

7<sup>^</sup>

# Conferenza Nazionale dei Servizi Trasfusionali

Vicenza | 24-26 maggio 2023



## Cos'è realmente il PBM?

*Sergio D'Antico*

*S.C. Banca del Sangue e Immunoematologia*

*A.O.U. Città della Salute e della Scienza di Torino*

Il sottoscritto, **Sergio D'Antico**, in qualità di Relatore dichiara che

*nell'esercizio della Sua funzione e per l'evento in oggetto, NON È in alcun modo portatore di interessi commerciali propri o di terzi; e che gli eventuali rapporti avuti negli ultimi due anni con soggetti portatori di interessi commerciali non sono tali da permettere a tali soggetti di influenzare le sue funzioni al fine di trarne vantaggio.*



# PBM: un cambio di mentalità?



“I concetti più difficili possono essere spiegati all'uomo più lento di comprendonio se non ne ha già un'idea; ma la cosa più semplice non può essere chiarita all'uomo più intelligente se è fermamente convinto di sapere già, senza ombra di dubbio, ciò di cui si parla.”

Leo Tolstoy

The following was the year before Karl Landsteiner discovered the ABO blood groups

INTERCOLONIAL MEDICAL CONGRESS OF AUSTRALASIA.

FIFTH SESSION.

BRISBANE, QUEENSLAND.

SEPTEMBER, 1899.

SECTION OF MIDWIFERY AND GYNÆCOLOGY.

THE SAVING OF BLOOD IN GYNÆCOLOGICAL OPERATIONS.

BY ARCHIBALD WATSON M.D. PARIS, F.R.C.S. ENG.,  
Professor of Anatomy and Physiology in the Adelaide University.

MR. PRESIDENT,—

Dr. Byrne, the courteous secretary of your Section, has paid me the compliment of inviting me to make some remarks on the saving of blood in gynæcological operations within the pelvis, on the principle, I presume, that "spectators see most of the game." Often, however, I have only appeared on the scene after the game was quite over, and in my opinion this latter factor should make any comments from one outside of your ranks appear less trivial than they otherwise might.

# The New England **1936** Journal of Medicine

VOLUME 215

SEPTEMBER 3, 1936

NUMBER 10

The Massachusetts Medical Society

SECTION OF MEDICINE

Lower Section Room, Municipal Auditorium, Springfield,  
Tuesday, June 9, 1936, 2 p. m.

**PRESIDING:**

Dr. William D. Smith, Boston, Chairman.  
Dr. Laurence B. Ellis, Boston, Secretary.

**CHAIRMAN SMITH:** Will the meeting please come to order.

The first duty of the Section is the selection of the Chairman and the Secretary for the coming year, and, in accordance with the usual custom, the Chair will appoint as the Nominating Committee to suggest names Dr. Dwight O'Hara, Chair-

man, Dr. George R. Minot and Dr. Chester M. Jones. They will report later and abide the pleasure of the Section.

I do not see Dr. Hamilton here. Apparently she is delayed, so we will pass on to the second paper. To those of us who have had our moments of indecision whether to transfuse or not to transfuse in some of our medical problems, Dr. Bock's paper should be of interest. His subject is "The Use and Abuse of Blood Transfusions."

## THE USE AND ABUSE OF BLOOD TRANSFUSIONS\*

BY ARTHUR V. BOCK, M.D.

**T**HE mass of literature on the subject of blood transfusions accumulated during the past twenty-five years is so great and most of it so readily available that one shows lack of temerity at least to attempt a discussion of the subject before this audience. The transfusion of blood may be a life-saving procedure under certain circumstances, it may be a necessary supportive measure under others, but it is too often undertaken when the doctor can think of nothing else to do after all other therapy has failed. My objective today is to discuss briefly the common surgical and medical conditions for which transfusion of blood is indicated, in which we can expect good physiological results, and to point out those conditions in which it is little more than a gesture, done, as it were, to satisfy the urge to do something.

SURGICAL INDICATIONS

plish two things, restoration of diminished blood volume and elevation of low blood pressure. Blood volume may be reduced by gross hemorrhage or it may be reduced by blood lost in the periphery of the body, as suggested by Freeman,<sup>2</sup> or by extravasation of serum through damaged capillaries. If hemorrhage has occurred, transfusion of blood, together with such supportive measures as heat, is the immediate indication. No other therapy is so successful. In shock without much or any hemorrhage, 6 per cent gum acacia in normal saline may be just as effective as blood, and has the advantage of greater availability. Repeated transfusions of blood or infusions of acacia may be necessary but, are usually not, if no delay has occurred in the first instance. Acacia may be used as a supportive measure until transfusion can be arranged. Prolongation of the shock state results in tissue anoxia, capillary dam-

... The trasfution of blood may be a life-saving procedure under certain circumstances, it may be a necessary supportive measure under orthers, but it is too often undertaken when the doctor can think of nothing else to do after all other therapy has failed. ...

The number of patients that are reported here indicates that this adverse effect may be occurring more frequently than is recognized generally. In 1978, Thien et al.<sup>3</sup> reported that three of 30 patients who were treated with prazosin developed incontinence but the paucity of reported cases since makes a 10% incidence most unlikely. Voluntary reports to an adverse drug reaction reporting scheme can not be used to calculate the incidence of adverse effects for the reporting is incomplete and, in Australia, the prescribing base is not known. However, prazosin was the 33rd most-commonly prescribed drug in the Australian Pharmaceutical Benefits scheme in 1984/1985; 1.165 million prescriptions were dispensed in a 12-month period. Some of the reports of incontinence may have been stimulated by publicity in Australia through the *Australian Adverse Drug Reactions Bulletin*,<sup>7</sup> but 16 of the reports had been received before its distribution.

Urinary incontinence is an infrequent adverse effect of drugs and, in a recent review, only neuroleptic agents and drugs that affected the alpha-adrenergic receptor (phentolamine, phenoxybenzamine, methyldopa, reserpine and prazosin) are mentioned.<sup>1</sup> In addition, recent reviews of urinary incontinence<sup>8</sup> have not mentioned drugs as a cause of incontinence even when the focus has been on patients

who have suffered a stroke who presumably have a high prevalence of hypertension.<sup>9</sup>

On the basis of the Australian experience, caution is suggested in the use of prazosin in elderly women. Urinary incontinence that develops in a patient who is taking prazosin is an indication for dosage reduction or drug withdrawal and will usually result in a return to continence.

#### Acknowledgements

This report was made possible by voluntary reporting to ADRA. Thanks are due to members of ADRA for assistance in preparation of this report.

#### References

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  8. Anonymous. Urinary incontinence in elderly patients [Editorial]. *Lancet* 1986; 2: 1316-1317.
  9. Currie CT. Urinary incontinence after stroke. *Br Med J* 1986; 293: 1322-1323.
- (Received July 17; accepted September 6, 1987)

## POINT OF VIEW

### The paradigm shift in blood transfusion

Since the discovery of the ABO blood-group system in 1900 by Karl Landsteiner, the history of blood transfusion has been one of continual progress, albeit with fits and starts, particularly in times of war. The collection, preservation and fractionation of blood is now a sophisticated science which was accepted until recently by donors, medical practitioners and patients as one of the most essential, well run and safe forms of medical therapy.<sup>1</sup> Since the development of blood banks, the provision of blood and blood products in most countries of the world has been dominated by the centralist bodies, with the system revolving around the donor.

James P. Isbister

from the donor to the recipient.

It is important to remember that in the early days of blood transfusion the procedure revolved around the patient's needs, but the donor was involved intimately in the process; the clinician was responsible for both the donor and the recipient, and on many occasions he or she can performed the blood-compatibility testing also. We see in those early days of blood transfusion the ultimate physical link between the donor and the recipient, which was necessary



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**Acknowledgements**

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**References**

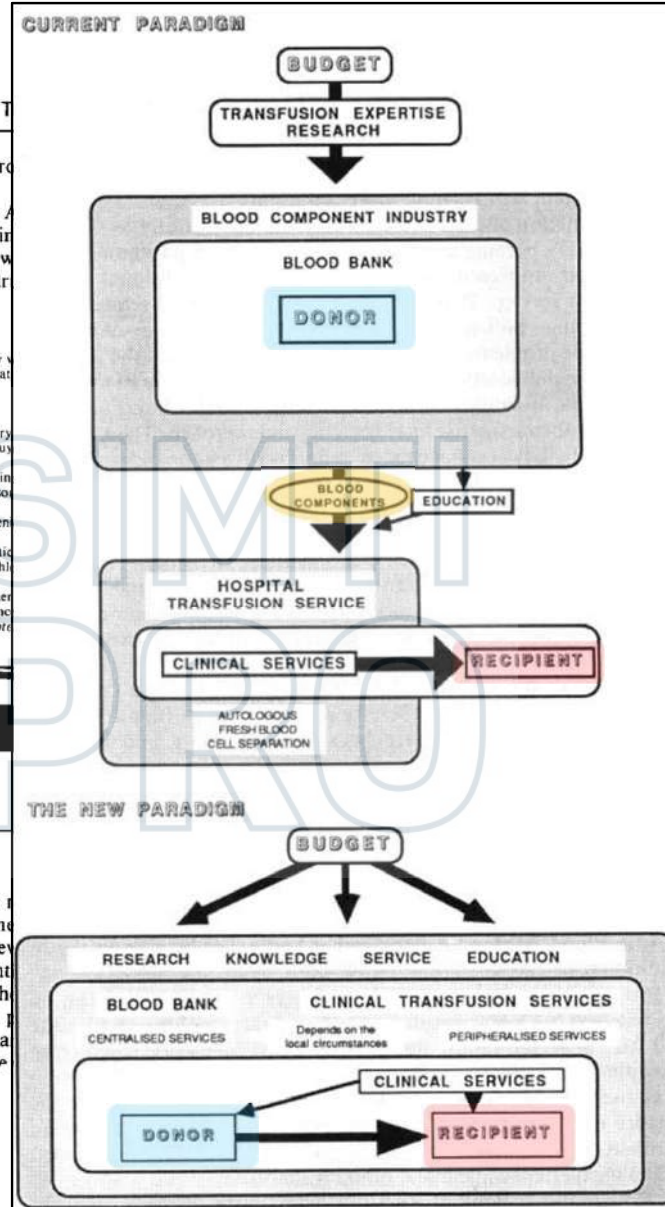
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  8. Anonymous. Urinary incontinen
  9. Currie CT. Urinary incontinenc
- (Received July 17; accepted Septe

**POINT OF VIEW**

**The paradigm shift in blood transfusion**

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## Patient blood management: the global view

*Aryeh Shander,<sup>1,2</sup> James Isbister,<sup>3</sup> and Hans Gombotz<sup>4</sup>*

change models

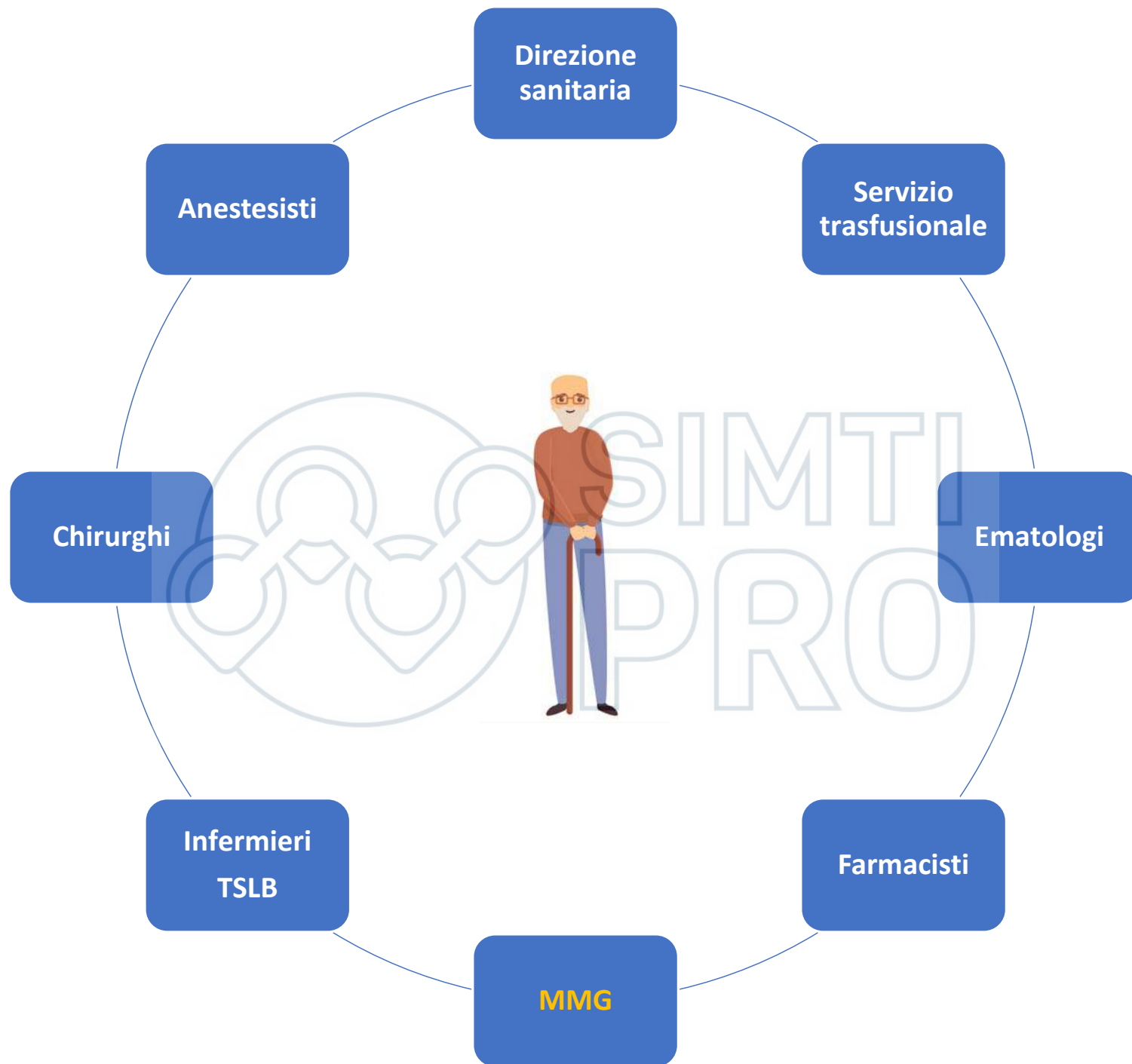
Lewin

Kotter

In the past, various change management models (especially for business and industry) have been created.<sup>57-65</sup> One early model of change, which was developed by the German-American psychologist Lewin,<sup>66</sup> served as a basic concept for Kotter's model.<sup>61,67</sup> Lewin described change as a three-stage process: he called the first stage "unfreezing," the second stage "change," and the third and final one "freezing." John Kotter's eight-step model,<sup>68</sup> on the other hand, integrates more important elements that are common in change management processes. It has already been successfully applied in many organizations in the industrial sector and, specifically, it aims to integrate the PBM concept in the Western Australia patient blood management program.<sup>69</sup> Thus, Kotter's model was chosen to be used to create the European PBM implementation guide.<sup>61</sup> His overarching concept will determine all the clinical and organizational measures to be adopted and adapted to the particular institutions.<sup>60,61,70</sup>



# **PBM: necessità / opportunità di interazione multidisciplinare?**



## Patient blood management in Europe

A. Shander<sup>1\*</sup>, H. Van Aken<sup>2</sup>, M. J. Colomina<sup>3</sup>, H. Gombotz<sup>4</sup>, A. Hofmann<sup>5</sup>, R. Krauspe<sup>6</sup>, S. Lasocki<sup>7</sup>,  
 T. Richards<sup>8</sup>, R. Slappendel<sup>9</sup> and D. R. Spahn<sup>10</sup>

**Table 1** Estimates of preoperative anaemia prevalence and transfusion rates in orthopaedic surgery patients in selected European countries. ESA, erythropoiesis-stimulating agents; Hb, haemoglobin; THR, total hip replacement; TKR, total knee replacement

Country	Prevalence of preoperative anaemia	Frequency of transfusion use
Austria	16–18%	TKR=41.3% (varied from 12% to 87% between centres); THR=42.5% (varied from 16% to 85% between centres); <10% receive predonated autologous blood; patients with anaemia receive 2 × amount of blood received by those without anaemia
France	Estimate: ~20% (no precise data)	Estimate: ~40% (despite ESA use)
Germany	Not known	Not known
Spain	In general, 18.3% (but almost one-third of patients have Hb levels of <13 g dl <sup>-1</sup> ) <sup>91</sup>	Transfusion risk (varies among centres): Hb ≤10 g dl <sup>-1</sup> : 93.2%; Hb=14 g dl <sup>-1</sup> : 19.75%; Hb=13 g dl <sup>-1</sup> : 40%
Switzerland	Estimates in selected centres: 16–21%	Estimates in selected centres: primary repair: 19–22%; repeat operations: 30–40%
The Netherlands	Estimate of anaemia (Hb levels of <13 g dl <sup>-1</sup> ): 15–20% for major orthopaedic surgery	TKR<2%; THR<5%
UK	<12 g dl <sup>-1</sup> in 15% and <13 g dl <sup>-1</sup> in 37% of patients (within 28 days of surgery)	57% of patients with a preoperative Hb level of <12 g dl <sup>-1</sup> ; 20% of patients with a preoperative Hb level of ≥12 g dl <sup>-1</sup>

**Pre-operative anaemia:  
prevalence, consequences and approaches to management**

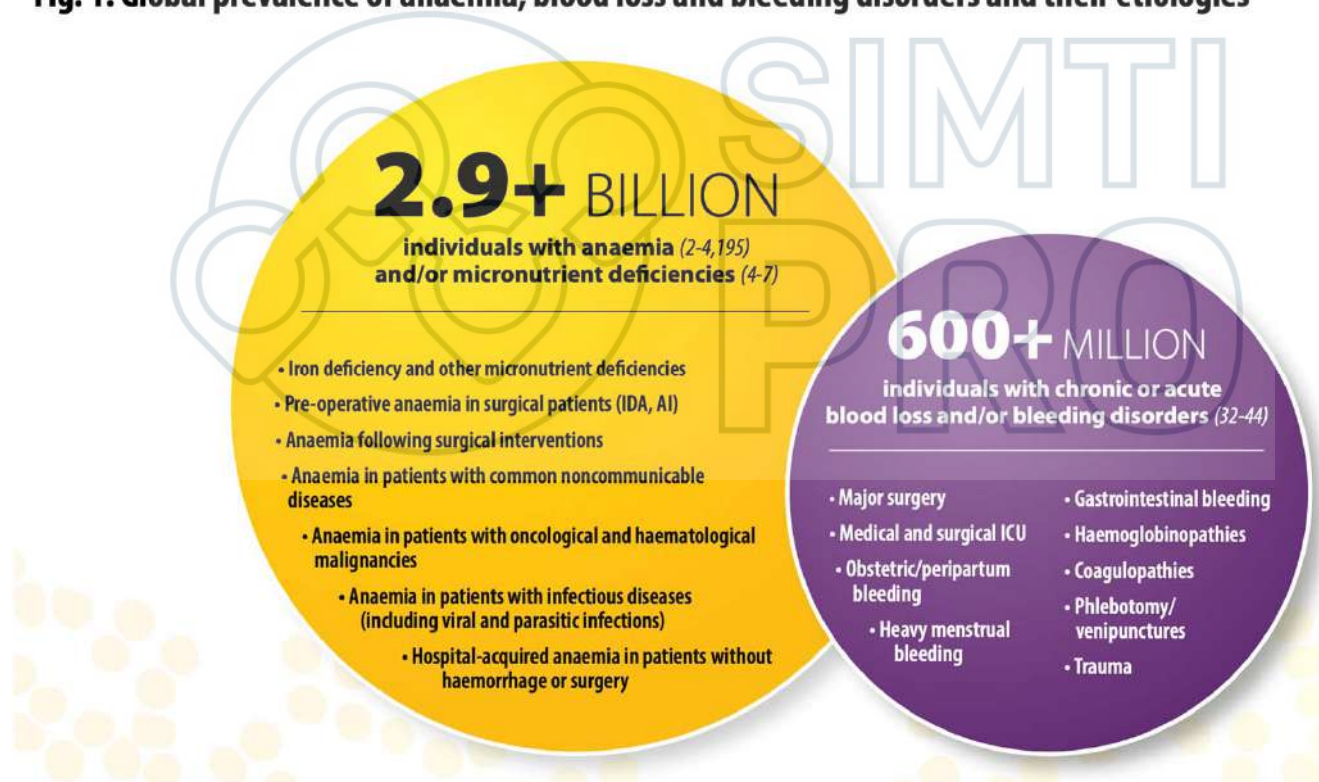
Manuel Muñoz<sup>1</sup>, Susana Gómez-Ramírez<sup>2</sup>, Arturo Campos<sup>3</sup>, Joaquín Ruiz<sup>3</sup>, Giancarlo M. Liumbruno<sup>4</sup>

... In **18** large observational studies encompassing over **650,000** surgical patients, the mean prevalence of pre-operative anaemia was around **35%**, varying between **10.5%** and **47.9%**



## “THE URGENT NEED TO IMPLEMENT PATIENT BLOOD MANAGEMENT”

Fig. 1. Global prevalence of anaemia, blood loss and bleeding disorders and their etiologies





Critchley HOD, Munro MG, Shakur-Still H, Roberts I.

## Menstruation should not be overlooked in control of anaemia.

Lancet. 2021;397:26.

Mansour D, Hofmann A, Gemzell-Danielsson K.

## A review of clinical guidelines on the management of iron deficiency and iron-deficiency anemia in women with heavy menstrual bleeding.

Adv Ther. 2021;38:201–225.

➔ Target WHO per il 2025: riduzione del 50% delle donne con anemia

# NO WOMAN NEED BECOME ANAEMIC

Most women are anaemic at some time in their lives, though it is not nearly so common as it used to be. Gone are the wan, romantic maidens of Queen Victoria's time.

**HELP FOR HOUSEWIVES by Clair Isbister.**



*Australian doctor and housewife. This is our third extract from her book, "What is Your Problem, Mother?"*

There is no need now for any Australian to go without the essentials or normal blood formation, but many still do — some through ignorance, some because they prefer rich things as alcohol, and most through carelessness.

The housewife often feeds her family, then settles down to a cup of tea and a slice of bread and jam, poor stuff for making good red blood!

Besides, anaemia is twice as common in women and adolescent girls as in men.

Anaemia really means a shortage in the red blood cells (the red pigment, haemoglobin, which carries oxygen) over the body. There may be insufficient red blood cells or insufficient red pigment in each.

The red cells are manufactured in the bone marrow from a variety of substances, one of which are made in other parts of the body, while others are taken in the diet.

**Difficulties**

There can be difficulties in manufacture, and absence of certain essentials can stop production.

Even if the manufacturing process is perfect, many things can happen to the cells: certain germs, drugs, and chemicals may destroy blood, and a common problem is blood loss from ulcers in the stomach or duodenum, from piles, and even heavy periods.

There are also times in our lives when there are greater demands on our blood, and it becomes extremely important that our bodies should be supplied with the right materials.

If I tell you something about these times and about the right materials, you will be better off than if I give you a long list of symptoms and say, "Go to the doctor if you get one."

After all, lots of very pale women have quite red lips, even without their lipstick, and are not anaemic at all.

And quite a lot of women who feel a bit tired and short of wind, and secretly imagine that they "have a beast," are suffering from anaemia that could be easily treated by attention to their diet.

You may be rather shocked to hear it, but liver injections are so good as a tonic.

Recent research work has established that liver and vitamin B<sub>12</sub> injections, which were once considered to have a general tonic effect, really have none.

Patients who were given injections of water did just as well as those who had liver injections or B<sub>12</sub>, provided they all got a diet containing the essentials and believed they were getting the tonic.

The periods in life that make special demands on blood supplies include those of most active growth—infancy and adolescence.

The baby grows very fast from birth to two years, and anaemia is common, particularly in premature babies, twins, and children who have had a lot of infections, even just colds.

Milk, with its low iron content, is often their main article of diet, so you must be alert to the results of infections and the need for the dietary extras.

At puberty bodies demand extra iron and calcium and protein for growth, and there's actually a big increase in the quantity of their blood.

All girls from puberty onwards lose blood regularly with their monthly periods; not a great deal of blood, and nothing that a normal girl can't cope with.

However, the blood has to be replaced, and the girls who are overworking or careless with their diet, and harassed

young mothers may not always get the essentials.

Then there is pregnancy and lactation. Babies get all their body-building substances from their mothers.

During birth the mother loses more blood, and while she feeds the baby at the breast she passes sufficient iron into the milk to give her baby enough.

Artificially fed babies, on cow's milk for five months without extra food, often get anaemic because nature didn't arrange for a cow to add this extra iron to milk. Her calf goes out and chews grass at a very tender age.

It is estimated that the process of carrying, bearing, and feeding a child needs a third of the mother's iron and she has to supply it to the baby.

The baby of an anaemic mother is not anaemic at birth, because nature sees that it gets its requirements, but it soon becomes anaemic later on owing to a lack of reserves of iron.

What do we need for making blood? I've mentioned iron several times, but the research chemists have identified many other substances that the body itself cannot make but which are needed.

They include vitamin B<sub>12</sub>, folic acid, unknown factors that occur in yeast and liver, certain fats, and metals such as iron, copper, and cobalt.

Don't think you should suck pennies, or have vitamin B<sub>12</sub> injections. Most of these substances are needed in very small quantities and a good diet of meat, eggs, liver, cheese, and wholemeal cereals contains them all.

In certain illnesses, when food is not being properly absorbed from the bowel, folic acid or vitamins, for instance, may have to be added.

If the anaemia has already developed, single essential substances may have to be replaced in bigger quantities than the diet can supply.

But that is the doctor's job; just now I am talking about prevention.

Other substances are needed for the body to be able to use the essential materials.

You need vitamin C and the vitamin B group, and certain proteins.

To supply vitamin B, Vegemite, Marmite, and wholemeal bread are easy to get; oranges and tomatoes provide vitamin C.

Blood-making isn't just a matter of chemistry. Hormones are very important; thyroid, ovaries, pituitary, and adrenal glands all work together in harmony, and a discord can cause anaemia.

Many middle-aged women have a mild thyroid deficiency and the strange anaemia of Victorian times, which used to affect young girls so severely that they died, was partly due to iron deficiency, but also to some ovarian disturbance at puberty.

**Not silly**

It may sound silly, but it is true that happiness and emotional balance matter probably as much as balanced diet in preventing anaemia.

I must sound a funny doctor warning people against pills and potions, but I am talking about preserving health and preventing anaemia.

I prescribe iron pills for iron-deficiency anaemia, and injections for pernicious anaemia just the same as other doctors.

And I don't disapprove of those extra vitamins in hot milk at examination time or some extra iron and vitamins during pregnancy.

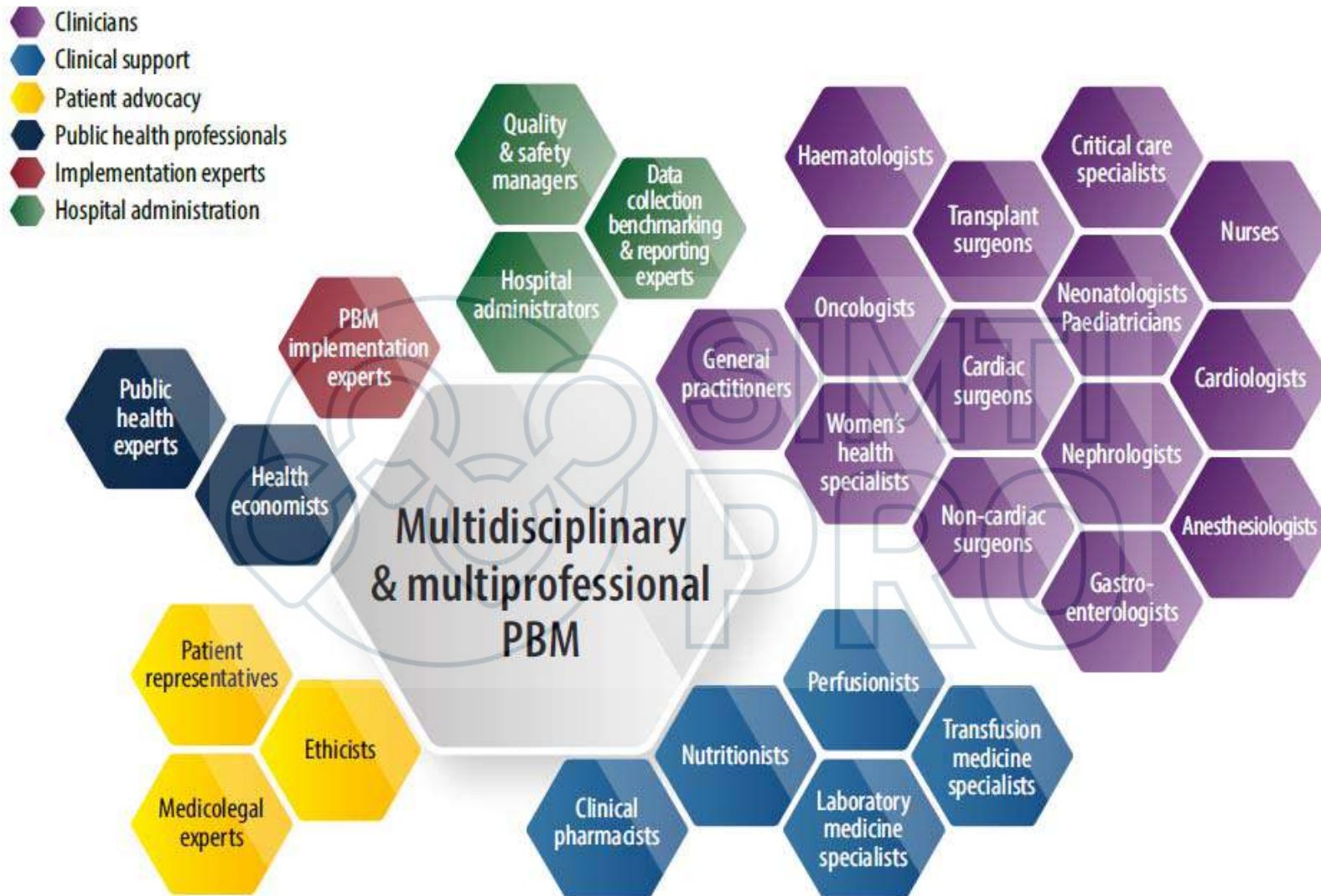
I'm pointing out that there are still many essential substances in the good food provided by nature that the scientists don't know about yet, so don't pin your faith on pills and tonics and refined foods.

July 23, 1958

PRICE 9

THE AUSTRALIAN Women's Weekly

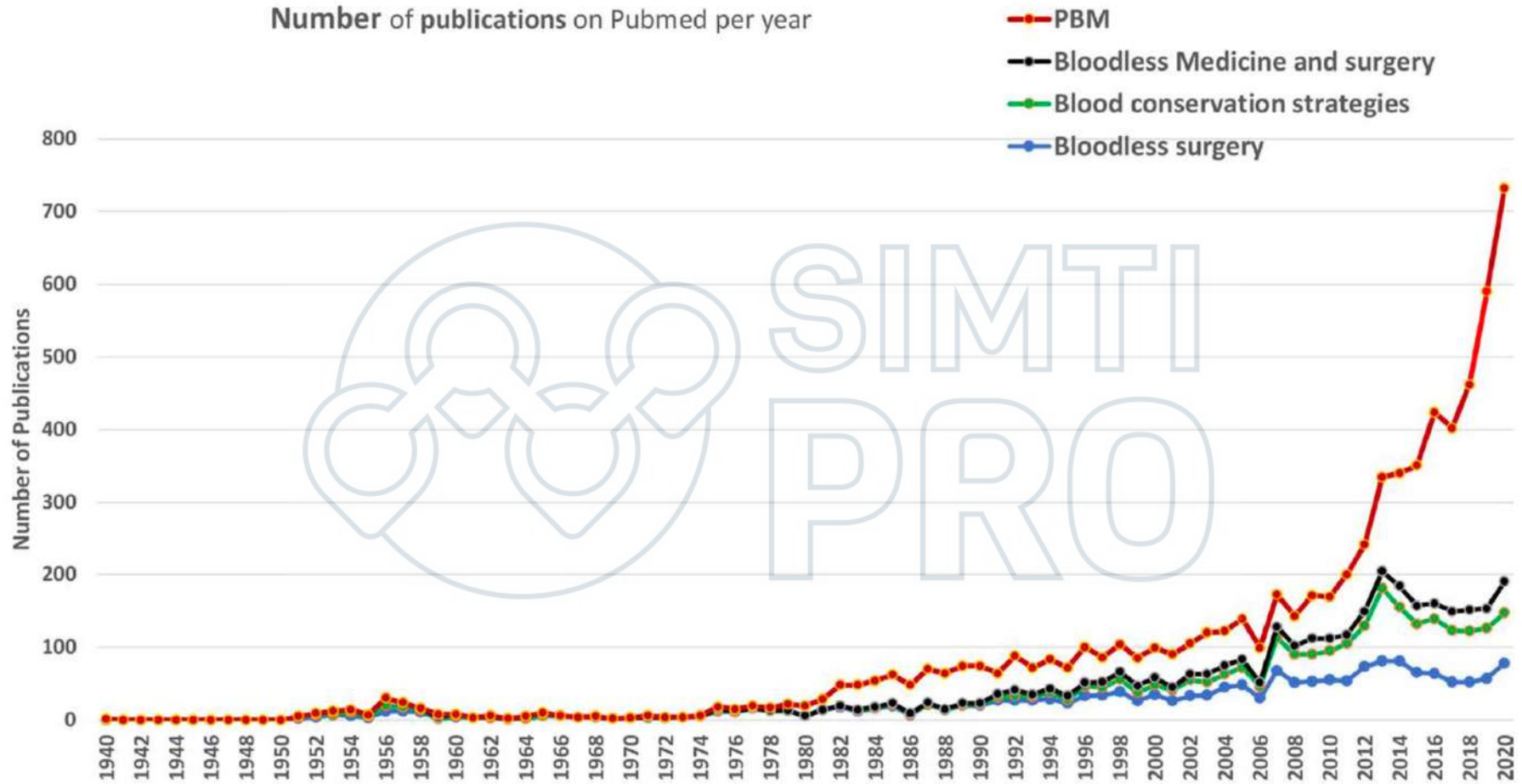
**Fig. 4. Stakeholders in multidisciplinary and multiprofessional PBM**





# PBM: evidence based medicine?





## Patient blood management in Europe

A. Shander<sup>1\*</sup>, H. Van Aken<sup>2</sup>, M. J. Colomina<sup>3</sup>, H. Gombotz<sup>4</sup>, A. Hofmann<sup>5</sup>, R. Krauspe<sup>6</sup>, S. Lasocki<sup>7</sup>,  
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- Evidence of the clinical and economic disadvantages of RBC transfusion in treating perioperative anaemia has prompted recommendations for its restriction and a growing interest in approaches that rely on patients' own (rather than donor) blood.
- Patient blood management aims to minimize the need for transfusion.
- Early detection and treatment of anaemia and minimizing blood loss are key strategies.

JAMA. 2019;321(10):983-997

**JAMA | Special Communication**

# Patient Blood Management Recommendations From the 2018 Frankfurt Consensus Conference

Markus M. Mueller, MD; Hans Van Remoortel, PhD; Patrick Meybohm, MD, PhD; Kari Aranko, MD, PhD; Cécile Aubron, MD, PhD; Reinhard Burger, PhD; Jeffrey L. Carson, MD, PhD; Klaus Cichutek, PhD; Emmy De Buck, PhD; Dana Devine, PhD; Dean Fergusson, PhD; Gilles Folléa, MD, PhD; Craig French, MB, BS; Kathrine P. Frey, MD; Richard Gammon, MD; Jerrold H. Levy, MD; Michael F. Murphy, MD, MBBS; Yves Ozier, MD; Katerina Pavenski, MD; Cynthia So-Osman, MD, PhD; Pierre Tiberghien, MD, PhD; Jimmy Volmink, DPhil; Jonathan H. Waters, MD; Erica M. Wood, MB, BS; Erhard Seifried, MD, PhD; for the ICC PBM Frankfurt 2018 Group

JAMA. 2019;321(10):983-997

**JAMA | Special Communication**

# Patient Blood Management Recommendations From the 2018 Frankfurt Consensus Conference

1. Preoperative Anemia Detection and Management
2. Iron Supplementation
3. Erythropoiesis-Stimulating Agents
4. Short-Acting Erythropoietins and Iron Supplementation
5. Restrictive ABT threshold (Hb<7.0 g/dL)
6. Restrictive ABT threshold (Hb<7.5 g/dL) in cardiac surgery
7. Restrictive ABT threshold (Hb<8.0 g/dL) in HIP fracture & cardiovasc. dis.
8. Restrictive ABT threshold (Hb<7-8 g/dL) Acute Gastrointestinal Bleeding
9. PBM Programs Implementation
10. Decision Support Systems



# Evidence-Based Medicine: Principles and Values as Illustrated by the Case of Patient Blood Management

Hans Van Remoortel<sup>1,2</sup> Emmy De Buck<sup>1,2</sup> Erhard Seifried<sup>3,4</sup> Philippe Vandekerckhove<sup>2,5,6</sup>

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Hamostaseologie 2023;43:16–21.

## Evidence-Based Medicine: Principles and Values as Illustrated by the Case of Patient Blood Management

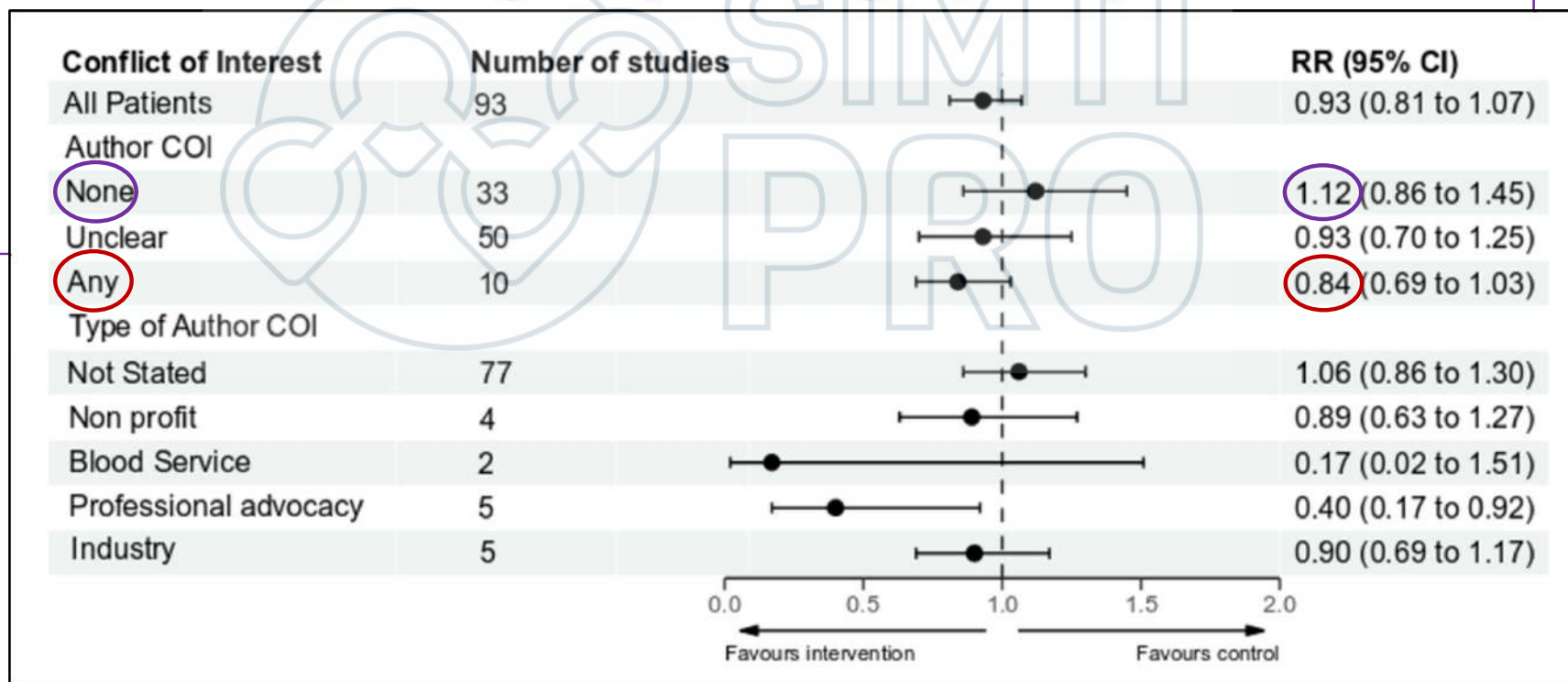
Hans Van Remoortel<sup>1,2</sup> Emmy De Buck<sup>1,2</sup> Erhard Seifried<sup>3,4</sup> Philippe Vandekerckhove<sup>2,5,6</sup>

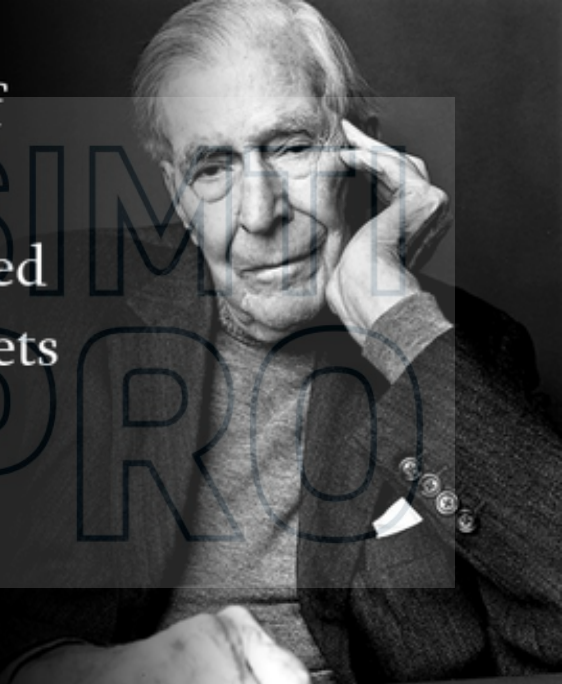
<sup>1</sup>C without erythro-stimulating agents (ESAs). The best available scientific evidence today  
<sup>2</sup>B indicates that preoperative intravenous (IV) or oral iron monotherapy may not be  
<sup>3</sup>D effective to reduce RBC utilization (low-certainty evidence). Preoperative IV iron  
<sup>4</sup>H supplementation in addition to ESAs is probably effective to reduce RBC utilization  
<sup>5</sup>G (moderate-certainty evidence), whereas oral iron supplementation in addition to ESAs  
<sup>6</sup>In may be effective to reduce RBC utilization (low-certainty evidence). The adverse events  
<sup>U</sup> of preoperative oral/IV iron and/or ESAs and their impact on patient-important  
<sup>5</sup>D outcomes (morbidity, mortality, quality of life) remain unclear (very low-certainty  
<sup>H</sup> evidence). Since PBM is a patient-centered approach, emphasis on monitoring and  
<sup>U</sup> evaluation of patient-important outcomes in future research is urgently needed.  
<sup>6</sup>B Finally, the cost-effectiveness of preoperative oral/IV iron monotherapy is unproven,  
<sup>H</sup> whereas preoperative oral/IV iron in addition to ESAs is extremely cost-ineffective.

# BMJ Open Reporting conflicts of interest in randomised trials of patient blood management interventions in patients requiring major surgery: a systematic review and meta-analysis

Marius Roman <sup>1</sup>, Oluwatomini Fashina,<sup>1</sup> Sara Tomassini,<sup>1</sup>  
Riccardo G Abbasciano,<sup>1</sup> Florence Lai <sup>1</sup>, Toby Richards,<sup>2</sup> Gavin Murphy<sup>1</sup>

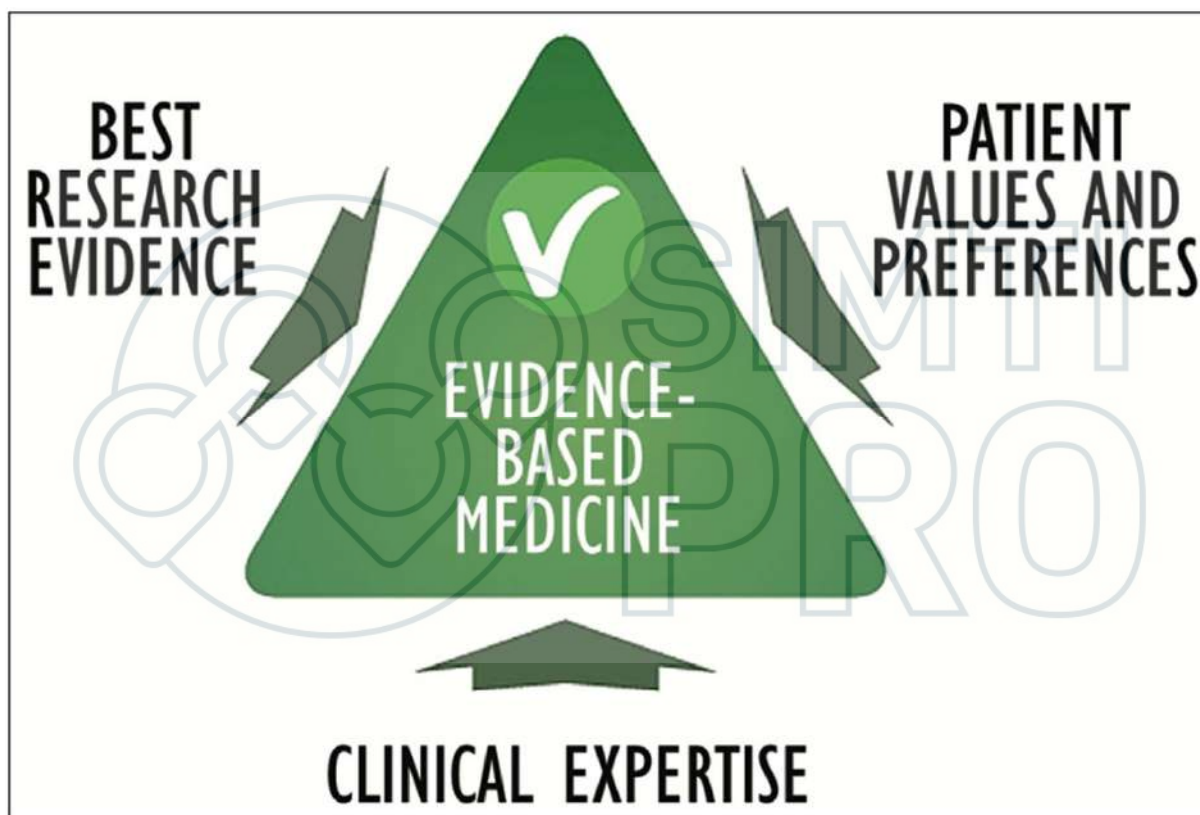
# BMJ Open Reporting conflicts of interest in randomised trials of patient blood management interventions in patients requiring major surgery: a systematic



A black and white portrait of John Kenneth Galbraith, an elderly man with glasses, resting his head on his hand. The image is partially obscured by a dark grey rectangular box containing text.

"Faced with the choice of  
changing one's mind and  
proving that there is no need  
to do so, almost everyone gets  
busy on the proof."

- John Kenneth Galbraith





# PBM: miglioramento dell'outcome?





# Errate convinzioni sulla terapia trasfusionale

- è tra le terapie più sicure
- è una terapia a basso costo
- ha un effetto immediato
- il paziente sta meglio



”Using diabetes mellitus as an example, management is not focused on **insulin** as the sole therapy given in response to an abnormality in the single laboratory parameter of **blood glucose**. Rather, a diverse group of health care professionals counsel the patient on nutrition and dietary management, exercise, and weight control.”



“...blood transfusions have been historically practiced as an **isolated therapy**, often by a practitioner not primarily responsible for the long-term health of the patient, without appropriate evaluation or risk-benefit assessment. This lack of stewardship and focus on transfusion as a therapy has resulted in minimal insight regarding **its effect on clinical outcomes**.”

RESEARCH

Open Access



# Pre-operative anemia and peri-operative transfusion are associated with poor oncologic outcomes in cancers of the esophagus: potential impact of patient blood management on cancer outcomes

Joseph P. Connor<sup>1\*</sup>, Eric Destrampe<sup>1</sup>, Daniel Robbins<sup>2</sup>, Aaron S. Hess<sup>1,3</sup>, Daniel McCarthy<sup>4</sup> and James Maloney<sup>4</sup>

RESEARCH

Open Access



# Pre-operative anemia and peri-operative transfusion are associated with poor oncologic outcomes in cancers of the esophagus: potential impact of patient blood management

**Objective** - 348 cases were analyzed. 64% of patients were anemic pre-operatively and 22% were transfused. Transfusion and anemia were closely related to each other. Transfusion but not anemia was associated with a protracted LOS. Transfusion and anemia were both associated with reduced survival however only anemia was associated with decreased survival in multi-variable modeling.

**Conclusions** - Pre-operative anemia and transfusion are closely associated, however only anemia was found to compromise survival in our esophageal cancer cohort, supporting the need for more aggressive evaluation and treatment of anemia. Adherence to restrictive transfusion guidelines offers an opportunity to reduce transfusion rates which may also improve short-term outcomes.

RESEARCH

Open Access



# Pre-operative anemia and peri-operative transfusion are associated with poor oncologic outcomes in cancers of the esophagus: potential impact of patient blood management on cancer outcomes

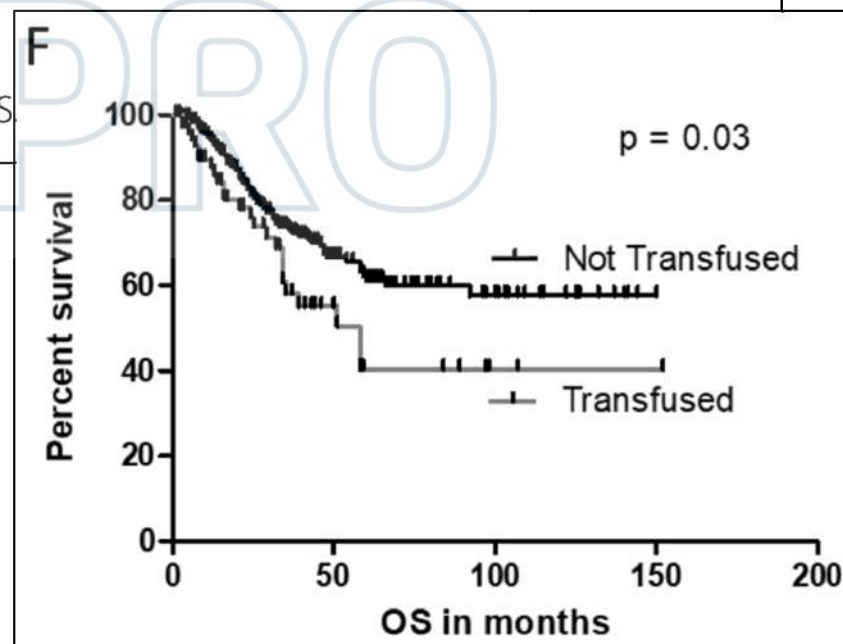
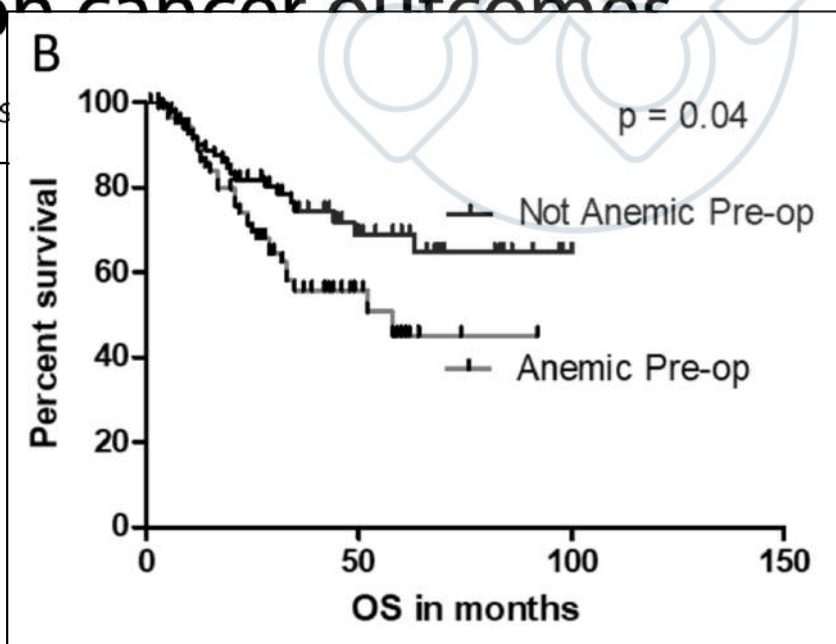
Joseph P. Connor<sup>1\*</sup>, Eric Destrampe<sup>1</sup>, Daniel Robbins<sup>2</sup>, Aaron S. Hess<sup>1,3</sup>, Daniel McCarthy<sup>4</sup> and James Maloney<sup>4</sup>

RESEARCH

Open Access



# Pre-operative anemia and peri-operative transfusion are associated with poor oncologic outcomes in cancers of the esophagus: potential impact of patient blood management on cancer outcomes



## ORIGINAL RESEARCH

### **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,<sup>1,2,3</sup> Axel Hofmann,<sup>4,5,6</sup> Simon Towler,<sup>7</sup> Kevin M. Trentino,<sup>8</sup>  
Sally A. Burrows,<sup>1</sup> Stuart G. Swain,<sup>8</sup> Jeffrey Hamdorf,<sup>9,10</sup> Trudi Gallagher,<sup>11,12</sup>  
Audrey Koay,<sup>11</sup> Gary C. Geelhoed,<sup>11,13</sup> and Shannon L. Farmer<sup>9,14</sup>*

- Studio retrospettivo **605.046** pazienti
- applicazione PBM su vasta scala (2008-2014)

## ORIGINAL RESEARCH

**TABLE 2. Key hospital-wide patient outcomes**

Outcome variable*	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013	2013-2014
<u>In-hospital mortality</u>						
Unadjusted rate, %	2.03	2.10	1.85	1.76	1.77	1.65
Adjusted OR (95% CI) <sup>†</sup>	Ref	1.01 (0.94-1.08)	0.95 (0.89-1.02)	0.89 (0.83-0.95)	0.81 (0.76-0.87)	0.72 (0.67-0.77)
<u>Hospital length of stay</u>						
Unadjusted mean, days	5.91	5.95	5.72	5.51	5.46	5.26
Adjusted rate ratio (95% CI) <sup>†</sup>	Ref	1.05 (1.03-1.07)	1.01 (0.99-1.03)	0.96 (0.94-0.98)	0.92 (0.90-0.94)	0.85 (0.84-0.87)
<u>28-Day readmissions</u>						
Unadjusted rate, %	11.42	11.82	12.74	13.57	13.27	12.42
Adjusted OR (95% CI) <sup>†</sup>	Ref	1.03 (0.99-1.07)	1.14 (1.10-1.18)	1.21 (1.17-1.26)	1.16 (1.12-1.20)	1.06 (1.02-1.10)
<u>Hospital-acquired infection‡</u>						
Unadjusted rate, %	—	2.34	2.04	1.78	1.80	1.95
Adjusted OR (95% CI) <sup>†</sup>	—	Ref	0.92 (0.85-0.99)	0.80 (0.74-0.87)	0.77 (0.71-0.83)	0.79 (0.73-0.86)
<u>Acute myocardial infarction-stroke‡</u>						
Unadjusted rate, %	—	0.50	0.48	0.40	0.42	0.36
Adjusted OR (95% CI) <sup>†</sup>	—	Ref	1.02 (0.86-1.20)	0.84 (0.71-1.00)	0.85 (0.71-1.00)	0.69 (0.58-0.82)

\* Shown are the unadjusted and adjusted patient outcomes by financial year over the period of the patient blood management program.

† Ratios and 95% confidence intervals are adjusted for hospital, age, sex, Diagnosis-Related Group (DRG) category, admission type, indigenous status, and comorbidities.

‡ Data were available for two of the four hospitals.

CI = confidence interval; OR = odds ratio; Ref = reference category.



# Transfusion Thresholds Can Be Safely Lowered in the Hip Fracture Patient: A Consecutive Series of 1,496 Patients

Sanjit R. Konda, MD

Rown Parola, MD

Cody R. Perskin, MD

Nina D. Fisher, MD

Abhishek Ganta, MD

Kenneth A. Egol, MD 

## ABSTRACT

**Introduction:** The purpose of this study is to identify optimal threshold hemoglobin (Hgb) and hematocrit (Hct) laboratory values to transfuse hip fracture patients.

# Transfusion Thresholds Can Be Safely Lowered in the Hip Fracture Patient: A Consecutive Series of 1,496 Patients

Sanjit R. Konda, MD

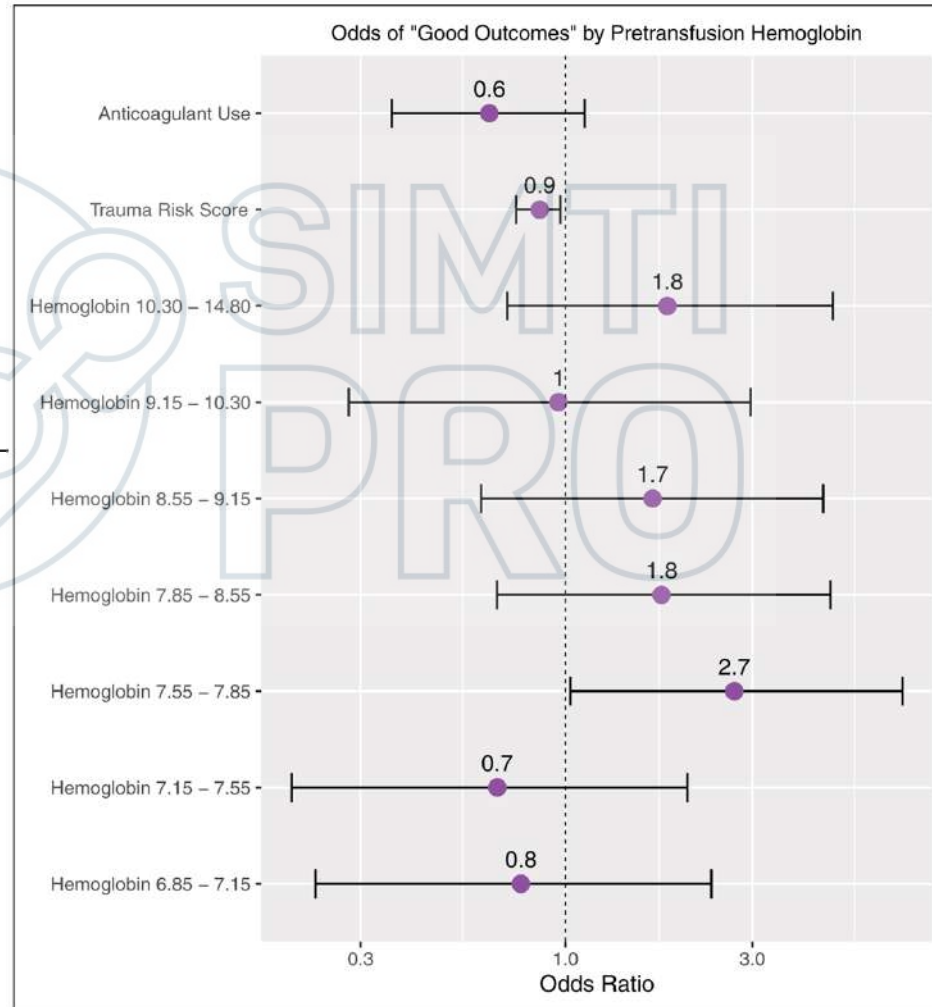
Rown Parola, MD

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Nina D. Fisher, MD

Abhishek Ganta, MD

Kenneth A. Egol, MD <sup>ID</sup>



al threshol  
to transfus

**Single-unit transfusions and hemoglobin trigger:  
relative impact on red cell utilization**

*William W. Yang,<sup>1</sup> Rajiv N. Thakkar,<sup>3</sup> Eric A. Gehrie,<sup>2</sup> Weiyun Chen,<sup>4</sup> and Steven M. Frank<sup>5</sup>*



## Single-unit transfusions and hemoglobin trigger: relative impact on red cell utilization

*William W. Yang,*

*Steven M. Frank<sup>5</sup>*

**RESULTS:** Univariate analysis revealed that both the increase in single-unit transfusions (from 38.0% to 70.9%;  $p < 0.0001$ ) and the decrease in RBC orders with an Hb trigger of at least 8 g/dL (from 45.7% to 25.0%;  $p < 0.0001$ ) were associated with decreasing RBC

utilization. Multivariate analysis showed that the increase in single-unit transfusions was an independent predictor of decreased RBC utilization, but the Hb triggers of both 7 and 8 g/dL were not. Overall, our PBM efforts

decreased RBC utilization from 0.254 to 0.185 units/patient (27.2%) across all three hospitals ( $p = 0.0009$ ).

**CONCLUSIONS:** A campaign promoting single-unit RBC transfusions had a greater impact on RBC utilization than did encouraging a restrictive transfusion trigger.

## **Patient Blood Management: a revolutionary approach to transfusion medicine**

Massimo Franchini<sup>1,2</sup>, Giuseppe Marano<sup>1</sup>, Eva Veropalumbo<sup>1</sup>, Francesca Masiello<sup>1</sup>, Ilaria Pati<sup>1</sup>, Fabio Candura<sup>1</sup>, Samantha Profili<sup>1</sup>, Liviana Catalano<sup>1</sup>, Vanessa Piccinini<sup>1</sup>, Simonetta Pupella<sup>1</sup>, Stefania Vaglio<sup>1,3</sup>, Giancarlo M. Liumbruno<sup>1</sup>

*<sup>1</sup>Italian National Blood Centre, National Institute of Health, Rome; <sup>2</sup>Department of Haematology and Transfusion Medicine, "Carlo Poma" Hospital, Mantua; <sup>3</sup>Department of Clinical and Molecular Medicine, "Sapienza" University of Rome, Rome, Italy*

Patient Blood Management programmes are an extraordinary tool for the improvement of patients' clinical outcomes.

**... national and international health authorities and medical societies should directly intervene by introducing regulatory measures and actions, issuing recommendations and providing resources to promote the effective implementation of PBM programmes.**

## Patient blood management: the global view

*Aryeh Shander,<sup>1,2</sup> James Isbister,<sup>3</sup> and Hans Gombotz<sup>4</sup>*

thresholds

a standard of care for all patients. As with any change, there are still some clinicians and others with the traditional approach to blood transfusion and blood banking that persist in searching for the Hb threshold (“trigger” in the past) for transfusing RBCs, the so-called holy grail.

outcome

However, the patient-centered approach incorporates many other treatments with transfusion in its rightful place. PBM does not focus on transfusion, but rather on identifying a medical condition that can be treated appropriately for the best clinical outcome. This approach has been steadily rising in acceptance and implementation throughout the medical community.

standard

Moving forward, PBM should become an integral part of postgraduate training, and players, including the government, should develop demonstration projects to further validate the positive administrative and clinical outcomes associated with the approach. PBM will most





# PBM: uno standard di cura?





## Table. Historical Perspective of Events Related to Patient Blood Management

Year/Period	Event
Early 1960s	Blood conservation methodology pioneered by Denton Cooley
1970–90	Epidemics of hepatitis C and HIV
1990	Patient Self Determination Act increased awareness of the ability and need to increase communication between patients and caregivers
1995	Formation of The National Association for Bloodless Medicine and Surgery
Late 1990s	The Network for Advancement of Transfusion Alternative (NATA) conceived
1999	Transfusion Requirements in Critical Care (TRICC) <sup>a</sup> trial published
2000	Society for the Advancement of Blood Management (SABM) created
1988–2016	Numerous “Transfusion Guidelines” published

<sup>a</sup>TRICC trial: Ref. 1.



**World Health  
Organization**

**World Health Assembly**  
Geneva, 17-21 May 2010  
Resolution WHA63.12

### **“Availability, safety and quality of blood products”**

... 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);

... 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 including, where appropriate, autologous transfusion, safe transfusion practices and patient blood management;



**World Health  
Organization**

**Global Forum for Blood Safety:  
Patient Blood Management**

14–15 March 2011, Dubai, United Arab Emirates

**“Concept Paper ”**

**... Patient blood management (PBM) is a patient-focused, evidence-based and systematic approach to optimize the management of patient and transfusion of blood products for quality and effective patient care.**

It 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, the use of alternatives to blood transfusion and blood conservation.



CNSI Un progetto condiviso con Simti, Siaarti e Anmdo sulla gestione globale dell'anemia

# La governance del patient blood

Programma operativo in tre fasi - Guidelines teoriche entro fine giugno

**O**ttimizzare la gestione della risorsa sangue è possibile unicamente mediante un approccio multiprofessionale, multidisciplinare, multimodale, ospedaliero e paziente-centrico per la gestione dell'anemia, l'ottimizzazione dell'emostasi e il risparmio di sangue nel peri-operatorio, l'emostasi chirurgica, e l'impiego degli emocomponenti e dei farmaci plasmoderivati. Il tutto si riserisce sulla definizione anglosassone di Patient Blood Management (Pbm), scaturita non da una specifica patologia o procedura, né da una disciplina o settore specifico della medicina, ma sulla buona gestione della risorsa sangue del paziente, spostando l'attenzione dall'emocomponente al paziente.

Questa strategia consente di raggiungere l'obiettivo ottimale mediante l'uso (combinato e condiviso tra gli specialisti di diverse discipline) di un insieme di tecniche (farmacologiche e non farmacologiche) che possono essere anche personalizzate al singolo paziente.

La strategia del Pbm - caldeggiata dall'Ons fin dal 2010 - va dunque oltre il concetto di suo appropriato degli emocomponenti e dei medicinali plasmoderivati proprio perché ne previene e riduce in modo significativo l'utilizzo, consentendo anche di ridurre i costi.

In queste pagine un focus sul Progetto Patient Blood Management Italia al centro dei lavori del congresso nazionale Simti in programma questa settimana.

**O**ttimizzare l'entropia del paziente, ridurre al minimo il sanguinamento, definire e ottimizzare la riserva fisiologica dell'anemia del singolo paziente: sono questi i "tre pilastri del Pbm", strategie per la riduzione del carico di patologia che caratterizza l'approccio patient-centric e non più emocomponente-centrico. Ognuno di questi tre pilastri, infatti, rappresenta, rispettivamente, la risposta strategica ai quali clinici che possono essere chiamati a intervenire e il ricorso alla terapia tradizionale: all'ospite, ovvero al sistema, la perdita ematica, il trauma.

La gestione globale dell'anemia (o la sua prevenzione) sono incluse nel primo pilastro ma in realtà sono parte integrante di tutti e tre i pilastri del Pbm. L'anemia rappresenta di fatto una controindicazione all'efficacia degli interventi di chirurgia elettiva. Infatti, l'anemia preoperatoria, anche se lieve, nei pazienti candidati a interventi di chirurgia maggiore è associata indipendentemente a un aumentato rischio di mortalità, mortalità e di ricovero tempi prolungati. Tuttavia è necessario valutare il rischio candidato e la chirurgia elettiva almeno 30 giorni prima della data programmata dell'intervento, per rilevare un'eventuale anemia e adottare le misure tempestive per ottimizzarla.

L'entropia, inoltre, uno studio recentemente pubblicato sul Journal of Hospital Medicine illustra che l'anemia si sviluppa anche durante l'ospedalizzazione nel 74% dei pazienti ed è associata a un significativo aumento della mortalità e della morbidità.

Questi dati confermano, dunque, che la migliore strategia per prevenire l'anemia e l'emorragia, soprattutto tradizionale nel post-operatorio è la rilevazione e la correzione della stessa nel periodo pre-operatorio, consentendo anche di ridurre i costi.

In queste pagine un focus sul Progetto Patient Blood Management Italia al centro dei lavori del congresso nazionale Simti in programma questa settimana.

I tre pilastri del Patient Blood Management (Pbm)		
Pilastro 1 Ottimizzazione dell'entropia	Pilastro 2 Contenimento della perdita ematica	Pilastro 3 Ottimizzazione della tolleranza all'anemia
Periodo pre-operatorio		
<ul style="list-style-type: none"> <li>• <b>Minimare l'anemia</b></li> <li>• Identificare e trattare le patologie di base che causano l'anemia</li> <li>• Rilevare il paziente, se necessario</li> <li>• Trattare le carenze metaboliche e le anemie sideropeniche, la anemia delle malattie croniche e le carenze funzionali di ferro del "non-ironical anemias"</li> <li>• Trattare le carenze di altri nutrienti</li> </ul>	<ul style="list-style-type: none"> <li>• Identificare e gestire il rischio emorragico</li> <li>• Contenimento del sanguinamento intraoperatorio</li> <li>• Attenti pianificazioni e preparazione della procedura</li> <li>• Preoperatorio, in caso molto selezionati</li> </ul>	<ul style="list-style-type: none"> <li>• Valutare/ottimizzare la riserva fisiologica del paziente e i fattori di rischio</li> <li>• Confermare la perdita di sangue attesa con quella tollerabile dal singolo paziente</li> <li>• Realizzare programmi di blood management individualizzati che includano tecniche di risparmio di sangue adattate al singolo caso</li> <li>• Adozione di soglie trasfusionali restrittive</li> </ul>
Periodo intra-operatorio		
<ul style="list-style-type: none"> <li>• <b>Adattare programmazioni</b> dell'intervento che vengono dopo l'ottimizzazione dell'entropia</li> </ul>	<ul style="list-style-type: none"> <li>• Tecniche metodiche e tecniche chirurgiche</li> <li>• Tecniche chirurgiche di risparmio del sangue</li> <li>• Tecniche di autotrasfusione</li> <li>• Tecniche farmacologiche a ripiena emostasi</li> <li>• Diagnostica puntuale di caso</li> </ul>	<ul style="list-style-type: none"> <li>• Ottimizzare la guida clinica</li> <li>• Correzione e ventilazione e trasfusione</li> <li>• Adozione di soglie trasfusionali restrittive</li> </ul>
Periodo post-operatorio		
<ul style="list-style-type: none"> <li>• <b>Identificare (l'entropia, se necessario) e rilevare le interazioni farmacologiche</b> che generano le emorragie</li> <li>• <b>Trattare post-operatorio</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Attento monitoraggio</b> del paziente e gestione del sanguinamento post-operatorio</li> <li>• <b>Pianificazione</b> appropriata dell'emostasi</li> <li>• <b>Monitoraggio</b> continuo e appropriato</li> <li>• <b>Trasfusione</b> solo quando indicato per sintomi</li> <li>• <b>Tecniche di autotrasfusione</b></li> <li>• <b>Contenimento</b> del sanguinamento intraoperatorio</li> <li>• <b>Capitale dell'emostasi e dell'anticoagulazione</b></li> <li>• <b>Monitoraggio</b> delle emorragie del tratto gastro-intestinale superiore</li> <li>• <b>Individualizzazione</b> della terapia</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Ottimizzare</b> la tolleranza all'anemia</li> <li>• <b>Pianificare</b> l'apporto di ossigeno</li> <li>• <b>Minimizzare</b> il consumo di ossigeno</li> <li>• <b>Adozione</b> di soglie trasfusionali restrittive</li> </ul>

## LA VOCE DEI DONATORI DI MANGUE

**«Il Pbm consente la massima valorizzazione della supply chain trasfusionale»**

Il Coordinamento Internazionale Volontari Italiani del Sangue (Civis) raggruppa le quattro principali associazioni e federazioni di donatori di sangue volontari e non remunerati, quasi 1 milione e 800 mila, con una percentuale di fidelizzazione dell'83%, tra i più elevati del mondo - operanti sull'intero territorio nazionale, cioè Ato, Fida, Franco e donatori di sangue della Civis. Il mondo del volontariato del sangue è uno dei tre attori del sistema trasfusionale italiano, insieme alle istituzioni sanitarie e ai professionisti, e costituisce l'anello iniziale della "supply chain" trasfusionale, fornendo un valore aggiunto al sistema stesso grazie all'apporto di protezione della cultura

dei volontari, delle guide, di cui si sta occupando il gruppo di lavoro "Pbm". Secondo Wladig, l'efficacia delle azioni di formazione si basa su tre elementi: la cosiddetta "3 T": time - la tempestività nella fornitura del prodotto transparency - la completa visibilità di tutti gli anelli della catena, cioè i fidelizzati (che danno in buona parte della trasparenza) in termini di efficacia ed efficienza; i donatori volontari di sangue giocano dunque un ruolo determinante nel modulare l'offerta quantitativa e qualitativa del loro dono sulla base delle prioritarie esigenze terapeutiche del paziente.

Civis, peraltro, è il primo sistema di donazione di sangue in Italia, che ha già in corso il progetto Patient Blood Management Italia. Nel 2010, l'Onm ha rilevato la necessità di adottare il

## Gli obiettivi del PBM

Il Patient Blood Management (PBM) è una strategia multidisciplinare e multimodale che mette al centro la salute e la sicurezza del paziente e migliora i risultati clinici basandosi sulla risorsa sangue dei pazienti stessi. Questo approccio riduce in modo significativo l'utilizzo dei prodotti del sangue, affrontando tutti i fattori di rischio trasfusionale modificabili ancor prima che sia necessario prendere in considerazione il ricorso alla terapia trasfusionale stessa.

Gli obiettivi del PBM sono:

- Miglioramento degli outcome clinici
- Prevenzione della trasfusione evitabile
- Riduzione dei costi di gestione

## IL PERCORSO DEL CNSI

### «Tre obiettivi europei da realizzare in 24 mesi»

La responsabilità della realizzazione di questo progetto è affidata all'Anemia (Austrian Institute of Technology) e coinvolge ospedali di cinque Nazioni: campo Germania, Danimarca, Portogallo, Croazia, Austria oltre che a esperti provenienti anche da Svizzera e Australia. Nella riunione delle autorità nazionali invitate a promuovere attivamente il Pbm e a collaborare al progetto guidato dall'Anemia.

Il progetto "Patient Blood Management" (Pbm) italiano è la risposta del Centro nazionale sangue alla richiesta dell'Organizzazione mondiale della Sanità - WHO/ISLT del 2010. Attualmente l'Australia è il primo esempio di sistema sanitario nazionale completamente conforme alla richiesta innovativa dell'Onm. Infatti, in questo Paese, la National Blood Authority, equivalente del Cnsi in Italia, ha prodotto delle linee guida nazionali multidisciplinari, "patient-centric", articolate in sei moduli, che affrontano il Pbm in diversi scenari: ai sanguinamenti critico-emorragici massivi; in peri-operatorio; e patologie mediche acute o croniche; di terapia intensiva; e ostetrica; e pediatrica/neonatale.

Le linee guida sopra citate rientrano in una politica nazionale che, garantendo standard di riferimento per tutti i professionisti coinvolti nei processi clinico-decisionali relativi alla terapia trasfusionale, certamente ha esercitato anche una forte influenza nell'attivazione di questa strategia innovativa da parte di numerose strutture ospedaliere in Australia.

Negli Usa, il Pbm è stato adottato da associazioni scientifiche del settore trasfusionale come la Association for Advancing Transfusion and Cellular Therapies, più nota come American Association of Blood Banks (Aabb), che ha recentemente pubblicato anche la prima edizione degli "Standard per il Programma di Patient Blood Management", e dalla "Society for the Advancement of Blood Management" (Sabm), ma anche dalla Joint Commission, l'organizzazione nazionale del 1951 con il fine di migliorare la qualità dell'assistenza sanitaria degli ospedali americani. Non a caso negli Usa sono presenti anche aziende private che offrono servizi di consulenza per l'implementazione del Pbm e i programmi ospedalieri di Pbm sono, attualmente, oltre 100.

In Europa, nonostante le iniziative educative del Network for Advancement of Patient Blood Management, Haemostasis and Thrombosis, una società scientifica multidisciplinare fondata nel 1998 e già nota come Network for the Advancement of Transfusion Alternatives (Nata), il Pbm è adottato, seppure limitatamente, in Spagna, Austria, Svizzera, Germania e Regno Unito. In occasione l'Olanda, dove gli ospedali hanno implementato il Pbm da oltre 10 anni. Tuttavia, recentemente, la Commissione europea ha finanziato un progetto di ricerca sulle buone pratiche in medicina trasfusionale che ha tre obiettivi:

- **Implementare** il Pbm in 5 ospedali universitari di diversi Stati membri;
- **Prevedere** una strategia che supporti una cultura nazionale nell'implementare il Pbm negli ospedali europei;

per Civis (Comitato internazionale del volontariato italiano del sangue) e per Cnsi (Comitato nazionale di gestione del sangue).

Per tutti gli obiettivi del programma nazionale di attivazione del Pbm dal 2012. Nel primo semestre del 2013 è stato formato un gruppo di lavoro multidisciplinare al fine di raggiungere questi traguardi. Il gruppo di lavoro è coordinato dal Cnsi ed è composto da rappresentanti del Cnsi stesso, della

Guiliano Zangini direttore Centro nazionale Sangue Istituto superiore di Sanità

Italia

P  
B  
M

RACCOMANDAZIONI  
PER L'IMPLEMENTAZIONE DEL PROGRAMMA DI  
PATIENT BLOOD MANAGEMENT

APPLICAZIONE IN CHIRURGIA ORTOPEDICA MAGGIORE ELETTIVA DELL'ADULTO

Si raccomanda che la rilevazione e il trattamento dell'anemia, e gli ulteriori eventuali approfondimenti clinico-diagnostici correlati, siano inseriti nell'ambito di una strategia globale di PBM e divengano un livello standard di assistenza erogato a tutti i pazienti candidati a interventi di chirurgia elettiva, specialmente se il rischio di sanguinamento per operatorio è consistente [1C].

a cura di

Stefania Vaglio, Domenico Prisco, Gianni Biancofiore, Daniela Rafanelli, Paola Antonielli, Michele Lisanti,  
Lorenzo Andreani, Leonardo Basso, Claudio Velati, Giuliano Grazzini, Giancarlo Maria Liembruno

<b>Raccomandazioni da adottare nel periodo <u>pre-operatorio</u>, <u>intra-operatorio</u> e <u>post-operatorio</u></b>	
1	I pazienti con coagulopatie e/o piastrinopatie congenite o acquisite, o anamnesi positiva per emorragia, o in trattamento con <u>anticoagulanti e/o antiaggreganti piastrinici</u> , sono gestiti in tutte le fasi in collaborazione con
2	In tutti i pazienti (ospedalizzati o ambulatoriali), ospitati per patologie cardiache, è raccomandata l'adesione a linee guida di medicina trasfusionale.
3	La soglia trasfusionale per le diverse categorie di pazienti è definita in base alle indicazioni delle linee guida di medicina trasfusionale.
4	Nei pazienti sottoposti ad interventi in cui si preveda una consistente perdita ematica e che non presentino fattori di rischio per ipercoagulabilità all'anamnesi preoperatoria, si suggerisce di considerare l'impiego di <u>acido tranexamico</u> .
5	Nei pazienti sottoposti ad interventi in cui si prevedano perdite ematiche di almeno 1000 mL o comunque $\geq$ al 20% della volemia, si raccomanda l'adozione di strategie multimodali che includano il ricorso integrato a tecniche di risparmio del sangue ( <u>recupero intra-operatorio, tecniche farmacologiche, chirurgiche e anestesiolgiche</u> ).
6	Le indicazioni alla trasfusione sono definite in base alle linee guida di medicina trasfusionale.
7	Il volume e la frequenza delle trasfusioni sono definiti in base alle linee guida di medicina trasfusionale.
9	Si raccomanda che tutti i pazienti adulti candidati a interventi di chirurgia maggiore elettiva per i quali sia stato impostato un programma multidisciplinare di interventi coordinati che preveda l'adozione delle tecniche farmacologiche o non farmacologiche finalizzate a <u>ottimizzare l'eritropoiesi, a contenere le perdite ematiche o a ottimizzare la tolleranza all'anemia</u> , prima di rilasciare il consenso a uno o più dei suddetti trattamenti, ricevano un'informazione esaustiva sulla loro situazione clinica e sulle strategie di contenimento del fabbisogno trasfusionale omologo incluse nel programma di <i>patient blood management</i> locale, anche mediante l'uso di materiale illustrativo redatto <i>ad hoc</i> dalla struttura ospedaliera.
10	Il valore target del Hb è definito in base alle linee guida di medicina trasfusionale.
11	L'anemia è definita in base alle linee guida di medicina trasfusionale.
12	Qualora mediamente disponibili, i test diagnostici di laboratorio (emoglobinico, ematocritico, nutrizionali) sono considerati di supporto nelle decisioni trasfusionali.
13	Poiché il valore di Hb è influenzato da fattori fisiologici e patologici, le misurazioni di Hb, quando rilevate, sono considerate di supporto nelle decisioni trasfusionali.
14	Successivamente all'adozione di una strategia di risparmio del sangue, si suggerisce di considerare l'impiego di strumenti <u>point-of-care (POC)</u> per la misurazione non invasiva e in continuo dell'Hb e dell'ematocrito.
15	Nei pazienti sottoposti ad interventi in cui si prevedano perdite ematiche di almeno 1000 mL o comunque $\geq$ al 20% della volemia, si raccomanda l'adozione di strategie multimodali che includano il ricorso integrato a tecniche di risparmio del sangue ( <u>recupero intra-operatorio, tecniche farmacologiche, chirurgiche e anestesiolgiche</u> ).
16	Ove indicata, si suggerisce di considerare l'impiego di strumenti POC per il <u>monitoraggio globale dell'emostasi</u> allo scopo di guidare la terapia sostitutiva dei fattori della coagulazione e di contenere il supporto trasfusionale con emocomponenti negli interventi di cardiocirurgia e in tutti gli interventi ad elevato potenziale emorragico o in presenza di sanguinamento.
20	Si suggerisce di adottare protocolli di somministrazione dei fluidi intra-operatori basati sui principi della ottimizzazione emodinamica.
21	Nei pazienti adulti sottoposti ad interventi in cui si preveda una consistente perdita ematica e che non presentino fattori di rischio per ipercoagulabilità all'anamnesi preoperatoria, si suggerisce di considerare l'impiego di <u>acido tranexamico</u> .
22	Nei pazienti sottoposti ad interventi in cui si prevedano perdite ematiche di almeno 1000 mL o comunque $\geq$ al 20% della volemia, si raccomanda l'adozione di strategie multimodali che includano il ricorso integrato a tecniche di risparmio del sangue ( <u>recupero intra-operatorio, tecniche farmacologiche, chirurgiche e anestesiolgiche</u> ).
23	Si raccomanda l'impiego di strumenti <u>point-of-care (POC)</u> per la misurazione non invasiva e in continuo dell'Hb e dell'ematocrito.
24	Si suggerisce l'impiego di strumenti POC per il <u>monitoraggio globale dell'emostasi</u> allo scopo di guidare la terapia sostitutiva dei fattori della coagulazione e di contenere il supporto trasfusionale con emocomponenti negli interventi di cardiocirurgia e in tutti gli interventi ad elevato potenziale emorragico o in presenza di sanguinamento.
25	In presenza di sanguinamento massivo in atto in corso di chirurgia maggiore elettiva e in associazione alla correzione della causa scatenante, in corso di trasfusione massiva, si suggerisce di trattare l'ipofibrinogenemia grave ( $< 1$ g/L) e persistente nonostante la terapia con <u>plasma fresco congelato</u> , con concentrato di <u>fibrinogeno*</u> (o, se non disponibile, con crioprecipitato).



## Supporting Patient Blood Management (PBM) in the EU

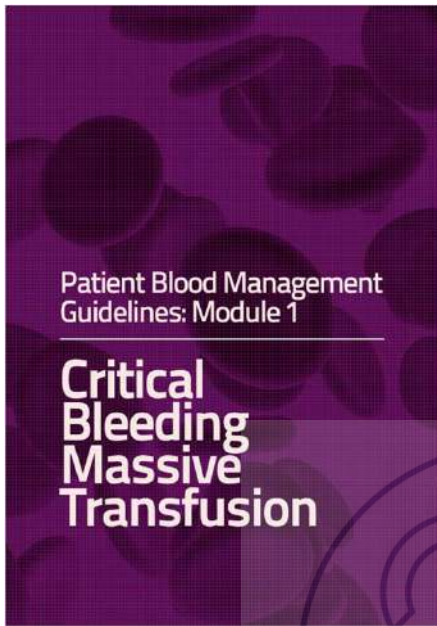
### A Practical Implementation Guide for Hospitals

March 2017

Commission of the  
European Communities  
European Commission

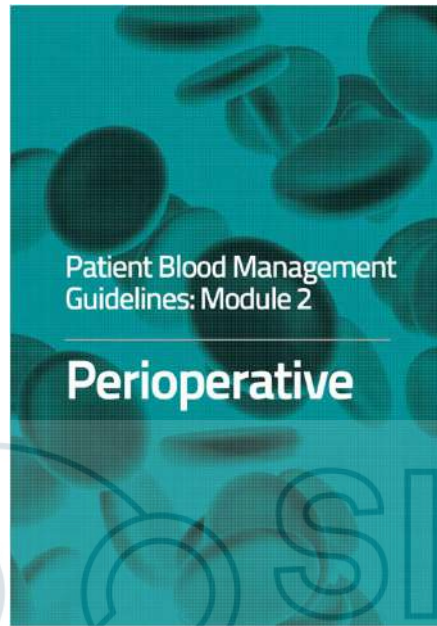
# Europa

3	How to implement PBM as a new standard of care.....	
3.1	Introduction.....	
3.2	Managing change from the default transfusion position to PBM .....	
3.2.1	Step 1 - Create urgency for PBM.....	
3.2.2	Step 2 - Form a powerful PBM group as guiding coalition.....	
3.2.3	Step 3 - Create a vision for PBM .....	
3.2.4	Step 4 - Communicating the PBM vision.....	
3.2.5	Step 5 - Empower the PBM group and remove obstacles .....	
3.2.6	Step 6 - Create short-term wins of PBM.....	
3.2.7	Step 7 - Build on the change .....	
3.2.8	Step 8 - Anchor PBM in culture.....	
3.3	PBM Implementation steps (Matrix) .....	



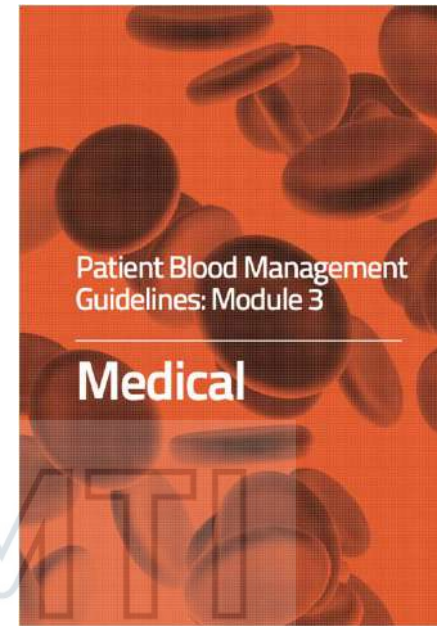
Patient Blood Management  
Guidelines: Module 1

## Critical Bleeding Massive Transfusion



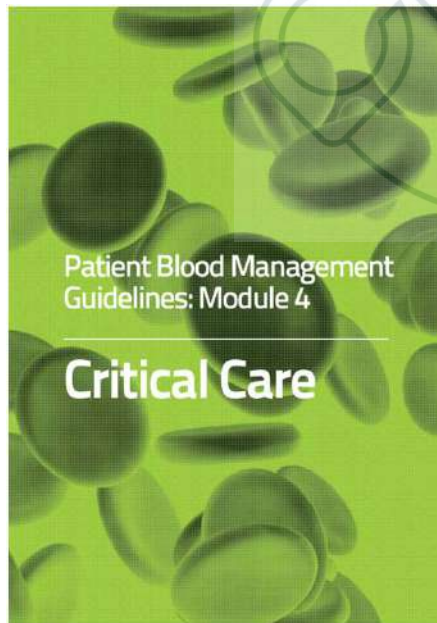
Patient Blood Management  
Guidelines: Module 2

## Perioperative



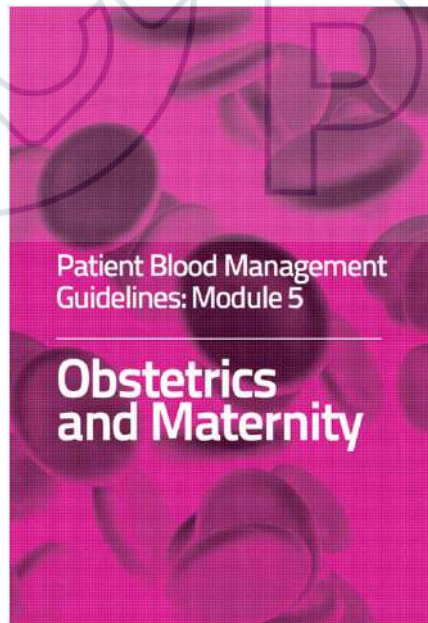
Patient Blood Management  
Guidelines: Module 3

## Medical



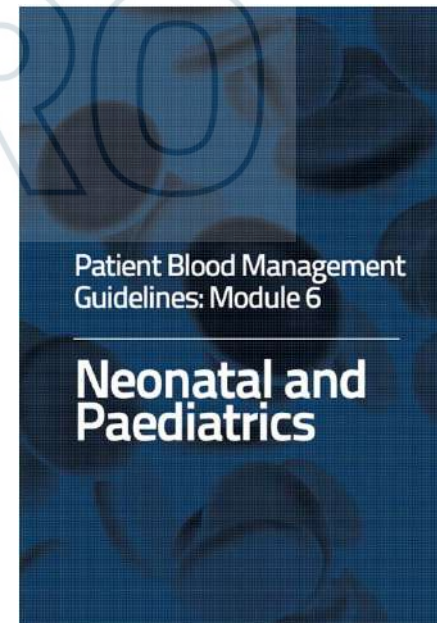
Patient Blood Management  
Guidelines: Module 4

## Critical Care



Patient Blood Management  
Guidelines: Module 5

## Obstetrics and Maternity



Patient Blood Management  
Guidelines: Module 6

## Neonatal and Paediatrics

**Australia**



## Maggiori «consumatori»

Facco et al. - Blood Transfus 2021; 19: 384-95

- 66.7% for a medical indication
- 32.4% for a surgical indication

Bruun et al. - Vox Sanguinis 2016; 111: 391–398

- 61% for a medical indication
- 36% for a surgical indication

**USA**

**THE JOINT COMMISSION PATIENT  
BLOOD MANAGEMENT  
PERFORMANCE MEASURES**

TAC OCT. 2011

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Transfusion consent (PBM-01)

Transfusion indication RBC (PBM-02)

Transfusion indication plasma (PBM-03)

Transfusion indication platelet (PBM-04)

Blood administration documentation (PBM-05)

Pre-operative anaemia screening (PBM-06)

Pre-operative blood type testing and antibody screening (PBM-07)

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## Patient Blood Management as Standard of Care

Aryeh Shander, MD,\* Arthur W. Bracey, Jr, MD,† Lawrence T. Goodnough, MD,‡ Irwin Gross, MD,§  
Nabil E. Hassan, MD,|| Sherri Ozawa, RN,\* and Marisa B. Marques, MD¶

PBM principles clearly recognize that to achieve improved patient outcomes, more than transfusion guidelines and transfusion avoidance are required. National and international organizations and policy makers are increasingly adopting and advocating PBM.

PBM is becoming, and must be considered, the standard of care or at least recognized as best practice. It avoids and mitigates risks by addressing clinical issues that may lead to transfusion long before transfusion is even considered.

## EDITORIAL

### **Patient Blood Management: the new standard**

**Donat R. Spahn, MD, FRCA**

*e-mail: donat.spahn@usz.ch*

*Institute of Anesthesiology*

*University and University Hospital of Zurich*

*Zurich, Switzerland*

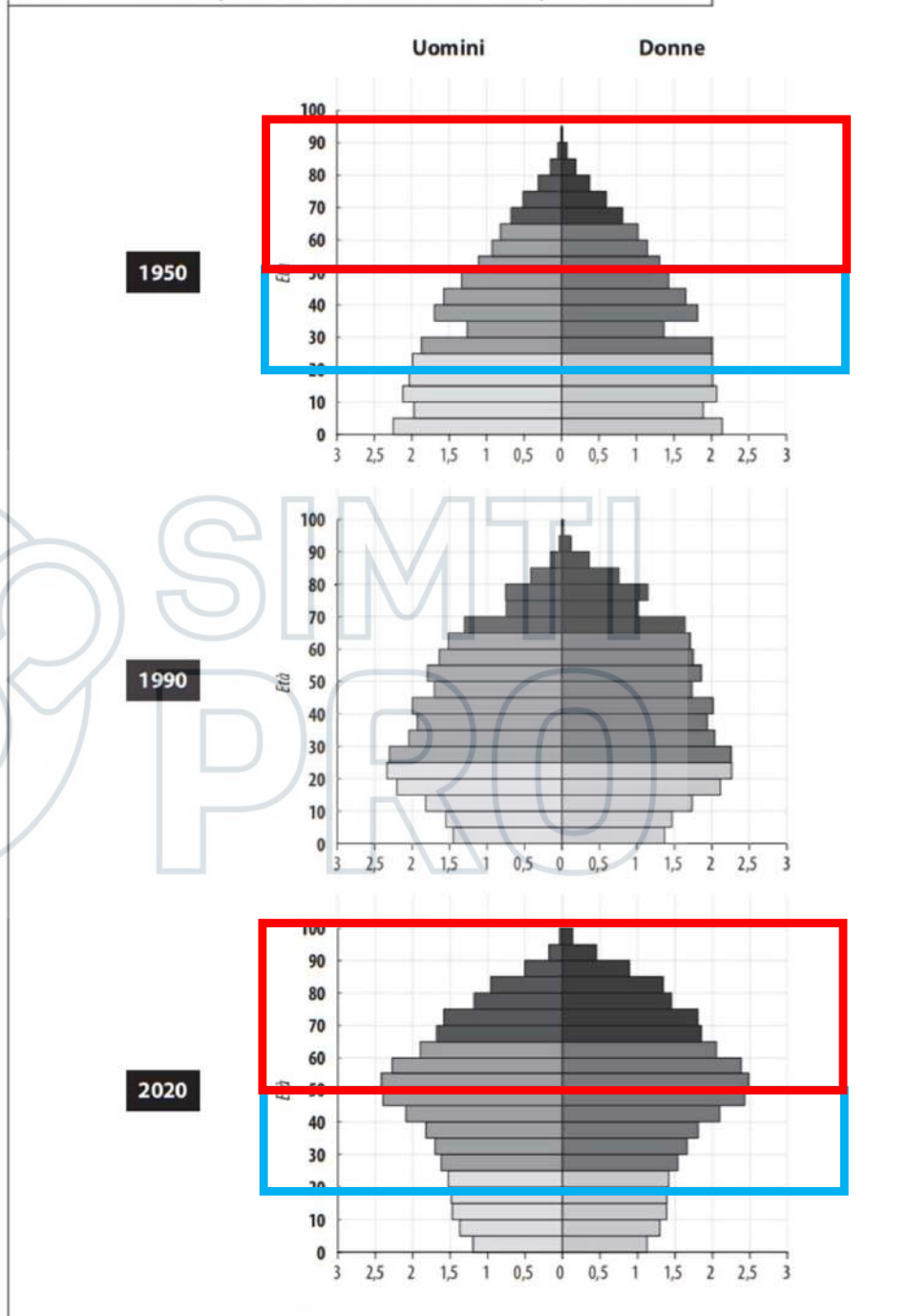
... The take home message is: PBM is safe and efficacious in improving patient outcome, in reducing the need for allogeneic blood product transfusion, and in lowering costs.



# **PBM: strumento di risparmio di sangue?**

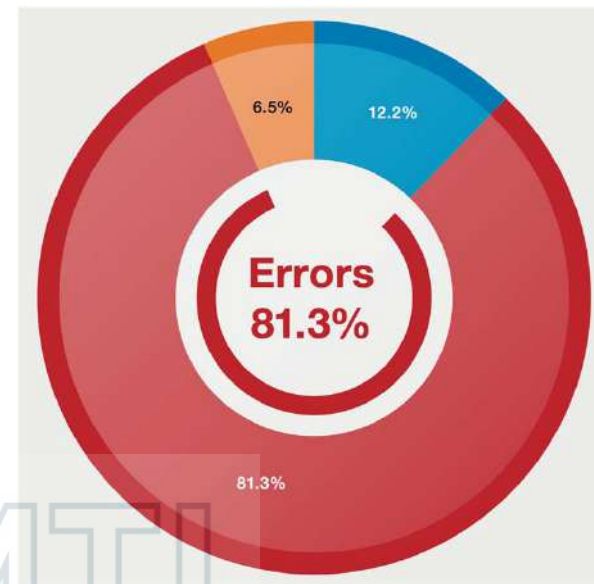
# Trend demografico in Italia

Grafico 1 - ITALIA, PIRAMIDE DELLE ETÀ: 1950, 1990 E 2020 (milioni)



Fonte: Onu, Department of Economic and Social Affairs, Population Division; World Population Prospects 2019, Volume II: Demographic Profiles

# Rischi della terapia trasfusionale



- trasfusione al paziente sbagliato
- reazione emolitica acuta ABO incompatibile
- reazione emolitica ritardata
- reazione allergica severa
- insufficienza respiratoria acuta (TRALI, TACO)
- sepsi
- infezioni
- immunomodulazione
- aumento morbilità / mortalità (fattore di rischio indipendente)



## ***Patient Blood Management***

### ***The Pragmatic Solution for the Problems with Blood Transfusions***

ALLOGENEIC erythrocyte transfusions are associated with increased mortality,<sup>1</sup> major adverse cardiac and noncardiac outcome,<sup>2</sup> and low output failure in cardiac surgery. Transfusion of allogeneic erythrocyte transfusions has also been found to be an independent factor increasing mortality in trauma, including traumatic brain injury,<sup>3</sup> burns,<sup>4</sup> liver transplantation, intensive care medicine,<sup>5</sup> and the treatment of acute coronary syndrome.<sup>6</sup> In addition, allogeneic erythrocyte, fresh frozen plasma, and platelet transfusions result in a several-fold increase in postoperative and nosocomial infections.<sup>6,7</sup> Further-

rocytes stored for more than 9 days having a significantly more pronounced deleterious effect.

The reason for cancer progression after blood transfusion is unclear, and the article by Atzil *et al.* did not precisely elucidate the mechanisms involved. The perioperative period is characterized by numerous processes that can induce abrupt elevation of risk factors for the outbreak of preexisting micrometastases and the seeding of new metastases. Here, deterioration of erythrocytes as a result of storage is demonstrated as a major cause for the cancer-promoting effect. Atzil *et al.* mainly discuss

**Donat R. Spahn, M.D., F.R.C.A.,\* Holger Moch, M.D.,†  
Axel Hofmann, M.E.,‡ James P. Isbister, M.B., F.R.A.C.P.§**

\*Institute of Anesthesiology, University Hospital Zürich, Zürich, Switzerland. donat.spahn@usz.ch. †Institute of Surgical Pathology, Department of Pathology, University Hospital Zurich, Zurich, Switzerland. ‡Medical Society for Blood Management, Laxenburg, Austria. §Department of Haematology, University of Sydney, Royal North Shore Hospital of Sydney, St. Leonards, New South Wales, Australia.

Current Opinion in Anaesthesiology 2008, 21:657–663

EDITORIAL COMMENT

## **Our own blood is still the best thing to have in our veins**

Tim Frenzel, Hugo Van Aken and Martin Westphal

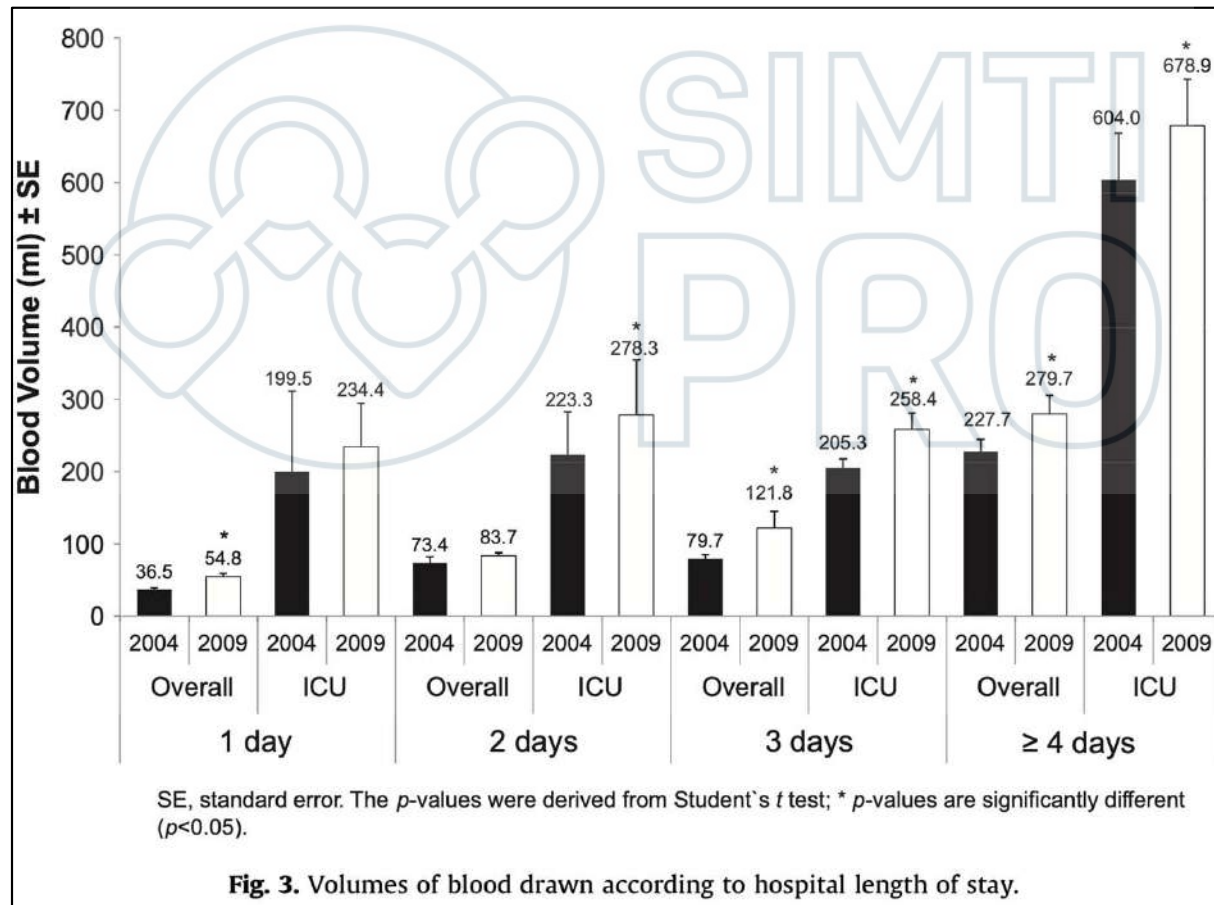
Taking into account the current evidence on this topic, it appears that **our own blood** is still the best thing to have in our veins.

## The increasing burden of phlebotomy in the development of anaemia and need for blood transfusion amongst trauma patients

Bernardino C. Branco <sup>a</sup>, Kenji Inaba <sup>a,\*</sup>, Reece Doughty <sup>a</sup>, Jennifer Brooks <sup>a</sup>, Galinos Barmparas <sup>a</sup>, Ira Shulman <sup>b</sup>, Janice Nelson <sup>b</sup>, Demetrios Demetriades <sup>a</sup>

<sup>a</sup> Division of Trauma and Surgical Critical Care, University of Southern California, Los Angeles, CA, United States

<sup>b</sup> Department of Pathology, University of Southern California, Los Angeles, CA, United States





# **PBM: strumento di risparmio economico?**

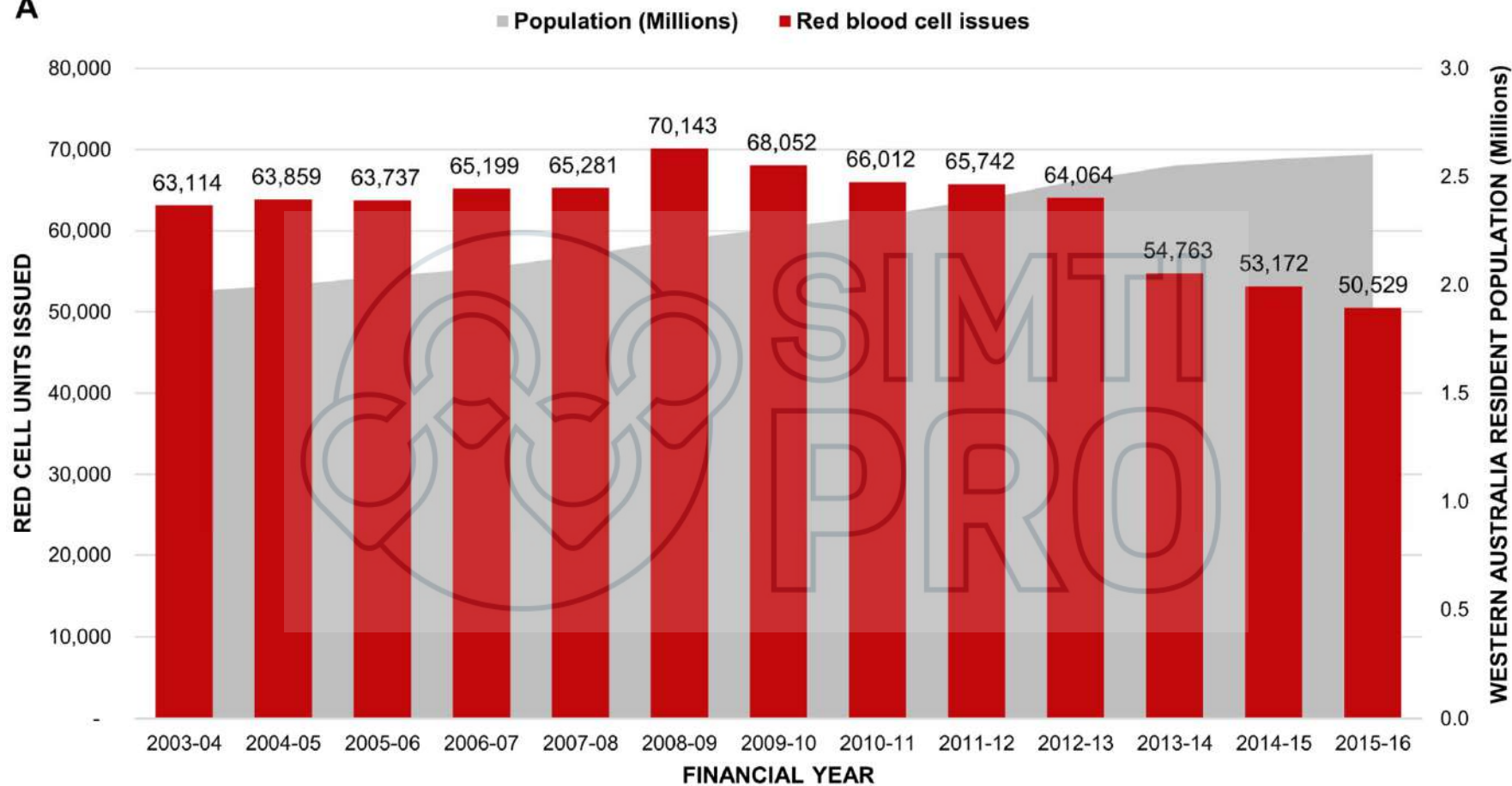
## ORIGINAL RESEARCH

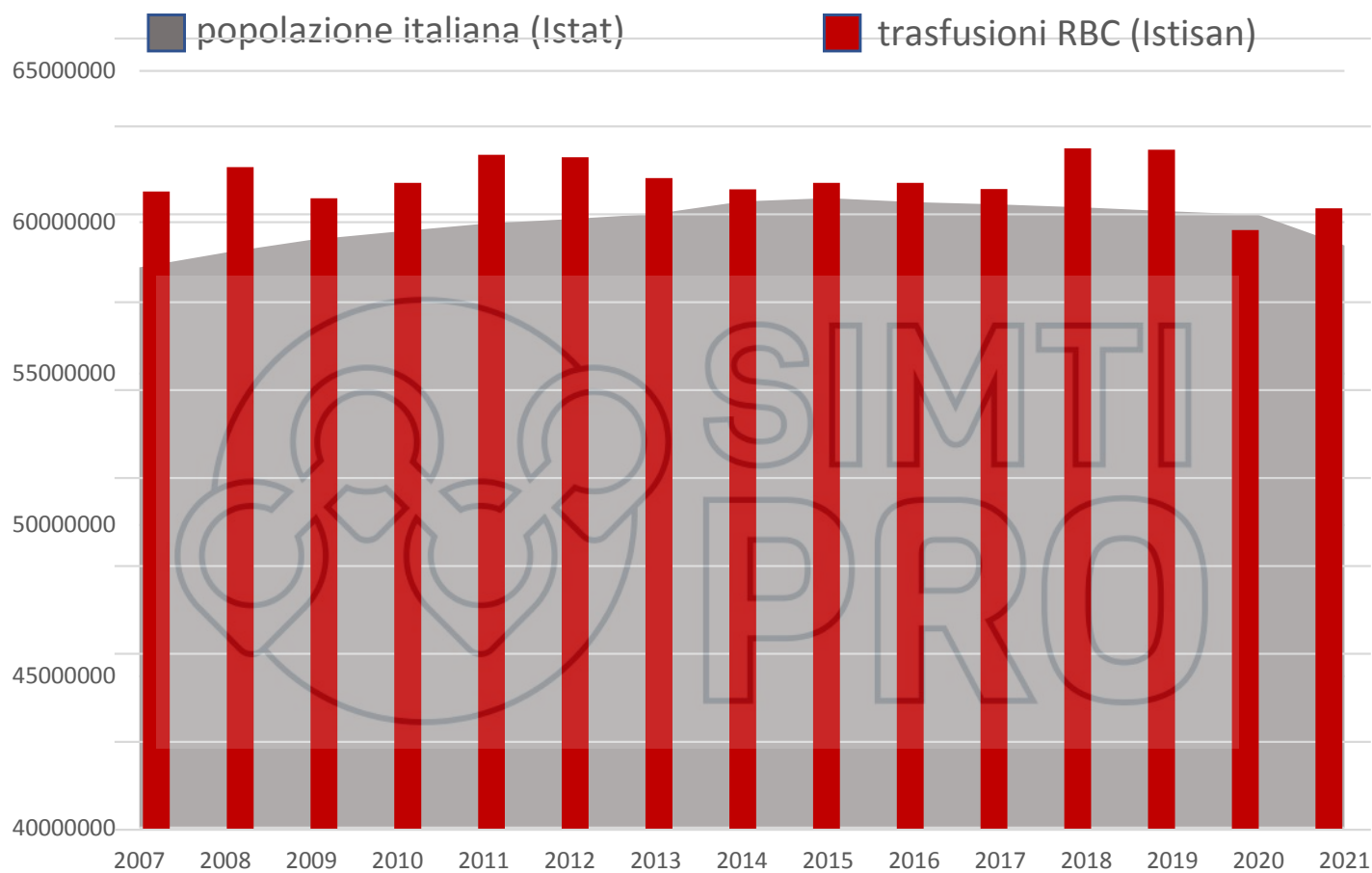
### **Improved outcomes and reduced costs associated with a health-system-wide patient blood management program: a retrospective observational study in four major adult tertiary-care hospitals**

*Michael F. Leahy,<sup>1,2,3</sup> Axel Hofmann,<sup>4,5,6</sup> Simon Towler,<sup>7</sup> Kevin M. Trentino,<sup>8</sup>  
Sally A. Burrows,<sup>1</sup> Stuart G. Swain,<sup>8</sup> Jeffrey Hamdorf,<sup>9,10</sup> Trudi Gallagher,<sup>11,12</sup>  
Audrey Koay,<sup>11</sup> Gary C. Geelhoed,<sup>11,13</sup> and Shannon L. Farmer<sup>9,14</sup>*

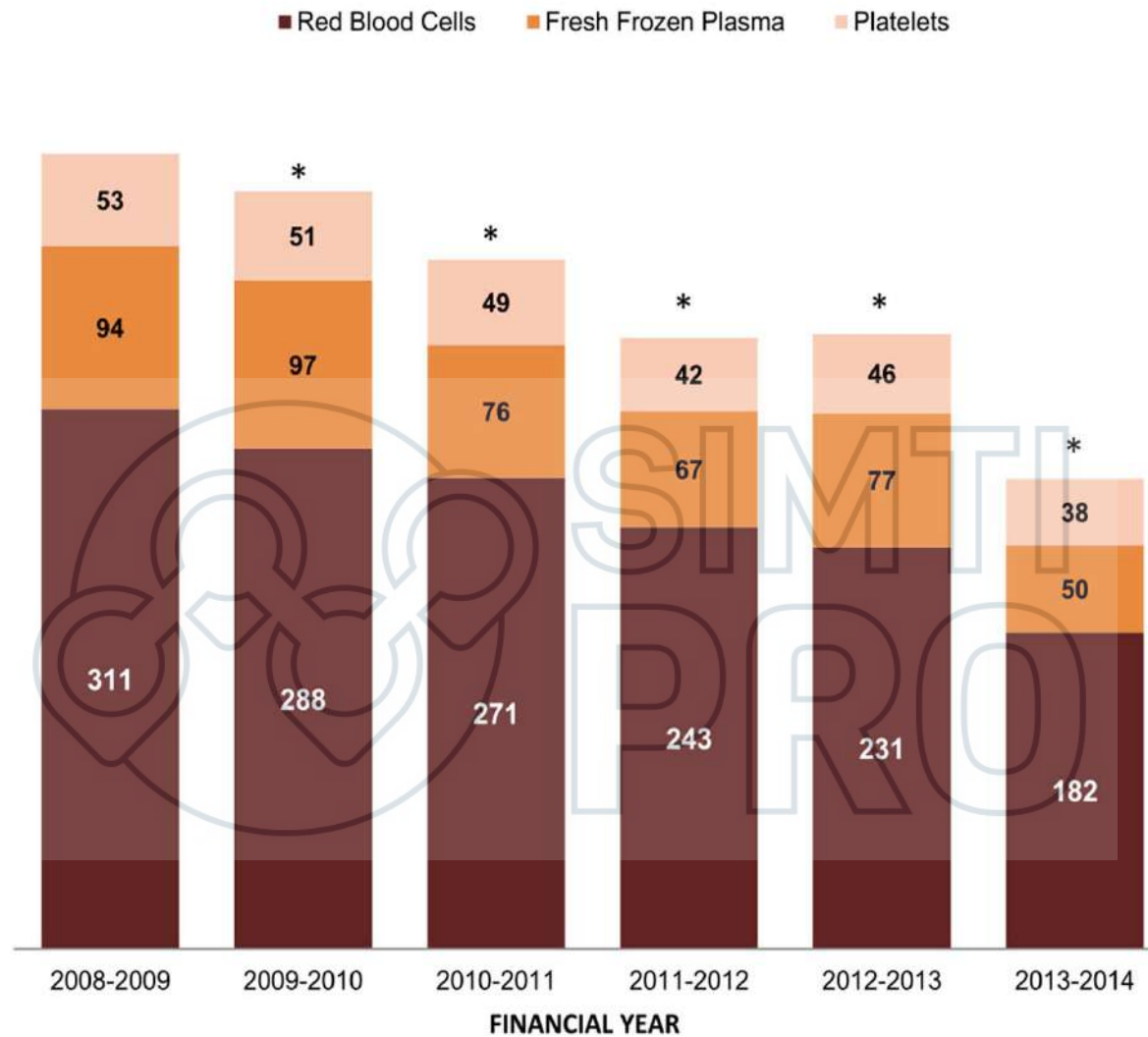
- Studio retrospettivo **605.046** pazienti
- applicazione PBM su vasta scala in Western Australia (2008-2014)

**A**









\* *p-value < 0.05, indicating the mean units transfused per 1000 discharges decreased significantly when compared to the reference year (2008-2009).*

## ORIGINAL RESEARCH

### 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,<sup>1,2,3</sup> Axel Hofmann,<sup>4,5,6</sup> Simon Towler,<sup>7</sup> Kevin M. Trentino,<sup>8</sup>  
Sally A. Burrows,<sup>1</sup> Stuart G. Swain,<sup>8</sup> Jeffrey Hamdorf,<sup>9,10</sup> Trudi Gallagher,<sup>11,12</sup>  
Audrey Koay,<sup>11</sup> Gary C. Geelhoed,<sup>11,13</sup> and Shannon L. Farmer<sup>9,14</sup>*

#### PRODUCT COST SAVINGS

Over the six-year study period  
blood product cost savings were:

**\$18.5M**

#### ACTIVITY BASED COST SAVINGS

...however with the hospital costs of administering a transfusion added,  
the gross savings are estimated to be between:

**\$80M – \$100M**

Blood Transfus 2019; 17: 16-26

## **A model-based cost-effectiveness analysis of Patient Blood Management**

Adina Kleinerüschkamp<sup>1</sup>, Patrick Meybohm<sup>1</sup>, Niels Straub<sup>2</sup>, Kai Zacharowski<sup>1</sup>, Suma Choorapoikayil<sup>1</sup>

*<sup>1</sup>Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy, University Hospital Frankfurt, Frankfurt; <sup>2</sup>Institute of Market Research, Statistics and Prognosis, Munich, Germany*

PBM-related costs of therapy exceeded costs of the control arm by **€ 150** per patient. However, total costs, including hospitalisation, were higher in the control-arm for both non-cardiac (**€ 2,885.11**) and cardiac surgery patients (**€ 1,760.69**)



# Is a Patient Blood Management programme economically reasonable?

*Lotta Hof<sup>a</sup>, Suma Choorapoikayil<sup>a</sup>, Patrick Meybohm<sup>b</sup> and Kai Zacharowski<sup>a</sup>*

## KEY POINTS

cost saving

- Intravenous iron supplementation in iron deficient anaemic patients, use of antifibrinolytic agents for the treatment of bleeding, use of cell salvage and an evidence-based transfusion strategy are associated with cost savings.

patient's value

- The performance of healthcare cannot be described by the sum of the overall costs, but has to take into account the value for the patients.

costs vary widely

- It is challenging to evaluate the costs and performance of comprehensive PBM programmes, because it is a multimodal and multidisciplinary concept.
- Analyses of single measures are rarely comparable, because healthcare costs vary widely between countries and healthcare systems.



# PBM: obbligo di legge?



Supplemento ordinario alla "Gazzetta Ufficiale", n. 300 del 28 dicembre 2015 - Serie generale

Spedis. abb. post. - art. 1, comma 1  
Legge 27-02-2004, n. 46 - Filiale di Roma

GAZZETTA  UFFICIALE  
DELLA REPUBBLICA ITALIANA

PARTE PRIMA

Roma - Lunedì, 28 dicembre 2015

SI PUBBLICA TUTTI I  
GIORNI NON FESTIVI

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N. 69

MINISTERO DELLA SALUTE

DECRETO 2 novembre 2015.

**Disposizioni relative ai requisiti di qualità e  
sicurezza del sangue e degli emocomponenti.**

GAZZETTA  UFFICIALE  
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06-85001 - LIBRERIA DELLO STATO

Art. 25.

*Sicurezza della trasfusione*

5. Al fine della prevenzione della trasfusione evitabile, sono definiti e implementati, sul territorio nazionale, specifici programmi (Patient Blood Management), con particolare riferimento alla preparazione del paziente a trattamenti chirurgici programmati, sulla base di linee guida da emanare a cura del Centro nazionale sangue entro sei mesi dall'entrata in vigore del presente decreto.

N. 69

DECRETO 2 novembre 2015.

**Disposizioni relative ai requisiti di qualità e sicurezza del sangue e degli emocomponenti.**







# **PBM: definizione** (in continua evoluzione...)



# A Global Definition of Patient Blood Management

Aryeh Shander, MD,\*† Jean-Francois Hardy, MD,‡§ Sherri Ozawa, RN,†|| Shannon L. Farmer, DHSc,¶##††  
Axel Hofmann, Dr.rer.medic,¶##‡‡ Steven M. Frank, MD,§§ Daryl J. Kor, MD,||¶¶ David Faraoni, MD,§##  
and John Freedman, MD,\*\*\*††† Collaborators

“Patient blood management is a patient-centered, systematic, evidence-based approach to improve patient outcomes by managing and preserving a patient’s own blood, while promoting patient safety and empowerment.”

- **IFPBM** - International Foundation for Patient Blood Management
- **NATA** - Network for the Advancement of PBM, Haemostasis and Thrombosis
- **SABM** - Society for the Advancement of Patient Blood Management
- **WAPBM** - Western Australia Patient Blood Management
- **ONTraC** - Ontario Nurse Transfusion Coordinators



**World Health  
Organization**

**Global Forum for Blood Safety:  
Patient Blood Management**

14–15 March 2011, Dubai, United Arab Emirates

**“Concept Paper ”**

... Patient blood management (PBM) is a patient-focused, evidence-based and systematic approach to optimize the management of patient and **transfusion of blood products** for quality and effective patient care.

It 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, the use of alternatives to blood transfusion and blood conservation.

# A Global Definition of Patient Blood Management

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# PBM e Servizi Trasfusionali



PERIODO	PILASTRO 1	PILASTRO 2	PILASTRO 3
	Ottimizzazione dell'eritropoiesi	Contenimento delle perdite ematiche	Ottimizzazione della tolleranza all'anemia
Pre-operatorio	<ul style="list-style-type: none"> <li>• Rilevare l'anemia.</li> <li>• Identificare e trattare la patologia di base che causa l'anemia.</li> <li>• Rivalutare il paziente, se necessario.</li> <li>• Trattare le carenze marziali e le anemie sideropeniche, le anemie delle malattie croniche e le carenze funzionali di ferro (la cosiddetta "iron-restricted erythropoiesis").</li> <li>• Trattare le carenze di altri ematinici.</li> </ul>	<ul style="list-style-type: none"> <li>• Identificare e gestire il rischio emorragico.</li> <li>• Contenimento del sanguinamento iatrogeno.</li> <li>• Attenta pianificazione e preparazione della procedura.</li> <li>• Predeposito, in casi molto selezionati.</li> </ul>	<ul style="list-style-type: none"> <li>• Valutare/ottimizzare la riserva fisiologica del paziente e i fattori di rischio.</li> <li>• Confrontare la perdita di sangue stimata con quella tollerabile dal singolo paziente.</li> <li>• Realizzare programmi di <i>blood management</i> individualizzati che includano le tecniche di risparmio del sangue adeguate al singolo caso.</li> <li>• Adozione di soglie trasfusionali restrittive.</li> </ul>
Intra-operatorio	<ul style="list-style-type: none"> <li>• Adeguata programmazione dell'intervento chirurgico dopo l'ottimizzazione dell'eritropoiesi.</li> </ul>	<ul style="list-style-type: none"> <li>• Emostasi meticolosa e tecniche chirurgiche.</li> <li>• Tecniche chirurgiche di risparmio del sangue.</li> <li>• Tecniche anestesologiche di risparmio del sangue.</li> <li>• Tecniche di autotrasfusione.</li> <li>• Tecniche farmacologiche e agenti emostatici.</li> <li>• Diagnostica <i>point of care</i>.</li> </ul>	<ul style="list-style-type: none"> <li>• Ottimizzare la gittata cardiaca, la ventilazione e l'ossigenazione.</li> <li>• Adozione di soglie trasfusionali restrittive.</li> </ul>
Post-operatorio	<ul style="list-style-type: none"> <li>• Stimolare l'eritropoiesi, se necessario.</li> <li>• Rilevare le interazioni farmacologiche che possono favorire e accentuare l'anemia post-operatoria.</li> </ul>	<ul style="list-style-type: none"> <li>• Attento monitoraggio del paziente e gestione del sanguinamento post-operatorio.</li> <li>• Riscaldamento rapido/mantenimento della normotermia (almeno che non esista una specifica indicazione per l'ipotermia).</li> <li>• Tecniche di autotrasfusione, se appropriate.</li> <li>• Contenimento del sanguinamento iatrogeno.</li> <li>• Gestione dell'emostasi e dell'anticoagulazione.</li> <li>• Profilassi delle emorragie del tratto gastro-intestinale superiore.</li> <li>• Profilassi/trattamento delle infezioni.</li> </ul>	<ul style="list-style-type: none"> <li>• Ottimizzare la tolleranza all'anemia.</li> <li>• Massimizzare l'apporto di ossigeno.</li> <li>• Minimizzare il consumo di ossigeno.</li> <li>• Adozione di soglie trasfusionali restrittive.</li> </ul>

# Servizio trasfusionale

- Garantire l'appropriatezza e la reale necessità della trasfusione **al di là** della sicurezza/ qualità/ compatibilità del prodotto (obiettivo l'outcome)
- Contribuire ai percorsi di PBM della propria Struttura Sanitaria per la messa in atto delle misure raccomandate per la prevenzione e il trattamento delle anemie
- Promuovere cultura e formazione sul corretto utilizzo della risorsa sangue

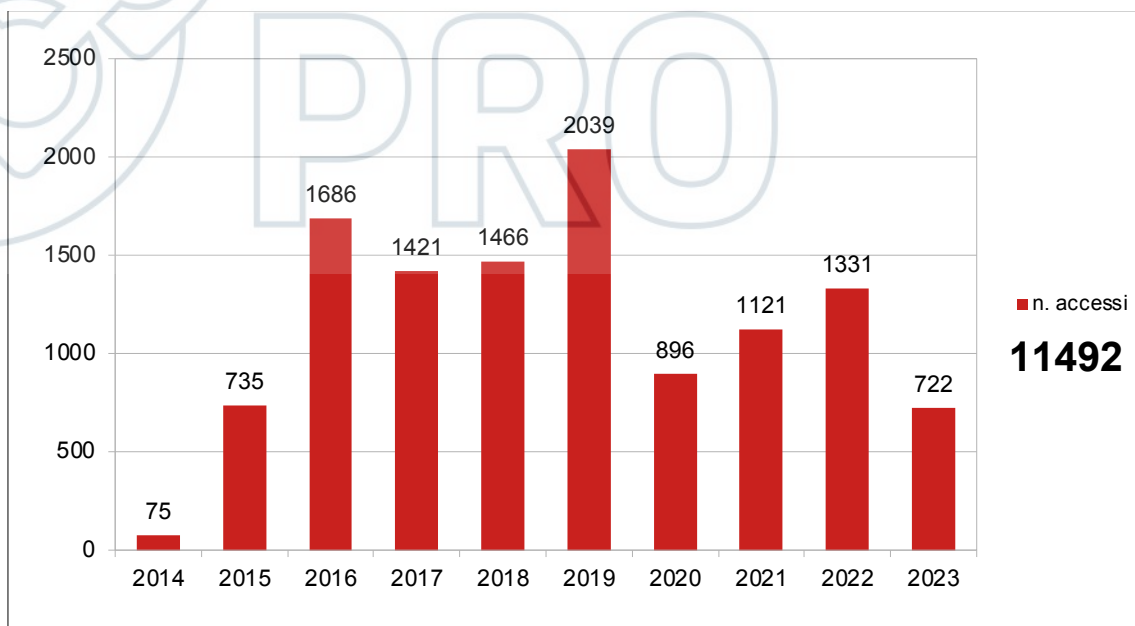
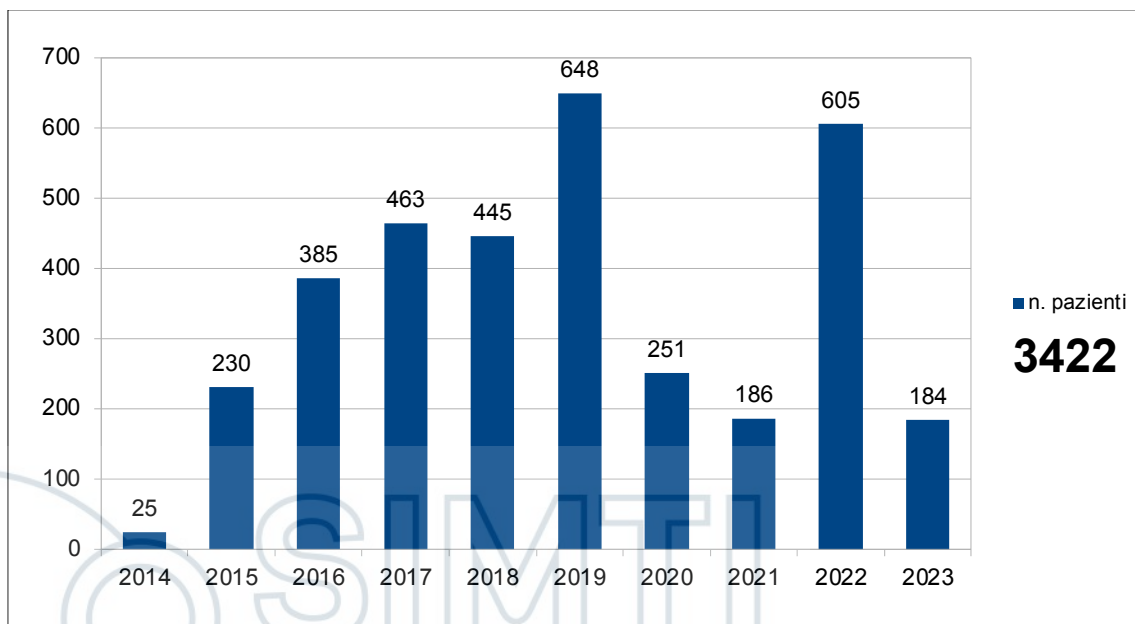




**PBM: attività presso la  
Città della Salute e della Scienza di Torino**

# Anemia clinic pre-ricovero

dal 2014 ad oggi



# Corsi di formazione aziendali

**2013** - FORMAZIONE DEL PERSONALE PER LA GESTIONE DELL'AMBULATORIO  
PATIENT BLOOD MANAGEMENT

**2013** - PROGETTO ED IMPLEMENTAZIONE DI UN AMBULATORIO  
MULTIDISCIPLINARE PER L'OTTIMIZZAZIONE EMATOPOIETICA IN PAZIENTI IN  
ATTESA DI INTERVENTO IN ELEZIONE

**2015** - PATIENT BLOOD MANAGEMENT: L'EVOLUZIONE DELLA TRASFUSIONE  
DI SANGUE

**2017 / 2019** - I TEST VISCOELASTICI DELLA COAGULAZIONE (TEG E ROTEM):  
A CHI, COME, QUANDO E PERCHÈ?

**2018 / 2019** - IL SANGUE: SICUREZZA, PATIENT BLOOD MANAGEMENT E  
DISSENSO

**2022 / 2023** – PREVENZIONE DELLA REAZIONE TRASFUSIONALE DA  
INCOMPATIBILITA' ABO: NORME, PROCEDURE, GESTIONE DEL PROCESSO

**2022 / 2023** - GESTIONE DELLA RISORSA SANGUE "IL PATIENT BLOOD  
MANAGEMENT" PBM

# Protocollo condiviso di gestione ospedaliera del paziente post-chirurgico in ambito di Patient Blood Management

- **giorno -1** Hb, saturazione transferrina, ferritina
- **intervento ch.** tecniche di risparmio di sangue, recupero i.o., acido tranexamico, normotermia, POC,
- **decorso** soglie restrittive, 1 unità se emodinamicamente stabili, solo prelievi per esami necessari (provette da 3 ml anzichè da 7 ml)
- **giorno +2 / +3** calcolo del ferro necessario per la risoluzione dell'anemia (Hb 13 g/dl – Hb attuale)
- **giorno +3 / +4** infusione Fe i.v. della dose calcolata
- **giorno +30** Hb, saturazione transferrina, ferritina

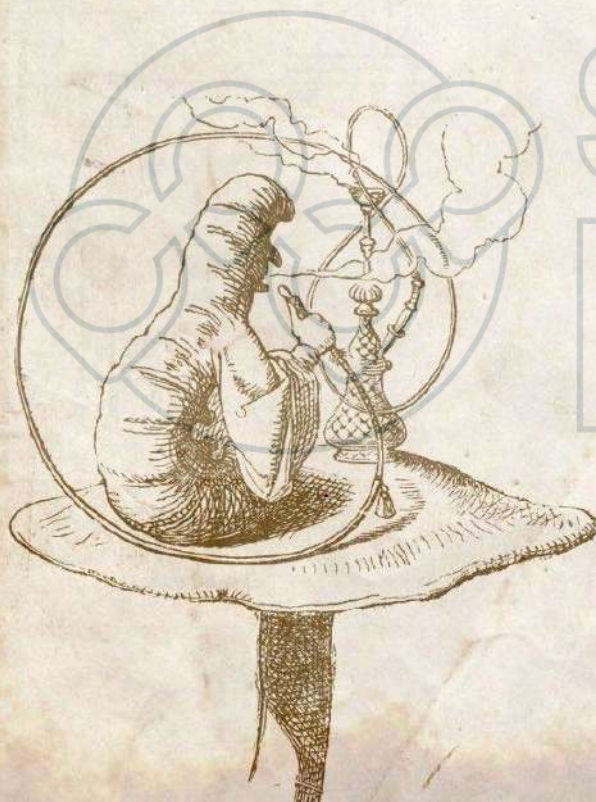




# Cos'è realmente il PBM?



Who are you?"  
said the Caterpillar.



"I-I hardly know, Sir, just  
at present—at least I know  
who I was when I got up  
this morning, but I think I  
must have been changed  
several times since then."

Alice