bacteremia, superficial &amp; deep sternal wound infection</td>
</tr>
<tr>
<td>Koch 2006&lt;sup&gt;30&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>11'963</td>
<td>In-hospital mortality, renal failure, postoperative ventilatory support, postoperative infection, cardiac and neurologic morbidity, overall postoperative morbidity</td>
</tr>
<tr>
<td>Koch 2006&lt;sup&gt;31&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>10'289</td>
<td>Long-term (10-years) survival</td>
</tr>
<tr>
<td>Koch 2006&lt;sup&gt;32&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>7'321</td>
<td>Functional recovery</td>
</tr>
<tr>
<td>Rogers 2006&lt;sup&gt;33&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>9'218</td>
<td>Infection</td>
</tr>
<tr>
<td>Chelemier 2002&lt;sup&gt;34&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>533</td>
<td>Bacterial infection</td>
</tr>
<tr>
<td>Leal-Noval 2001&lt;sup&gt;35&lt;/sup&gt;</td>
<td>Cardiac surgery</td>
<td>738</td>
<td>Infection, pneumonia</td>
</tr>
</tbody>
</table>


Hofmann Zurich 2017-06-12
## Meta-Analyses comparing Liberal vs. Restrictive Transfusion Strategies

<table>
<thead>
<tr>
<th></th>
<th>RCTs</th>
<th>Patients</th>
<th>RBC Txns in restrictive group</th>
<th>Hospital mortality in restrictive group</th>
<th>Infections in restrictive group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carson 2012</td>
<td>19</td>
<td>6,264</td>
<td>-39%</td>
<td>-23%</td>
<td>-19%</td>
</tr>
<tr>
<td>Rohde 2014</td>
<td>18</td>
<td>7,593</td>
<td>n.a.</td>
<td>n.a.</td>
<td>-12%/-18%</td>
</tr>
<tr>
<td>Salpeter 2014</td>
<td>3</td>
<td>2,364</td>
<td>*-43%</td>
<td>-26%</td>
<td>-14%</td>
</tr>
<tr>
<td>Holst 2015</td>
<td>31</td>
<td>9,813</td>
<td>-44%</td>
<td>n.s.</td>
<td>-27%</td>
</tr>
<tr>
<td>Carson 2016</td>
<td>31</td>
<td>12,587</td>
<td>-43%</td>
<td>#n.s.</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

*Transfusion rate
# 30-day mortality

Carson J.L. et al. Cochrane Database of Systematic Reviews, 2012
Carson JL et al. Cochrane Database of Systematic Reviews, 2016
The Rationale behind PBM: Defeating the Triad
Triad of Independent Risk Factors for Adverse Outcomes

- Anemia & Iron Deficiency
- Blood Loss & Bleeding
- Transfusion

<table>
<thead>
<tr>
<th>1st Pillar</th>
<th>2nd Pillar</th>
<th>3rd Pillar</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Optimise red cell mass</strong></td>
<td><strong>Minimise blood loss &amp; bleeding</strong></td>
<td><strong>Harness &amp; optimise physiological reserve of anaemia</strong></td>
</tr>
<tr>
<td>• Detect anaemia</td>
<td>• Identify and manage bleeding risk</td>
<td>• Assess/optimise patient’s physiological reserve and risk factors</td>
</tr>
<tr>
<td>• Identify underlying disorder(s) causing anaemia</td>
<td>• Minimise iatrogenic blood loss</td>
<td>• Compare estimated blood loss with patient-specific tolerable blood loss</td>
</tr>
<tr>
<td>• Manage disorder(s)</td>
<td>• Procedure planning and rehearsal</td>
<td>• Formulate patient-specific management plan using appropriate blood conservation modalities to minimise blood loss, optimise red cell mass and manage anaemia</td>
</tr>
<tr>
<td>• Refer for further evaluation if necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Treat suboptimal iron stores/iron deficiency/anaemia of chronic disease/iron-restricted erythropoiesis</td>
<td>• Meticulous haemostasis and surgical techniques</td>
<td></td>
</tr>
<tr>
<td>• Treat other haematinic deficiencies</td>
<td>• Blood-sparing surgical devices</td>
<td>• Optimise cardiac output</td>
</tr>
<tr>
<td>• Note: Anaemia is a contraindication for elective surgery</td>
<td>• Anaesthetic blood conserving strategies</td>
<td>• Optimise ventilation and oxygenation</td>
</tr>
<tr>
<td></td>
<td>• Autologous blood options</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Maintain normothermia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pharmacological/haemostatic agents</td>
<td>• Optimise anaemia reserve</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Maximise oxygen delivery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Minimise oxygen consumption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Avoid/treat infections promptly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Restrictive transfusion thresholds</td>
</tr>
</tbody>
</table>

Perioperative multidisciplinary multimodal patient-specific team approach

Hofmann et al. Current Opinions in Anaesthesiology 2012
Patient Blood Management (PBM) is an evidence-based bundle of care to optimize patient outcomes by managing and preserving a patient's blood.
Anaemia and Bleeding

Management

of Patient Blood
= managing the patient’s own blood to save lives and improve overall outcomes

with Donor Blood
= saving lives by correcting Hb-values with transfusion


EDITORIAL COMMENT

Our own blood is still the best thing to have in our veins
Tim Frenzel, Hugo Van Aken and Martin Westphal
PBM Results
Implementation of a patient blood management monitoring and feedback program significantly reduces transfusions and costs

• 3Y interventional cohort study 2012-2014 (n=101’794)
• Interventions
  • Mandatory guidelines 2012-04
  • PBM monitoring and feedback program 2014-01
• Outcome parameters
  • Units transfused (RBC, FFP, PLT)
  • Total transfusion cost
  • Clinical outcomes

Mehra et al. Transfusion 2015
• Recording of each transfusion and
  • Recipient
  • Site of transfusion
  • Physician responsible for the transfusion with his/her departmental affiliation
  • Last Hb, PT, F-V and platelet count prior to transfusion
• Quarterly benchmark reports sent to department heads on guideline conformity
• Thresholds transgressed >10% → meeting with DH for specific explanation case by case
Cost savings: > 2‘000‘000 $

Total Blood Products -27%

RBCs -24%

PLTs -25%

FFP -37%

Mehra et al. Transfusion 2015
A template for the world: Western Australia PBM Project
Improved outcomes and reduced costs associated with a health-system–wide patient blood management program: a retrospective observational study in four major adult tertiary-care hospitals

Michael F. Leahy,1,2,3 Axel Hofmann,4,5,6 Simon Touler,7 Kevin M. Trentino,8 Sally A. Burrous,1 Stuart G. Suwain,9 Jeffrey Hamdorf,9,10 Trudi Gallagher,11,12 Audrey Kooy,13 Gary C. Geelhoed,11,13 and Shannon L. Farmer8,14

BACKGROUND: Patient blood management (PBM) programs are associated with improved patient outcomes, reduced transfusions and costs. In 2008, the Western Australia Department of Health initiated a comprehensive health-system–wide PBM program. This study assesses program outcomes.

STUDY DESIGN AND METHODS: This was a retrospective study of 605,046 patients admitted to four major adult tertiary-care hospitals between July 2008 and June 2014. Outcome measures were red blood cell (RBC), fresh-frozen plasma (FFP), and platelet units transfused; single-unit RBC transfusions; pretransfusion hemoglobin levels; elective surgery patients anemic at admission; product and activity-based costs of transfusion; in-hospital mortality; length of stay; 28-day all-cause emergency readmissions; and hospital-acquired complications.

RESULTS: Comparing final year with baseline, units of RBCs, FFP, and platelets transfused per admission decreased 41% (p < 0.001), representing a saving of AUS18,507,032 (US$14,078,256) and between AUS$80 million and AUS$100 million (US$78 million and US$97 million) estimated activity-based savings. Mean pretransfusion hemoglobin levels decreased 7.9 g/dL to 7.3 g/dL (p < 0.001), and anemic elective surgery admissions decreased 20.6% to 14.4% (p = 0.001). Single-unit RBC transfusions increased from 33.3% to 63.7% (p < 0.001). There were risk-adjusted reductions in hospital mortality (odds ratio [OR], 0.72; 95% confidence interval [CI], 0.67–0.77; p < 0.001), length of stay (incidence rate ratio, 0.85; 95% CI, 0.84–0.87; p < 0.001), hospital-acquired infections (OR, 0.79; 95% CI, 0.73–0.86; p < 0.001), and acute myocardial infarction–stroke (OR, 0.69; 95% CI, 0.59–0.82; p < 0.001). All-cause emergency readmissions increased (OR, 1.06; 95% CI, 1.02–1.10; p = 0.001).

CONCLUSION: Implementation of a unique, jurisdiction-wide PBM program was associated with improved patient outcomes, reduced blood product utilization, and product-related cost savings.
Quality, safety, and effectiveness initiative with resource and economic implications.

Primary aim: improving medical and surgical patient outcomes while achieving significant cost savings by applying PBM principles.
Retrospective observational study to assess the impact on key outcome measures in all emergency and elective adult acute-care multi-day stay inpatients (n=605,046) admitted to the 4 major adult tertiary-care hospitals July 2008 – June 2014.

Hospitals perform majority of high-complexity procedures performed in WA including cardiac, major trauma, burns, and obstetrics referral services

Multivariate analysis to control for potential confounders and changes in patient case-mix

Key program performance indicators

Compared to baseline year, implementation was associated in year 6 with:

- **41% reduction in blood product usage** (P<0.001)
- RBC txn Hb threshold decreased from 7.9 to 7.3 g/dL (P<0.001)
- Single-unit RBC txn increased from 33% to 64% (P<0.001)
- Proportion admitted anemic decreased from 20.8% to 14.4% (P=0.001)
- **Product acquisition cost savings** of AU$18.5M
- Estimated **activity-based cost savings** $80 - $100M
- A one-time **investment of $4.5M** to cover 5-year change management and implementation process.

Key Patient Outcomes

In-hospital mortality: 28% ↓ (95% CI, 0.67 to 0.77; P<0.001)
Length of hospital stay: 15% ↓ (95% CI, 0.84 to 0.87; P<0.001)
Infection: 21% ↓ (95% CI, 0.73 to 0.86; P<0.001)
AMI/Stroke: 31% ↓ (95% CI, 0.58 to 0.82; P<0.001)
Readmission: 6% ↑ (95% CI, 1.02 to 1.10; P<0.001)

= additional non-valorized cost savings

Patient Blood Management: the new standard

Preoperative anemia, surgical loss, and transfusion of allogeneic blood products all adversely affect patient outcome. Patient Blood Management (PBM) aims to reduce the need for blood transfusions preemptively to improve patient safety and outcome. The three pillars of PBM consist of treating preoperative anemia, reducing perioperative blood loss, and optimizing anemia tolerance. In addition, the use of restrictive, evidence-based, and patient-centered transfusion triggers is an integral part of PBM.

Implementing one or more PBM measures has indeed improved certain patient outcomes in the past, and some of these studies included well over 100,000 patients. What is then so unique in the landmark study by Leary and colleagues in this issue of TRANSFUSION in which they describe the success of the health system-wide PBM program implementation in Western Australia? Its uniqueness includes:

- The largest ever number of patients studied: 60,594.
- Multi-centric: four major adult tertiary care hospitals.
- Health system-wide PBM program not focused on surgical disciplines alone.
- Multiple outcomes assessed:
  - Safety
  - Clinical outcomes
  - Transfusions
  - Costs
- Duration of the study: 6 years.

The results are indeed impressive. The authors report a progressively reduced adjusted-in-hospital mortality (−28%), a shorter hospital length of stay (−15%), less hospital-acquired infections (−21%), and a reduced rate of myocardial infarction or stroke (−31%). Transfusions of allogeneic blood products were also reduced by 41% whereas transfusions of red blood cells (RBCs) were down 41%, fresh-frozen plasma (FFP) down 47%, and platelets (PLTs) down 27%. These trends resulted in reduction of blood product acquisition costs of more than US$18M and a reduction of activity-based transfusion costs of more than US$80M.

The percentage of elective patients admitted with anemia decreased from 20.8% to 14.4%. This result can be attributed to consistent identification and treatment of existing anemia and iron deficiency in the weeks before hospitalization. To my knowledge, this study is the first worldwide so far reporting a substantial reduction of the preoperative anemia rate. This achievement is highly remarkable given the logistic complexity of preoperative anemia treatment.

How was this program better than any other PBM program so far? The current article does not give a definitive answer. However, the extremely intense educational activity of the proponents of the Western Australia PBM program already described in a previous report by Leary and colleagues in 2014 may be a key element in increasing the awareness of the high incidence of preoperative anemia and iron deficiency and its negative consequences on outcomes. In addition, hospital physicians and referring general practitioners could consult readily accessible diagnostic and therapeutic algorithms (http://www.healthnetworks.health.wa.gov.au/modulo/4017). Ironically, the highest-quality studies on the success of pre- and postoperative anemia treatment were published years after the start of the Western Australia PBM program. However, a consensus is growing that elective surgery should be delayed until anemia correction. This movement started with individual claims. Then experts stopped a prospective randomized study on the efficacy of preoperative treatment of iron deficiency anemia with intravenous (IV) iron due to a much more favorable outcome in the treatment group as compared to placebo group. Finally, a professional society (Association of Anaesthetists of Great Britain and Ireland [AAGBI]) recommended delaying elective surgery until anemia correction in patients with an expected blood loss of more than 500 mL or an expected transfusion rate of more than 10%. In addition, preoperative correction of iron deficiency without anemia has become recognized as likely to be beneficial for patient outcome.

The time course of the improvements of the clinical outcomes is highly interesting. For most clinical outcomes, it took 2 to 3 years until they became significantly improved (Table 2 of the paper). This lag period may well explain why other big PBM programs could only detect trends toward an improvement in clinical outcomes since most analyses published so far analyzed only the first year after the implementation of
Improved outcomes and reduced costs associated with a health-system-wide patient blood management program: a retrospective observational study in four major adult tertiary-care hospitals

Overview of attention for article published in Transfusion, February 2017

This research output has an Altmetric Attention Score of 449. This is our high-level measure of the quality and quantity of online attention that it has received. This Attention Score, as well as the ranking and number of research outputs shown below, was calculated when the research output was last mentioned on 20 April 2017.


Altmetric has tracked 7,615,667 research outputs across all sources so far. Compared to these this one has done particularly well and is in the 99th percentile: it's in the top 5% of all research outputs ever tracked by Altmetric.
PBM as a New Standard of Care
WHA63.12 adopted by resolution May 21, 2010:

„Bearing in mind that patient blood management means that before surgery every reasonable measure should be taken to optimize the patient’s own blood volume, to minimize the patient’s blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia following WHO’s guide for optimal clinical use (three pillars of patient blood management)“
Priorities for Action

**Hospital/Institutional Level**

1. Benchmark transfusion prescription and practices
2. Develop transfusion protocols based on generic/national guidelines, abandon transfusion triggers as surrogate markers
   - a. Assess clinical and physiologic condition for deciding on transfusion
   - b. Define symptoms, physical signs, and interpret laboratory results, based on individual patients
3. Set up multi-disciplinary teams for managing blood use in patients
4. Put in practice the use of:
   - a. Standardized transfusion request form
   - b. Standardized transfusion outcome form
5. Develop clinical transfusion process, as part of hospital quality system and participate in hospital accreditation programmes
6. Establish mechanisms for improving communication and coordination among various stakeholders in patient care
7. Establish and activate hospital transfusion committees (HTC)
8. Designate transfusion officers in hospitals
9. Provide pre-service and in-service training for clinicians, nurses and midwives on blood use
10. Collect a minimum set of data on patient transfusion outcomes
National Level

1. Obtain commitment of the government through policy and legal framework for HTCs and for multi-disciplinary approach for blood use in patient management
2. Identify major national clinical needs, and based on these, develop and implement national guidelines on blood use including patient blood management
3. Based on guidelines, develop algorithms for prescribing
4. Develop standards for hospital transfusion system, as part of hospital standards
5. Establish a minimum data set that can be captured at each hospital
6. Develop national or regional public health networks and their integration within the haemovigilance systems
7. Introduce technologies to facilitate decision for transfusion prescription
8. Conduct multi-centric studies
   a. Patient outcomes
   b. Alternatives
9. Conduct benchmarking studies to compare practices in different hospitals and clinicians
10. Start hospital accreditation programmes, including clinical transfusion as part of this programmes
11. Provide training for clinicians, nurses and midwives on blood use
12. Develop professional leadership skills to lead and manage hospitals across the country to strengthen hospital transfusion systems
13. Develop educational curriculum
   a. Pre-service
   b. In-service
   c. Post graduate educations (multiple discipline)
14. Focus on outcome research
15. Translate - Make available current evidence through desk research - meta analysis
   a. Move forward on randomized control trials (RCT)
   b. Need more funding for RCT in Patient Blood Management
**International Level**

1. Develop and provide generic tools for collection of minimum transfusion outcome and patient outcome data at national level
2. Develop and provide tools for clinical transfusion audits
3. Collect global data on blood use and transfusion outcome
4. Establish global observatory on transfusion data
5. Modify 'WHO Aide-Memoire on 'Clinical Use of Blood'' to get patient management and clinicians' perspectives
6. Promote and support research on inappropriate blood use in developing countries
7. Share opinions and information through WHO Global Forum on Blood Safety and expand to involve multiple clinical disciplines
8. Review WHO list of essential medicine to include agents to reduce need for blood transfusion
9. Disseminate information on best transfusion practices
10. Develop patient-oriented handbooks on blood use
11. Promote and support evidence based reviews
12. Promote and support research on other transfusion modalities (e.g., Washed v Unwashed red cells) during intra-operative cell salvage
13. Develop key performance indicators
   a. functioning HTC
   b. clinical transfusion process
14. Develop generic curriculum for nurse and medical students on blood use
15. Acknowledge countries providing data to promote the countries not currently providing data
National Priorities

The Commission leads and coordinates improvements in safety and quality in health care across Australia, including the promotion, support and encouragement of the implementation of safety and quality initiatives.

A collaborative and consultative approach is undertaken in priorities of the health system that benefit from national coordination. Under its legislation the Commission has wide ranging functions that also include the formulation of safety and quality standards and indicators.

National Patient Blood Management Collaborative

The Commission has been engaged by the Department of Health to lead the National PBM Collaborative, in consultation with the National Blood Authority and the states and territories, to promote appropriate care in relation to the use of blood across Australia.
Patient Blood Management Guidelines: Module 2 - Perioperative

Development of this module was achieved through clinical input and expertise of representatives from the Colleges and Societies listed below and an independent consumer advocate (see Appendix A).

Australian College for Emergency Medicine
Australian and New Zealand College of Anaesthetists
Australian and New Zealand Intensive Care Society
Australian and New Zealand Society of Blood Transfusion
Australian Orthopaedic Association
Australian Red Cross Blood Service
College of Intensive Care Medicine of Australia and New Zealand
Haematology Society of Australia and New Zealand
Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
Royal College of Nursing Australia
Royal College of Pathologists of Australasia
Thalassaemia Australia

The National Blood Authority gratefully acknowledges these contributions. College and Society endorsement of this Module can be found at http://www.nba.gov.au

Funding, Secretariat and Project Management was provided by the National Blood Authority Australia. The systematic review methods, writing of the document or development of the final recommendations and practice points have not been influenced by the views or interests of the funding body.
3.2 Effect of anaemia on outcomes

Question 4 (Aetiological question) (GNQ1)
In patients undergoing surgery, is anaemia an independent risk factor for adverse outcomes?

Preoperative anaemia is independently associated with an increased risk of morbidity and mortality.

3.3 Effect of red blood cell transfusion on outcomes

Question 5 (Interventional question) (GNQ2)
In patients undergoing surgery, what is the effect of RBC transfusion on patient outcomes?
RBC, red blood cell

In cardiac & non-cardiac surgery, RBC transfusion is independently associated with increased morbidity & mortality. This relationship is dose dependent.

Preoperative anaemia is associated with increased hospital length of stay in non-cardiac surgery

In cardiac & non-cardiac surgery, RBC transfusion is associated with significantly longer stays in hospital and ICU.
National Safety and Quality Health Service Standards

September 2012

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTHCARE

NSQHS STANDARDS

2012

Standard 7
Blood and Blood Products
Safety and Quality Improvement Guide

October 2012

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTHCARE

NSQHS STANDARDS

SOUTHERN OCEAN

AUSTRALIA REPORT MAP
Produced by the Australian Surveying and Land Information Group (AUSLIG)
A business unit of the Department of Administrative Services
PO Box 3, Belconnen, ACT, 2615 Telephone: 1800 800 175
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HYPOMETRIC

Population areas:
Greater than 1 000 000
100 001 - 1 000 000
20 001 - 100 000
Less than 20 000
Population figures based on 1991 Census data
Core Project Team
- Hans Gombotz, Linz
- Axel Hofmann, Zurich
- Kai Zacharowski, Frankfurt
- Günter Schreier, Graz
- Peter Kastner, Graz

Expert Panel
- Philippe Van der Linden, Brussels
- Donat Spahn, Zurich
- Peter Rehak, Graz
- Astrid Nørgaard, Copenhagen
- Shannon Farmer, Perth
- Jens Meier, Linz
- Johann Kurz, Vienna

Teaching Hospitals
- Rigshospitalet / University Hospital Copenhagen
  Astrid Nørgaard
- University Hospital Centre, Zagreb
  Branka Golubić-Čepulić
- Hospital Universitario de Santa Maria, Lisbon
  Hugo Pinto Vilela, Lucindo Ormonde
- Medical University of Vienna / Vienna General Hospital
  Klaus Markstaller
- Universitätsklinikum Frankfurt
  Kai Zacharowski

EU-PBM
Supporting Patient Blood Management (PBM) in the EU
A Practical Implementation Guide for Hospitals

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety
Directorate B - Health systems, medical products and innovation
Unit B.4 - Medical products: quality, safety, innovation

Authors
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www.ait.ac.at / www.europe-pbm.eu
Building national programmes of Patient Blood Management (PBM) in the EU

A Guide for Health Authorities

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
Directorate B - Health systems, medical products and innovation
Unit B.4 - Medical products: quality, safety, innovation

Authors
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www.ait.ac.at / www.europe-pbm.eu
Donabedian’s quality framework: Ensuring PBM as the new standard of care

What is the public health care structure to care for the patient?  
Quality of Structure

What is done to the patient?  
Quality of Process

What happens to the patient?  
Quality of Outcome

Structural deficits represent major obstacle for health-system wide PBM implementation

Numerous hospitals worldwide including some EU-PBM pilot sites with well coordinated PBM processes

Evidence demonstrates improved outcome and patient safety with PBM

Identifying PBM gaps with Donabedian’s model

Find more under chapter 4
Structural problems

• PhD students - Structural Challenges

• PhD Students- Educational Challenges
1. Create urgency for PBM
2. Form a powerful PBM group as guiding coalition
3. Create a vision for PBM
4. Communicate the PBM vision
5. Empower the PBM group and remove obstacles
6. Create short-term wins of PBM
7. Build on the change
8. Anchor PBM in culture
a. PBM requires a basic data set

Figure 4. Step 1: Mandatory introduction of basic key performance indicators (KPI) for inpatients: RBC transfusion rate, transfusion index and rate of patients admitted with and/or operated with anaemia.
PBM project feasibility

STEP II: Advanced KPIs

EPAS
Electronic Patient Administration System

LIS
Laboratory information System

TIS
Transfusion Information System

Key information
- Patient demographics
- Admission data
- ICD Diagnoses & procedures
- Patient outcomes
- Transfusion data (type, units)
- Lab values (pre/post transfusion)
- Lab values (admission/discharge)

Advanced KPIs for in- and outpatients
- Transfused units (RBC, FFP, PLT, Cryo) per 1000 discharges
- Anaemia rate at admission and discharge
- Rate of single RBC units transfused
- Mean RBC transfusion triggers and targets
- Mean pre/post PLT transfusion platelet counts
- Mean pre/post FFP transfusion INR counts

Figure 5. **Recommended integration of different data sources to provide advanced KPIs which allow continuous surveillance of the utilisation of blood and blood components (RBC, FFP, PLT, Cryoprecipitate)** (144, 145).
PBM and the Transfusion Establishment: Threat or Opportunity?
Huge opportunity to take on a proactive role in PBM:

Avoiding anaemia and bleeding disorders in general and particularly prior to hospitalizations.
• Anaemia detection & management centers
• PBM experts/consultants
• PBM nurses
• PBM monitoring, data management and benchmarking
• PBM outcomes research
• PBM education
• PBM online training courses/CME
• PBM certification
The Global Health Care Crisis
Health Care Expenditures - All Providers (selected countries)

OECD Health Data 2017

Competing with
- Housing
- Food
- Transportation
- Education
- Recreation
- Energy
- Insurance
- Social welfare ...
Health Care Expenditures - All Providers (selected countries)

OECD Health Data 2017
The Current Imperative: Improve Productivity
The Cost of Health Care
How much are we spending?

$2.5 Trillion
spent in the U.S. on health care in 2009

$1 Billion
The Cost of Health Care
How much is waste?

$765 Billion
30% of 2009 total health care spending

Source: Data from workshop presentations and discussions summarized in The Healthcare Imperative
The Cost of Health Care
How much is waste?

- Unnecessary Services: $210 Billion
- Excessive Administrative Costs: $190 Billion
- Fraud: $75 Billion
- Inefficiently Delivered Services: $130 Billion
- Prices That Are Too High: $105 Billion
- Missed Prevention Opportunities: $55 Billion

Source: Data from workshop presentations and discussions summarized in The Healthcare Imperative.
<table>
<thead>
<tr>
<th>Industry</th>
<th>Productivity improvement rates, 1990–2007, %</th>
<th>Average growth in employment, %</th>
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<tr>
<td>Computers and semiconductors</td>
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<td>1.4</td>
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<tr>
<td>Internet and data processing</td>
<td>7.2</td>
<td>1.0</td>
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<td>Telecom services and broadcasting</td>
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<td>0.8</td>
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<td>Retail trade</td>
<td>4.0</td>
<td>1.0</td>
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<tr>
<td>Information, other</td>
<td>3.8</td>
<td>0.9</td>
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<td>Wholesale trade</td>
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<td>Utilities</td>
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<td>Finance</td>
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<td>1.0</td>
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<tr>
<td>Manufacturing (excluding computers)</td>
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<td>–1.3</td>
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<tr>
<td>Transportation</td>
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<td>1.7</td>
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<tr>
<td>Real estate and leasing</td>
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<td>Professional and business services</td>
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<td>Recreation, hotels, and restaurants</td>
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<td>Mining</td>
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<td>Other services</td>
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<td>Healthcare</td>
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</tr>
</tbody>
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Source: Bureau of Economic Analysis; Centers for Medicare and Medicaid Services; Haver Analytics; McKinsey analysis
A Guide to Productivity: Cost-effectiveness
Cost-Effectiveness Concept

Costs ($)

$100,000

$50,000

Outcome

Prime Quadrant

No-go Quadrant

A

B

C

Outcome

1

2
Cost-Effectiveness Concept

Costs ($)

Outcome

Prime Quadrant

Unnecessary Services $210 Billion
Excessive Administrative Costs $190 Billion
Prices That Are Too High $105 Billion
Fraud $75 Billion
Inefficiently Delivered Services $130 Billion
Missed Prevention Opportunities $55 Billion

A
B
C
D
E

-$50,000

1
2
A huge missed opportunity:
As a standard of care, managing the patients’ own blood rather than resorting to donor blood!

⇒ PATIENT BLOOD MANAGEMENT
Summary
Anaemia, blood loss and transfusion are modifiable risk factors for adverse outcomes.

- **PBM addresses these risks:**
  - Reduced mortality
  - Reduced morbidity
  - Reduced transfusions, thus leading to improved safety
  - Reduced LOS
  - Less cost

- PBM recommended as STANDARD OF CARE by the WHO, EC/EU, NBA, NHS, ESA, EBA, ACSQHC, SABM, IFPBM, AABB, ARC Blood Service and others
PBM SA

- Guiding Coalition- Publication
- IT infrastructure integration
- Guidelines
- Training of Blood service PBM champions
- Creating awareness National, Provincial, Private, Patient groups
- Visit NBA
- Congress
- Research projects
- Training pre-graduate and post graduate level
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Vernon Louw, MBChB(Stell), MMed (Int Med)(Stell), PhD(HPE)(UFS)
Cristina Lundgren, MB, ChB; FFA (SA); PhD; MSc Med, Health Law and Bi
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