PBM vision globale & grandes actions internationales

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SFVTT Montpellier 2022

Conflits d'intérêts

- J'ai, et/ou mon institution, avons reçu des subventions des laboratoires:
  - *Vifor Pharma*
  - *Pfizer*
  - *Masimo*
  - *Pharmacosmos*

- Public grants (from French ministry of Health)
  - PHRC 2015: HiFIT study
  - PHRC 2019: MIVAR Study

HIFIT

MIVAR

Objectif Zero Transfusion

D'où vient-on?

1991

Nous sommes responsables…
… pas coupables !?

Le risque infectieux n'est pas le seul !

TRALI

TACO

Poumon

Muszynski *Transfusion* 2017

infections nosocomiales

Rohde *JAMA* 2014

TRIM

Cancer

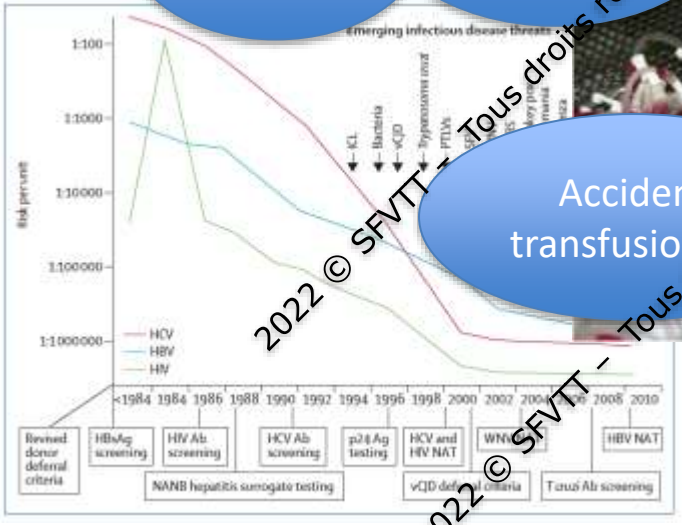
Cata *BJA* 2013

Atzil *Anesthesiology* 2008

Accident transfusionnel

Lésions du « storage »

Baeck *JCI* 2012



Goodnough *Lancet* 2013

Il faut mettre en place une épargne transfusionnelle !

Organisation mondiale de la santé

1. Mise en place de services de transfusion sanguine bien organisés, coordonnés au niveau national, de politiques transfusionnelles reposant sur des données probantes, efficaces et éthiques, ainsi que de la législation et réglementation nécessaires pour garantir la mise à disposition rapide d'approvisionnements suffisants en sang et en produits sanguins sécurisés pour tous les patients ayant besoin d'une transfusion.
2. Collecte de sang, de plasma et d'autres produits sanguins auprès de donneurs volontaires non rémunérés réguliers, à faible risque, grâce au renforcement des systèmes de don à une prise en charge efficace des donneurs, soins et conseils compris.
3. Dépistage avec assurance de la qualité des infections à transmission transfusionnelle, dont le VIH, l'hépatite B et C et la syphilis, tests de confirmation des résultats de tous les donneurs réagissant aux marqueurs d'infections, recherche des groupes sanguins et tests de compatibilité et systèmes de transformation des produits sanguins (composants pour la transfusion et produits dérivés du plasma), le cas échéant, pour répondre aux besoins des soins de santé.
4. Usage rationnel du sang et des produits sanguins pour réduire les transfusions superflues et les risques associés aux transfusions, recours à d'autres solutions que la transfusion, si possible, et bonnes pratiques cliniques en matière de transfusion, y compris prise en charge des patients.
5. Mise en œuvre progressive de systèmes de qualité efficaces, y compris gestion de la qualité, normes, bonnes pratiques de fabrication, documentation, formation du personnel et évaluation de la qualité.

Endorsement

2010

World Health Organization

Sixty-third World Health Assembly

Date: 17-21 May 2010
Location: Geneva, Switzerland

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)"

Pillar 1:

Optimizing the patient's own blood volume

Pillar 2:

Minimizing the patient's blood loss

Pillar 3:

Optimizing the patient-specific physiological tolerance of anaemia

2011

World Health Organization

Global Forum for Blood Safety: Patient Blood Management

14 -15 March 2011, Dubai, UAE

Organized by WHO HQ/Geneva and Sharjah Blood Transfusion and Research Centre and co-sponsored by the Government of United Arab Emirates (UAE)

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 on transfusion prescription

GOVERNMENT

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 clinical research - meta analysis
    a. Move forward on randomized control trials
    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-Mémoire on 'Clinical Use of Blood*' to get patient management and clinicians' perspective
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

British Journal of Anaesthesia 109 (1): 55–68 (2012)
Advance Access publication 24 May 2012 · doi:10.1093/bja/aes139

BJA

Patient blood management in Europe

A. Shander[1*], H. Van Aken[2], M. J. Colomina[3], F. Gombotz[4], A. Hofmann[5], R. Krauspe[6], S. Laszlo[7], T. Richards[8], R. Slappendel[9] and D. R. Spahn[10]

Table 2 PBM practices in orthopaedic surgery in selected European countries. COX, cyclo-oxygenase; CRP, C-reactive protein; EPO, recombinant human erythropoietin; ESA, erythropoiesis-stimulating agents; Hb, haemoglobin; MCH, mean corpuscular haemoglobin; MCV, mean cell volume; NSAID, non-steroidal anti-inflammatory drugs; PBM, patient blood management; SOC, standard of care; TBC, total blood count; TSAT, transferrin saturation

Country	Assessment procedures, responsible person, and haematological parameters	If present, is preoperative anaemia investigated further?	Anaemia management	Are PBM strategies in place for major elective surgery?
France	Patient assessed 2 days before operation when no planned indication for ESA, 30 days before operation when ESA planned Tests: Hb concentration only, platelet count Responsible person: anaesthetist	Usually not	Usually intra- or postoperative transfusion to address anaemia Preoperative transfusion only when anaemia is profound or if surgery is delayed/cancelled (rare) ESA are used mainly in hip surgery Responsible person: anaesthetist	No

En Europe:
Quelques initiatives locales
Pays-Bas « champions »

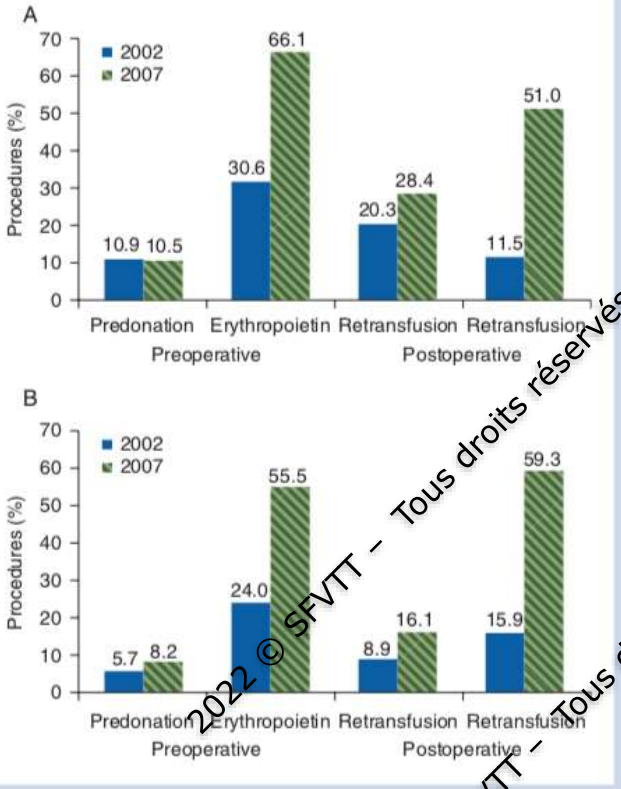


Fig 2 Results of a national survey of rates of autologous pre-operative blood donation, erythropoietin use and autologous retransfusion in patients undergoing (A) hip or (B) knee arthroplasty in 2002 and 2007 in the Netherlands.[91]

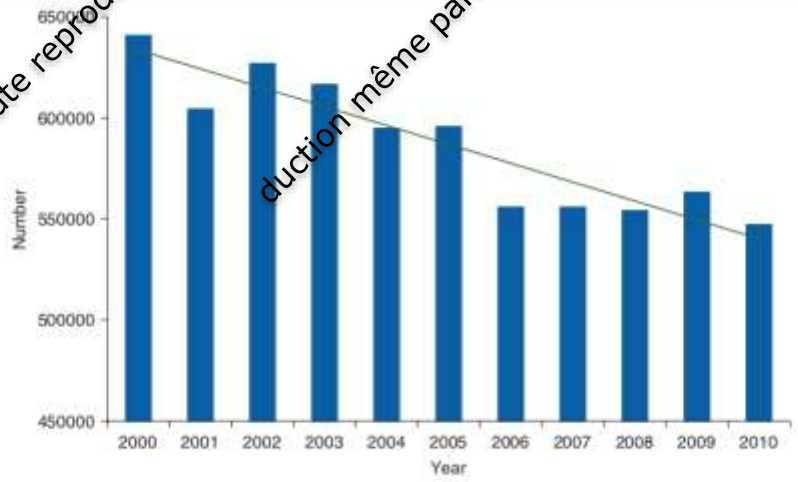


Fig 3 Number of allogeneic transfusions in the Netherlands from 2000 to 2010.[91]

Shander *BJA* 2012

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2011

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NATIONAL BLOOD AUTHORITY
AUSTRALIA

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Enter your keyword

Ensuring Supply | Best Practice | Blood Systems | Data & Research | About Blood | Publications & Tools

Home » Best Practice » National Standard for Blood and Blood Products Safety and Quality

- National Standard
  - Standard 7 and the Patient Blood Management (PBM) Guidelines
  - Pathology Service Provider Obligations Under NSQHS Standard 7 – Blood and Blood Products
- Case Studies
- Stewardship
- Patient Blood Management
- Immunoglobulin (Ig)
- Prophylactic use of Rh D immunoglobulin in maternity care
- Fresh Blood Products
- Bleeding Disorders
- Education and Training
- Haemovigilance
- NBA sponsored awards

National Standard for Blood and Blood Products Safety and Quality

The first edition of the Australian Commission on Safety and Quality in Health Care (ACSQHC) National Safety and Quality Health Service (NSQHS) Standards was released in 2011. It became mandatory for assessment of hospitals and day procedure services from 1 January 2013. One of the ten standards focuses on blood and blood products (Standard 7).

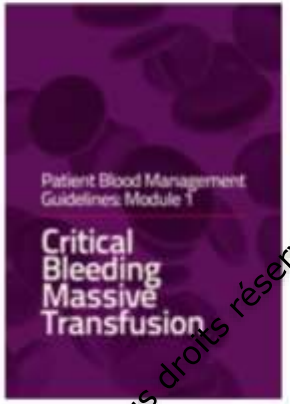
Following a review, the second edition of the NSQHS Standards was endorsed by Health Ministers and released in November 2017. The second edition was developed by the ACSQHC in consultation with Australian Government state and territory partners (including the National Blood Authority), consumers, the private sector and other stakeholders. Assessment against the second edition commenced from 1 January 2019.

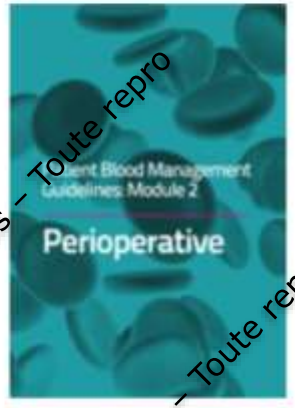
A document mapping the actions in the second edition to the first edition can be found on the ACSQHC website.

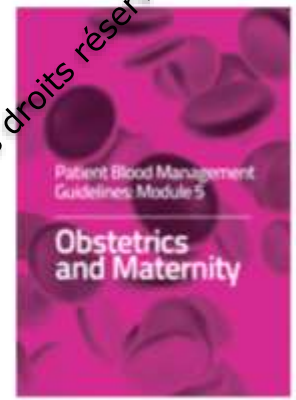
Standard 1: Clinical Governance and Standard 2: Partnering with Consumers combine to form the clinical governance framework for all health service organisations. They support and integrate with all the clinical standards, which cover specific areas of patient care. In the second edition, Standard 7: Blood Management replaces the first edition Standard 7: Blood and blood products.

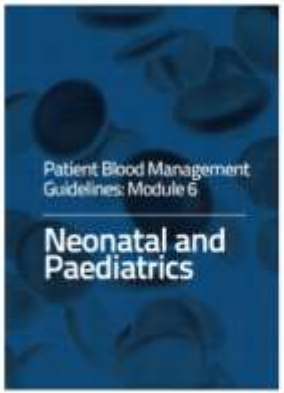
Patient Blood Management Guidelines

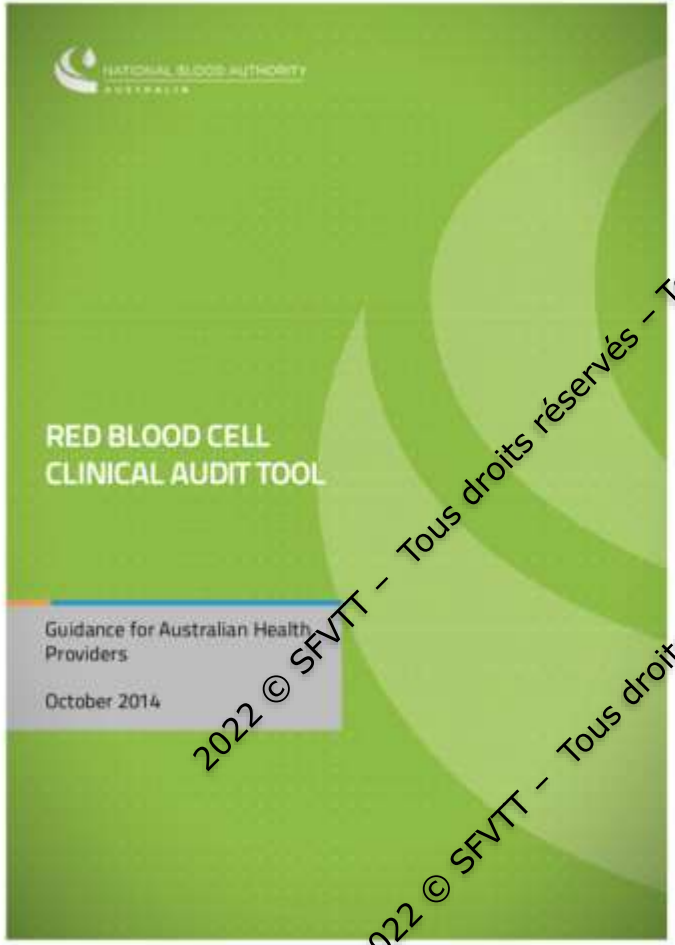
Visit Patient Blood Management Guidelines to access the latest modules in the Guidelines or click on the images below to go directly to the relevant module.

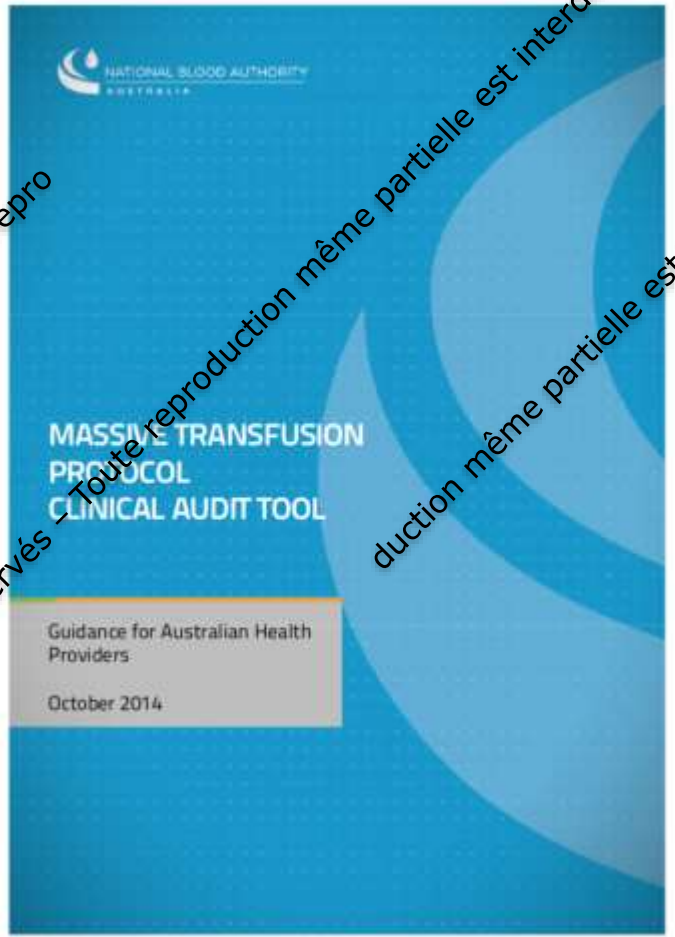






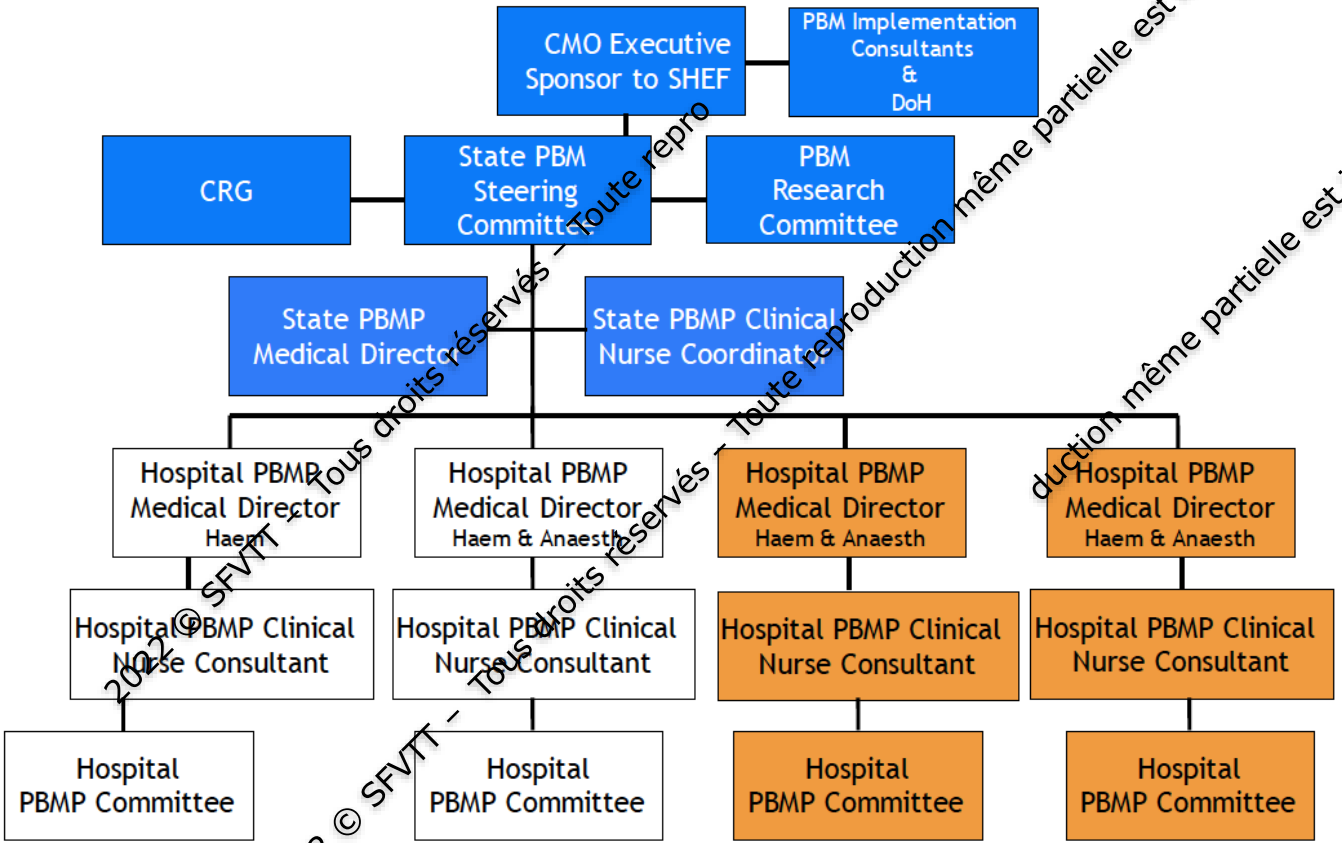




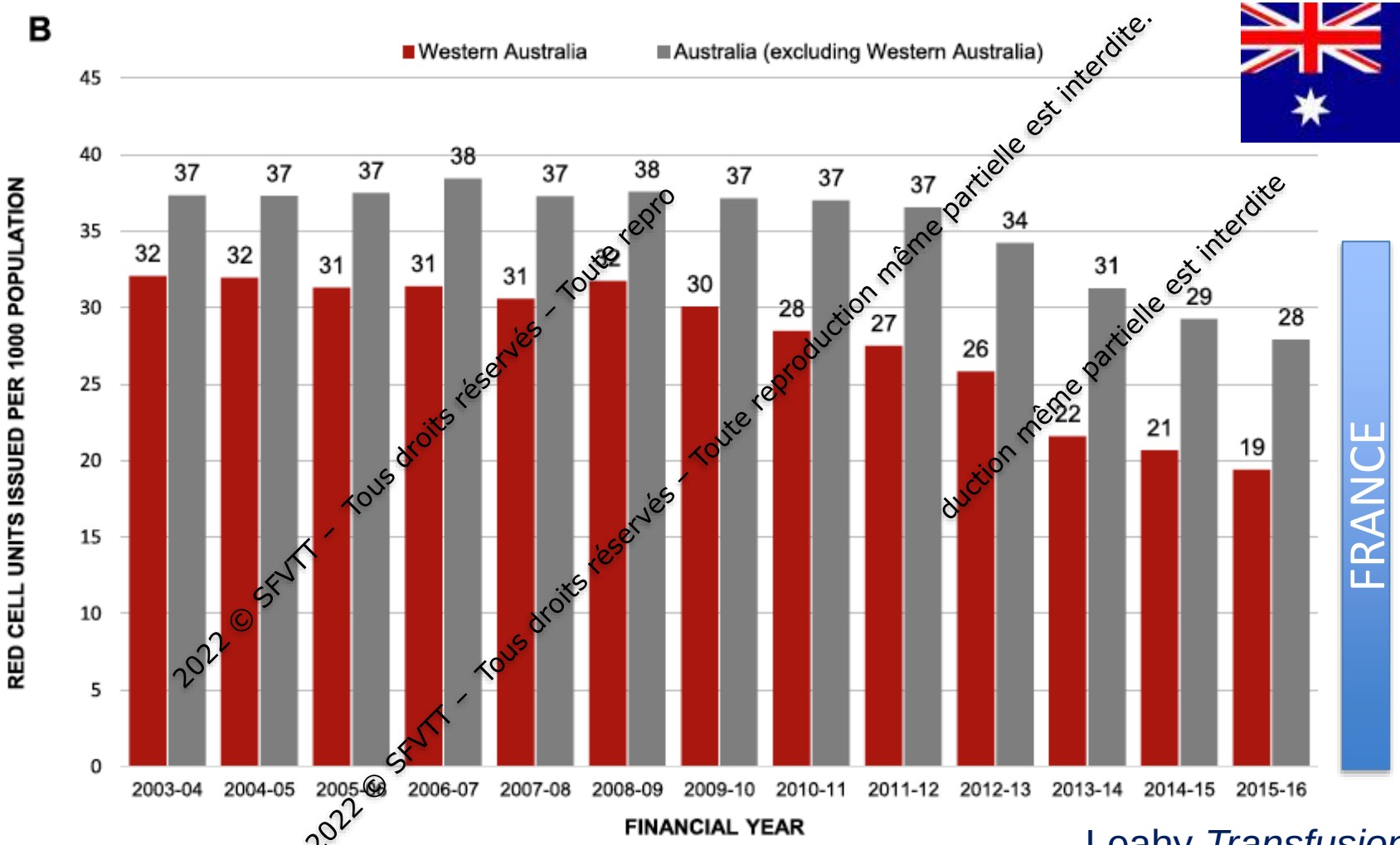


RESOURCES AVAILABLE INCLUDE

PBM Program Leadership Structure



Leahy *Transfusion* 2017



Leahy *Transfusion* 2017

CHALLENGES IN BLOOD SERVICES

Based on GDBS 2015

2015

No blood preparedness system
during emergency situation

Inadequacy in policy, regulations, governance & financing

60-70% MS with blood policy, legislation, oversight system

Poor access to blood during emergency

Insufficient supply of blood products

66 Member States with donation rate <10/1000

Sub-optimal clinical practices

Patient Blood Management not in place

Deficiencies in safety, effectiveness and quality

Lack of availability of PDMPs

Limited use of component
Low vol & poor quality of plasma

80% of donated blood was tested in LMICs

Slide: Courtesy of Dr. Yuyun Maryuningsih
Team Lead Blood and other Products of Human Origin, WHO

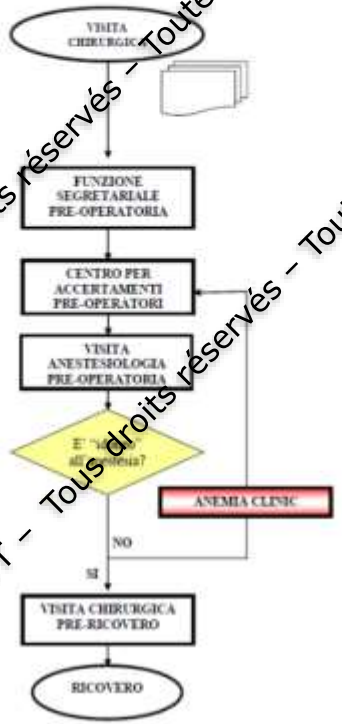
2016

Ravvisata l'opportunità di richiamare l'attenzione delle Aziende Sanitarie e dei Servizi Trasfusionali sulla necessità di presidiare in modo rigoroso l'appropriatezza dell'utilizzo clinico del sangue e dei suoi emocomponenti e dove applicabile dei medicinali plasmaderivati, attraverso la puntuale e sistematica applicazione del Decreto del Ministro della Salute 2 novembre 2015, recante "Disposizioni relative ai requisiti di qualità e sicurezza del sangue e degli emocomponenti" nonché attraverso le attività dei Comitati ospedalieri per il buon uso del sangue e delle cellule staminali da sangue cordonale di cui all'articolo 17, comma 2, della Legge 219/2005;

Considerato che il Patient Blood Management è un approccio multiprofessionale e multidisciplinare e valutato che i provvedimenti da adottare presso le Aziende Sanitarie conseguenti alla applicazione della presente Linea Guida risultano sostenibili, anche in termini economici, a fronte del vantaggio ottenibile in termini di sicurezza della trasfusione e di contenimento del fabbisogno trasfusionale e dei costi correlati alla terapia trasfusionale;

Al fine di ridurre in modo significativo l'utilizzo degli emocomponenti e dei medicinali plasmaderivati prevenendo la trasfusione evitabile;

Flow-chart pre-operatoria PBM - paziente sottoposto ad intervento di chirurgia maggiore ortopedica elettiva e inserito nel percorso del Patient Blood Management

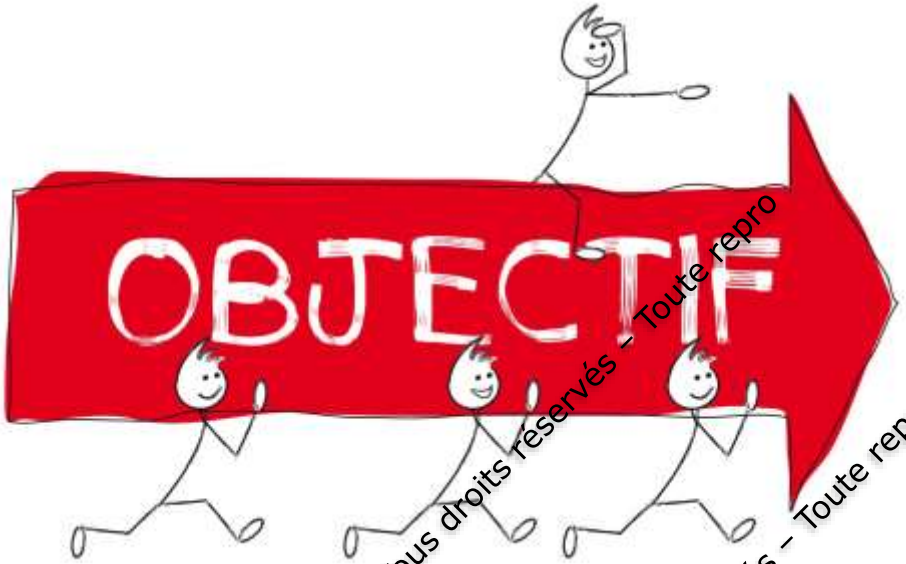


Durante la visita il chirurgo, utilizzando il QUESTIONARIO PRE-OPERATORIO PBM, effettua l'anamnesi coagulativa e dei fattori di rischio specifici per il rischio emorragico.
Prescrive gli specifici accertamenti pre-operatori e le connsulenze specialistiche (Trasfusionista, esperto in Emostasi e Trombosi, Cardiologo, ecc.), se necessarie.
Invia il paziente alla Funzione Segretariale Pre-operatoria.

Programma la data di esecuzione degli accertamenti pre-operatori e della visita anestesiologica.
Al paziente, consegna la brochure informativa.

Il paziente accede all'ambulatorio nel giorno stabilito ed effettua gli accertamenti pre-operatori (diagnostica di laboratorio, strumentale).

Il paziente effettua la visita anestesiologica pre-operatoria.
Consulto in Anemia Clinic.



Réduire les transfusions évitables

2017

Action de la commission Européenne

Des guides pratiques

WESTERN AUSTRALIA
PATIENT BLOOD MANAGEMENT PROGRAM

The Western Australian Patient Blood Management Program recently published the world's largest study on patient blood management outcomes. The study included over 600,000 patients admitted to Western Australia's four major adult hospitals between July 2008 and June 2014. Over the six-year study period, the program was associated with:

IMPROVED PATIENT OUTCOMES

mortality	infection	AMI/stroke	length of stay
DECREASED 28%	DECREASED 21%	DECREASED 31%	DECREASED 15%

IMPROVED KEY PROGRAM INDICATORS

pre-operative anaemia	pre-transfusion haemoglobin	single unit transfusions
DECREASED FROM 21% TO 14%	DECREASED FROM 79g/L TO 73g/L	INCREASED FROM 33% TO 64%

REDUCTIONS IN UNITS OF BLOOD TRANSFUSED

41% decrease in red blood cells	47% decrease in plasma	27% decrease in platelets

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

For more information see: Leahy MF et al. Improved outcomes and reduced costs associated with a health system-wide Patient Blood Management program. *Transfusion*.

better health • better care • better value

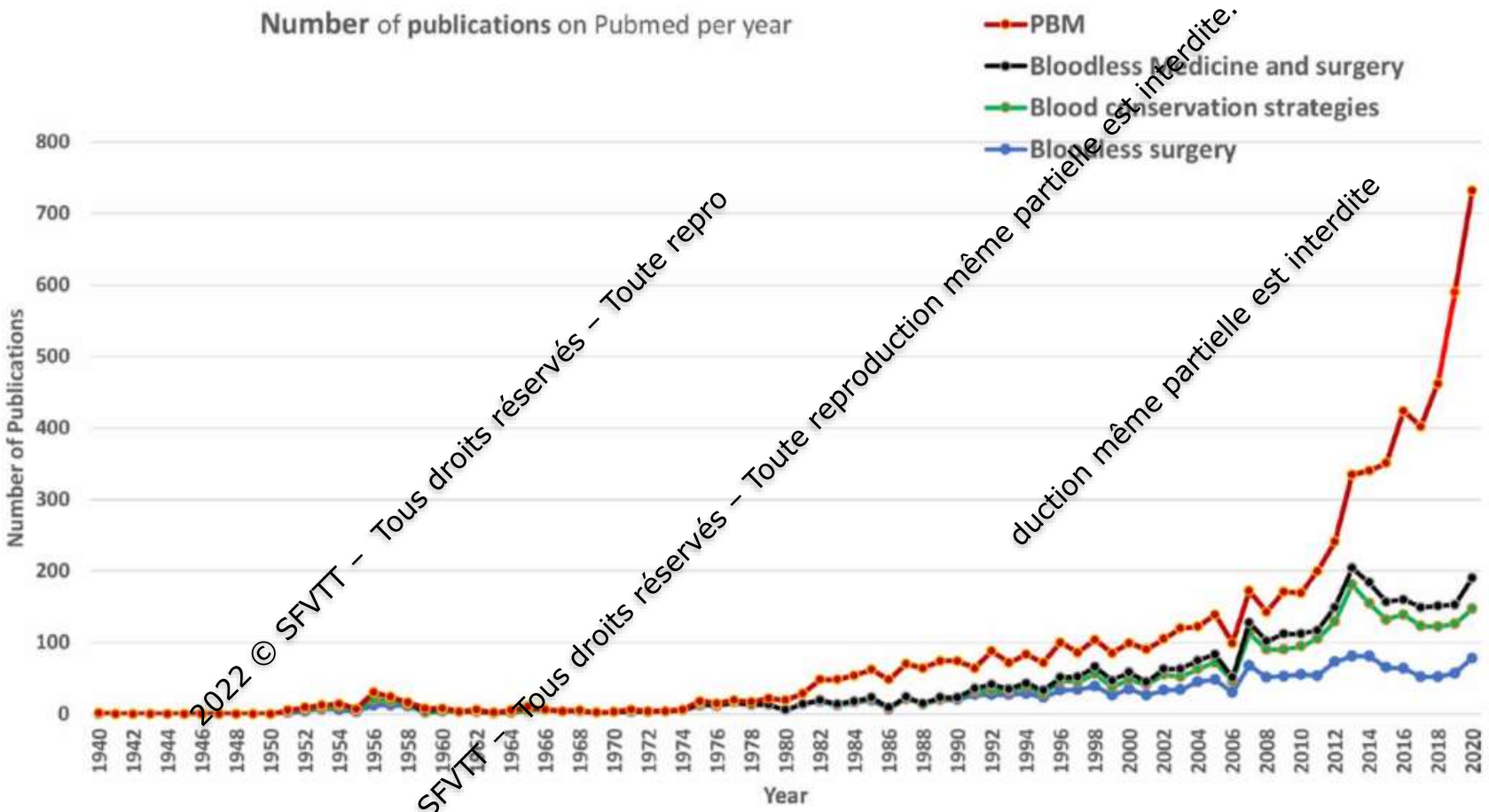
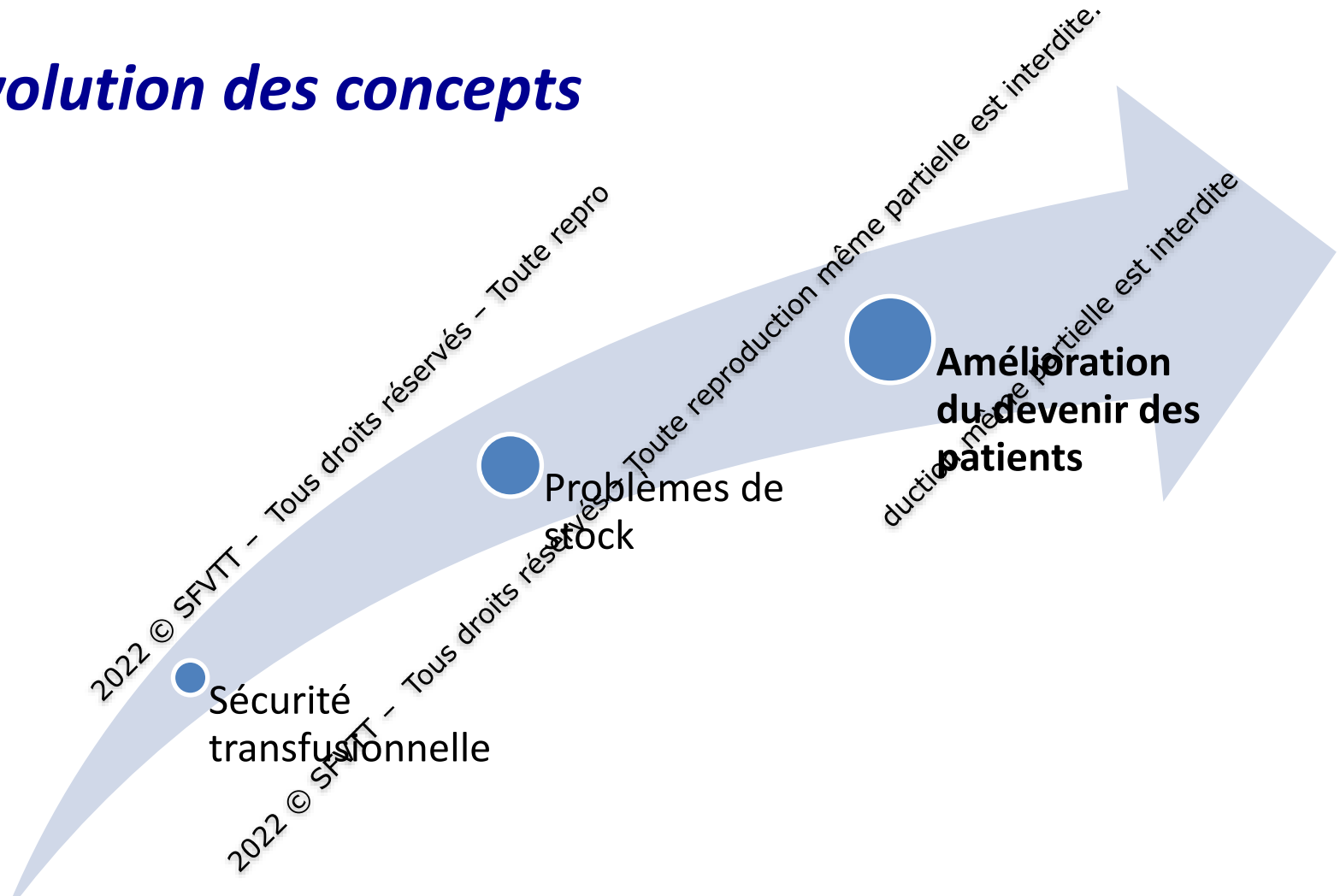
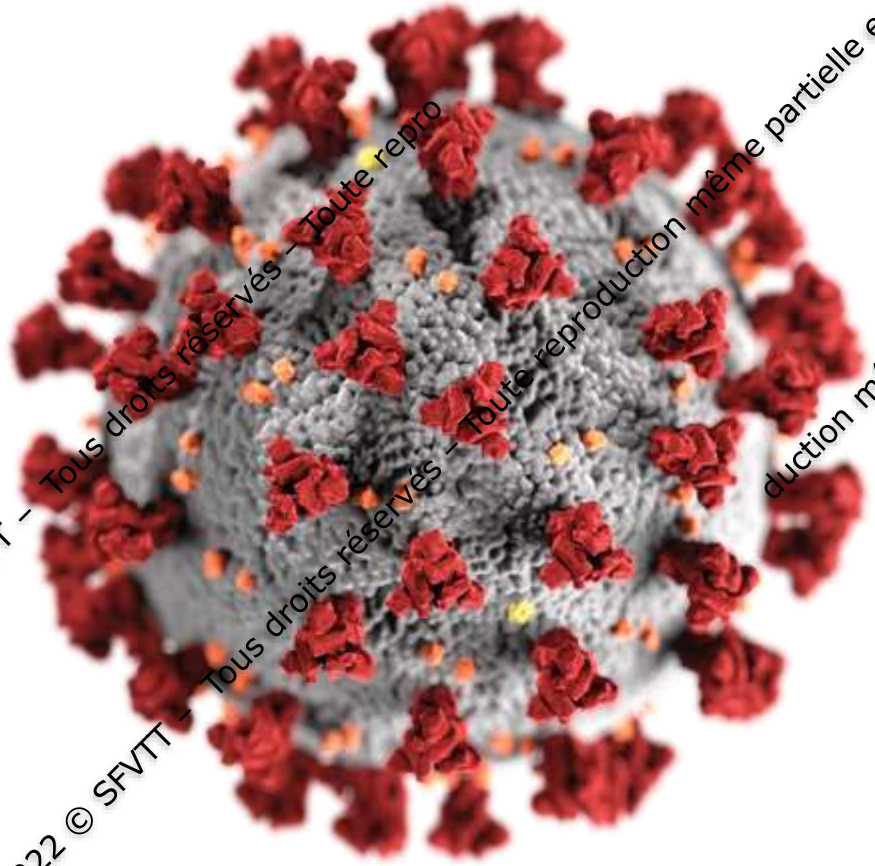


Figure. Growth in the annual number of publications indexed in PubMed focusing on PBM and related disciplines. PBM indicates patient blood management.

Shander *A&A* 2022

Evolution des concepts





SPECIAL ARTICLE

Essential Role of Patient Blood Management in a Pandemic: A Call for Action

Aryeh Shander, MD,* Susan M. Goobie, MD,† Matthew A. Warner, MD,‡ Matti Aapro, MD,§ Elvira Bisbe, MD, PhD,‖ Angel A. Perez-Calatayud, MD,¶ Jeannie Callum, MD,# Melissa M. Cushing, MD,** Wayne B. Dyer, PhD,†† Jochen Erhard, MD,‡‡ David Faraoni, MD, PhD,§§ Shannon Farmer, MBS, ‖‖¶¶ Tatyana Fedorova, PhD,## Steven M. Frank, MD,*** Bernd Froessler, MD, PhD,†††‡‡‡ Hans Gombotz, MD,§§§ Erwin Gross, MD,‖‖‖¶¶¶ Nicole R. Guinn, MD,### Thorsten Haas, MD,**** Jeffrey Hamdorf, MD, PhD,†††† James P. Isbister, MD,‡‡‡‡ Mazyar Javidroozi, MD, PhD,* Hongwen Ji, MD,§§§§ Young-Woo Kim, MD,‖‖‖‖ Daryl J. Kor, MD,¶¶¶¶ Johann Kurz, PhD,####***** Sigismond Lasocki, MD, PhD,††††† Michael F. Leahy, MBChB,‡‡‡‡‡ Cheuk-Kwong Lee, MD,§§§§§ Jeong Jae Lee, MD, PhD,‖‖‖‖‖ Vernon Louw, MBChB, PhD,¶¶¶¶¶ Jens Meier, MD,##### Anna Mezzacasa, PhD,****** Manuel Munoz, MD, PhD,†††††† Sherri Ozawa, RN,‡‡‡‡‡‡ Marco Pappalardi, MD,§§§§§§ Nina Shander, BS,‖‖‖‖‖‖‖ Donat R. Spahn, MD,¶¶¶¶¶¶ Bruce D. Spiess, MD,######* Jackie Thomson, MBChB,******* Kevin Trentino, MPH,†††††††‡‡‡‡‡‡‡ Christoph Zenger, PhD,§§§§§§§ and Axel Hofmann, Dr.rer.medic,‖‖‖‖‖‖‖‖¶¶¶¶¶¶¶¶####### on behalf of the International Foundation of Patient Blood Management (IFPBM) and Society for the Advancement of Blood Management (SABM) Work Group

Shander *A&A* 2020

2020

Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19)

Interim guidance
20 March 2020

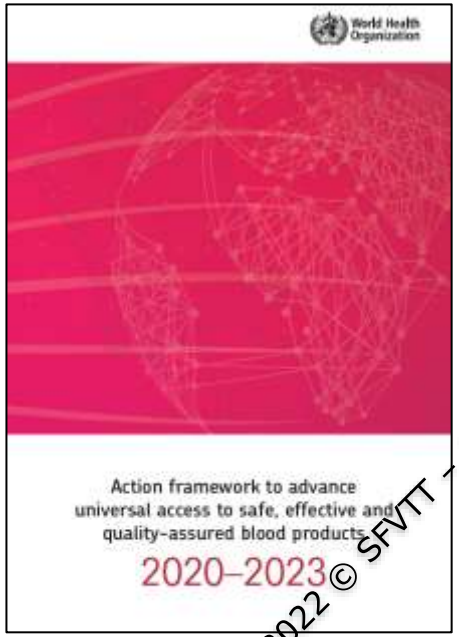
World Health Organization

4. Managing the demand for blood and blood products

Blood services should continually assess their blood stocks carefully in anticipation of uncertainty in the scale of collection activities. During widespread transmission, demand for blood and components may decrease as the health care system shifts toward treating increasing numbers of COVID-19 patients and elective surgeries and non-urgent clinical interventions are deferred. But blood transfusions will still be necessary for emergency situations such as trauma, post-partum haemorrhage, severe infant anaemia, blood dyscrasias, and urgent surgeries requiring availability of blood. Increased stocks may also be needed to support COVID-19 patients with severe sepsis or requiring extracorporeal membrane oxygenation support.

Good patient blood management will help safeguard blood stocks. The blood service must clearly communicate with health care professionals responsible for transfusion activities to ensure that blood and components are only used when clinically appropriate.

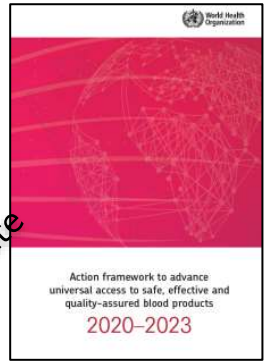
2020



The six strategic objectives are:

1. an appropriately structured, well coordinated and sustainably resourced national blood system;
2. an appropriate national framework of regulatory controls, national standards and quality assessment programmes;
3. functioning and efficiently managed blood services;
4. effective implementation of patient blood management to optimize clinical practice of transfusion;
5. effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems;
6. partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

Slide: Courtesy of Dr. Axel Hofmann



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Patient Blood Management

Optimal Blood Use

patient outcomes

Slide: Courtesy of Dr. Axel Hofmann

SPECIAL ARTICLE

A Global Definition of Patient Blood Management

Aryeh Shander, MD,*† Jean-Francois Hardy, MD,‡§ Cherri 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.

Shander A, Hardy JF, Ozawa S, et al. A Global Definition of Patient Blood Management. Anesth Analg. Feb 10 2022

International Foundation for Patient Blood Management
www.ifpbm.org

SABM
www.sabm.org

nata
www.nataonline.com

Western Australia Patient Blood Management Group

Definition also endorsed by

American Society of Anesthesiologists (ASA)
American Society of Extracorporeal Technology (AmSECT)
Anemia Working Group Espana (AWGE)
Asia-Pacific Society for Patient Blood Management (ASPBM)
Chinese Society for Patient Blood Management (CSPBM)
Korean Society for Patient Blood Management (KPBM)
Korean Society of Anesthesiologists (KSA)
Malaysian Society of Haematology (MSH)
National Association of Specialists in Patient Blood Management (NASPBM)
Ontario Nurse Transfusion Coordinators Program, Canada (ONTRraC)
Sociedad IberoAmericano de Patient Blood Management (SIAPBM)
Society of Cardiovascular Anesthesiologists (SCA)
South African National Blood Service (SANBS)

Shander *A&A* 2022

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Dat

Home / Publications / Overview / The urgent need to implement patient blood management: policy brief

The urgent need to implement patient blood management: policy brief

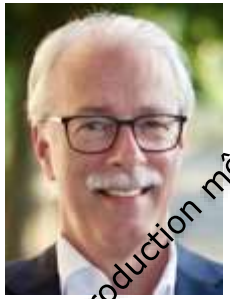
19 October 2021 | Policy brief

WHO's External Steering Committee


Neil Blumberg


Irwin Gross
Co-chair


Jeff Hamdorf


Axel Hofmann
Chair


James Isbister

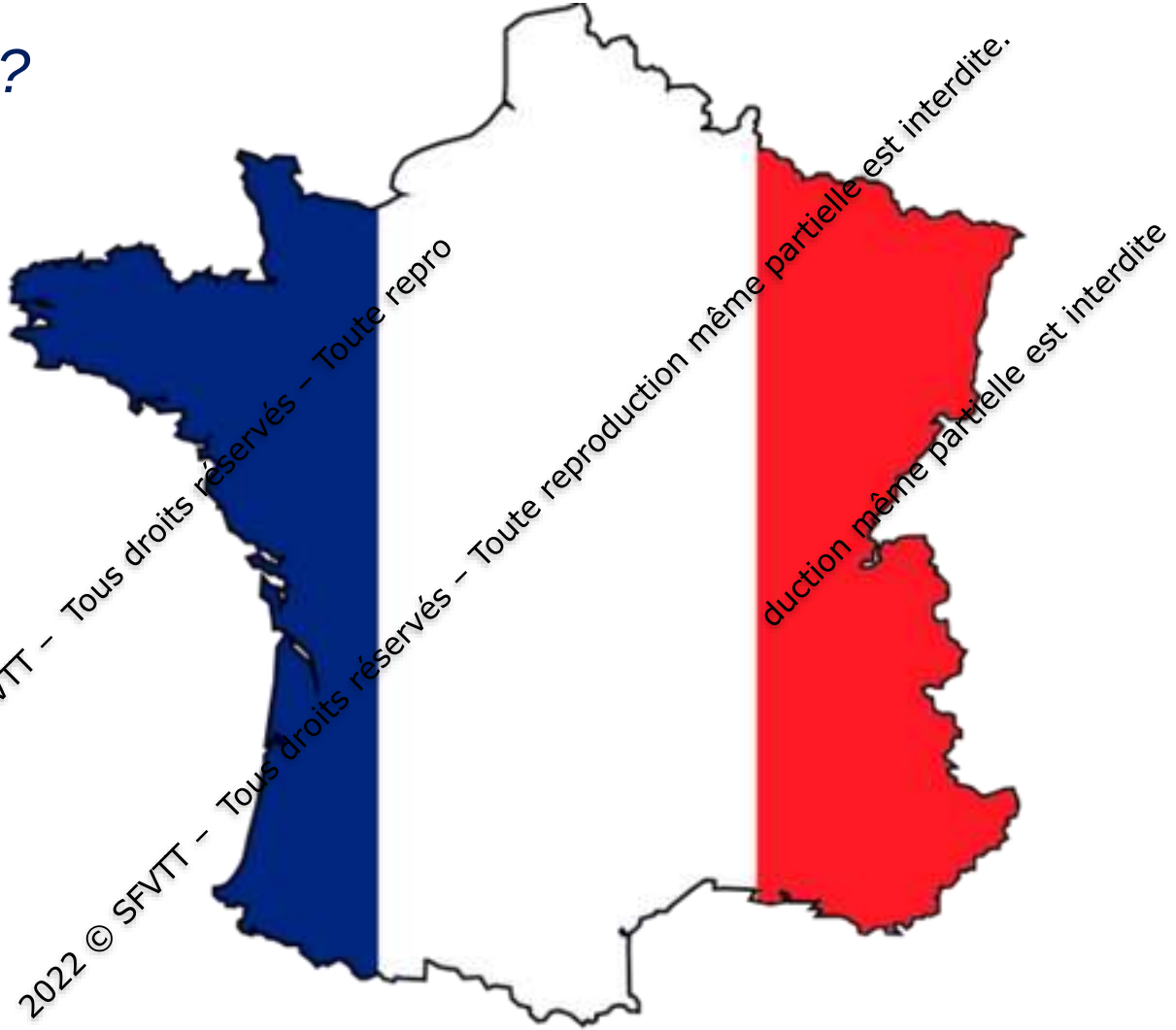

Aryeh Shander

Tasked with the development of

- **PBM Policy Brief and**
- **Guidance Document on PBM Implementation**

with support of 70 international PBM experts

Et chez nous?

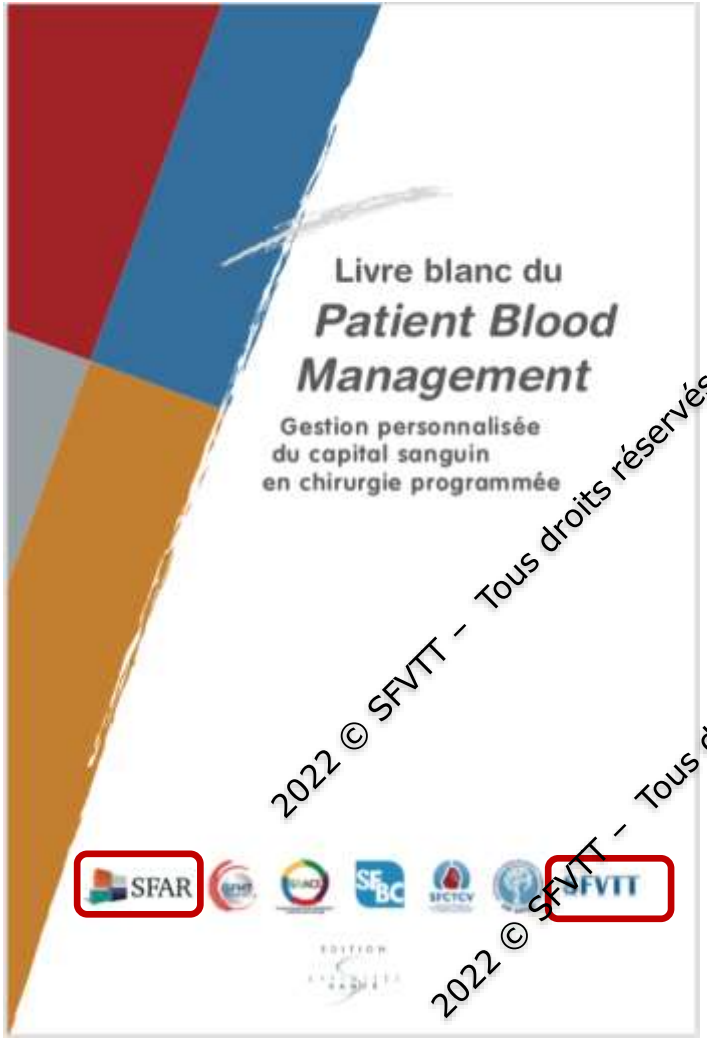


2018

2035, la transfusion sanguine à l'heure d'une médecine de prévention. Les évolutions dans la prise en charge des patients et des compétences du personnel de santé s'inscrivent dans un contexte de transformation plus large des pratiques de soins, valorisant une approche moins curative et plus préventive de la médecine. Les produits sanguins sont au cœur de cette nouvelle dynamique, notamment à travers la prévention des complications transfusionnelles, en agissant davantage sur les facteurs de risques.

Cette médecine transfusionnelle de prévention devra également valoriser un meilleur usage des produits sanguins à travers une généralisation des politiques de *patient blood management*. S'appuyant sur des formations et des outils dédiés (algorithmes transfusionnels et meilleures organisations périopératoires), cette approche vise à tendre à une plus juste utilisation des produits sanguins.

Autant d'initiatives qui portent un meilleur accompagnement des patients et un conseil transfusionnel renforcé auprès des prescripteurs pour inscrire la transfusion au cœur de la transformation de l'offre de soins à l'horizon 2035.

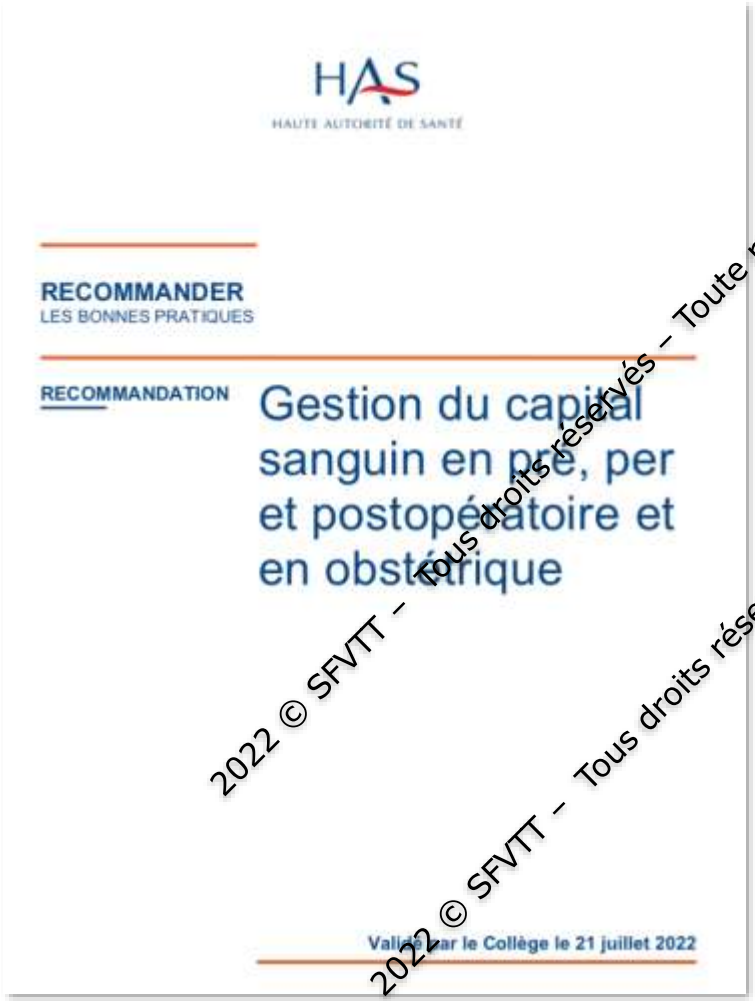


1ère Réflexion nationale sur le PBM

2018

Dix propositions du comité scientifique

- 1. Appliquer les mesures incontournables de la prise en charge anesthésique peropératoire
- 2. Appliquer les incontournables chirurgicaux
- 3. Dépister et prendre en charge l'anémie et la carence martiale en chirurgie programmée
- 4. Mieux utiliser les tests de biologie délocalisée en hématologie pour optimiser la gestion des produits sanguins labiles au bloc chirurgical
- 5. Appliquer les bonnes « tactiques » transfusionnelles
- 6. Faciliter la décision et le suivi des pratiques transfusionnelles
- 7. Sensibiliser et informer l'ensemble de la chaîne décisionnelle du monde hospitalier des modalités, enjeux et résultats de la démarche de PBM
- 8. Intégrer le PBM dans les programmes de récupération améliorée après chirurgie (RAAC)
- 9. Expérimenter l'instauration d'un forfait PBM au sein d'un parcours de RAAC
- 10. Créer la fonction de coordonnateur médical des activités périopératoires au sein des établissements MCO



2022

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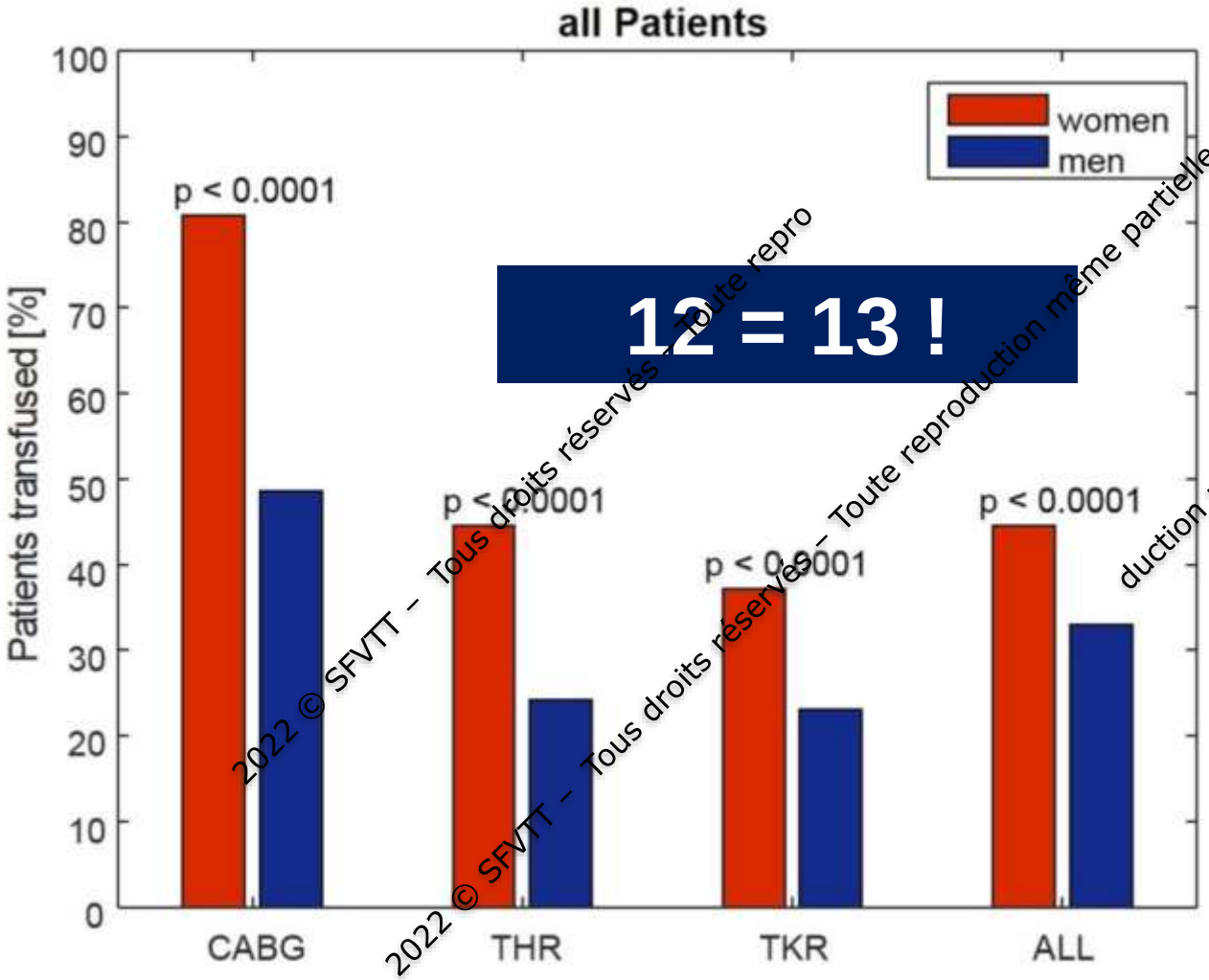
- Gestion PRE-opératoire
- Gestion PER-opératoire
- Gestion POST-opératoire

- Gestion en obstétrique

Gestion PRE-opératoire

- **Dépistage Anémie et Carence martiale SYSTEMATIQUE** en cas de chirurgie à risque hémorragique (A) ou de fragilité (A)
- Traitement pour **Hb < 13 g/dL chez Homme et Femme** (A)
- Traitement anémie par carence martiale (A) (Ferritine <100 µg/L et/ou TSAT <20%)(C) avec du FER IV (B)
- **ASE en Orthopédie et chirurgie cardiaque** (A)
- **ASE en cas d'anémie inflammatoire** (AE)

Non à la discrimination !



12 = 13 !

Les femmes sont plus transfusées

- N=6530 pts, 23 centres
- Transfusion jusqu'à J5 post-op

Gombotz *BMJ Open* 2016

HAUTE AUTORITÉ DE SANTÉ

HAS
HAUTE AUTORITÉ DE SANTÉ

EPO pré-op

Meta-analyse
(EPO+FER *vs FER*)

25 RCT, 4719 pts
RR transfusion 0.58

Kei *Can J Anesth* 2019

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HAS
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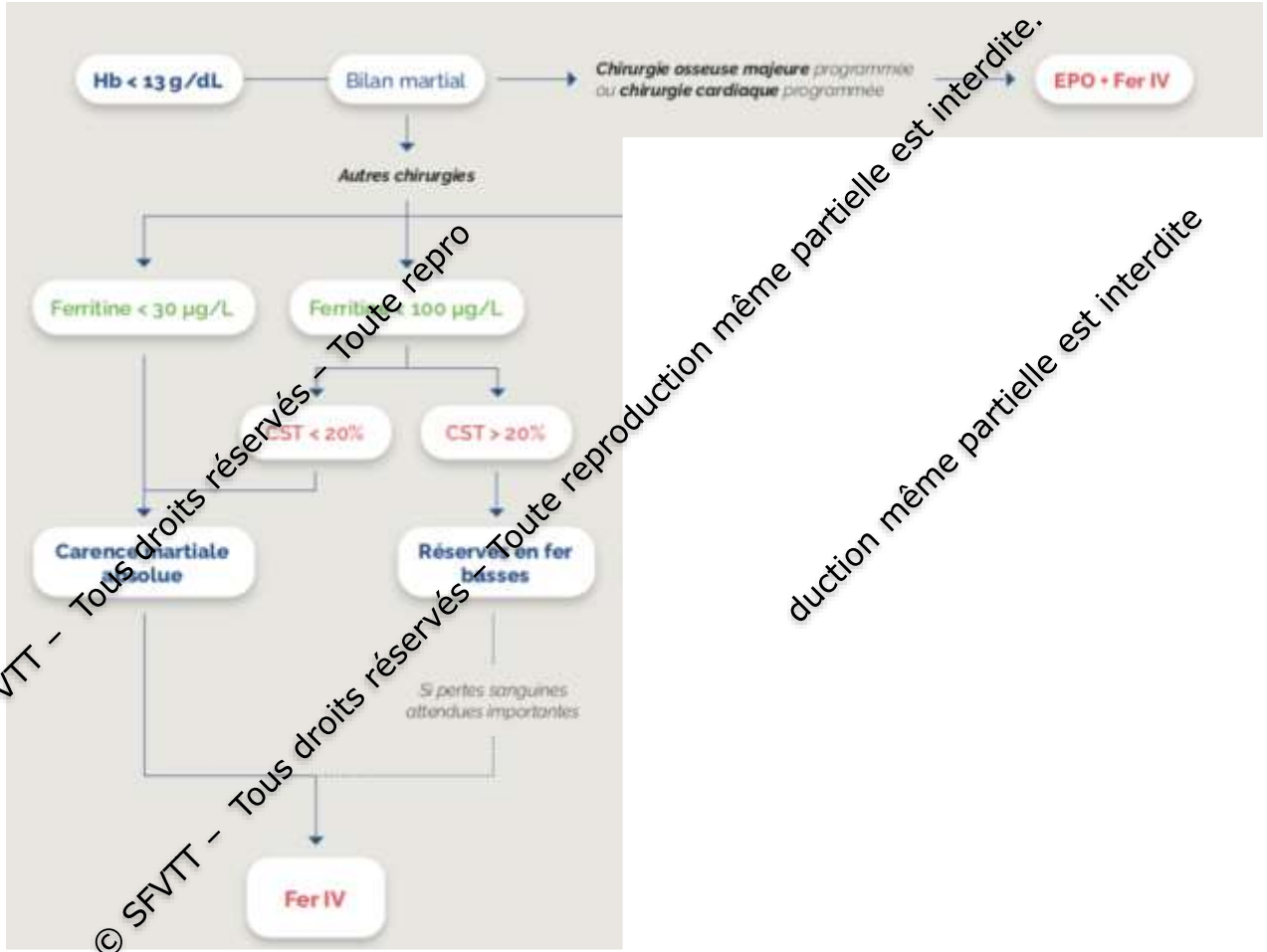
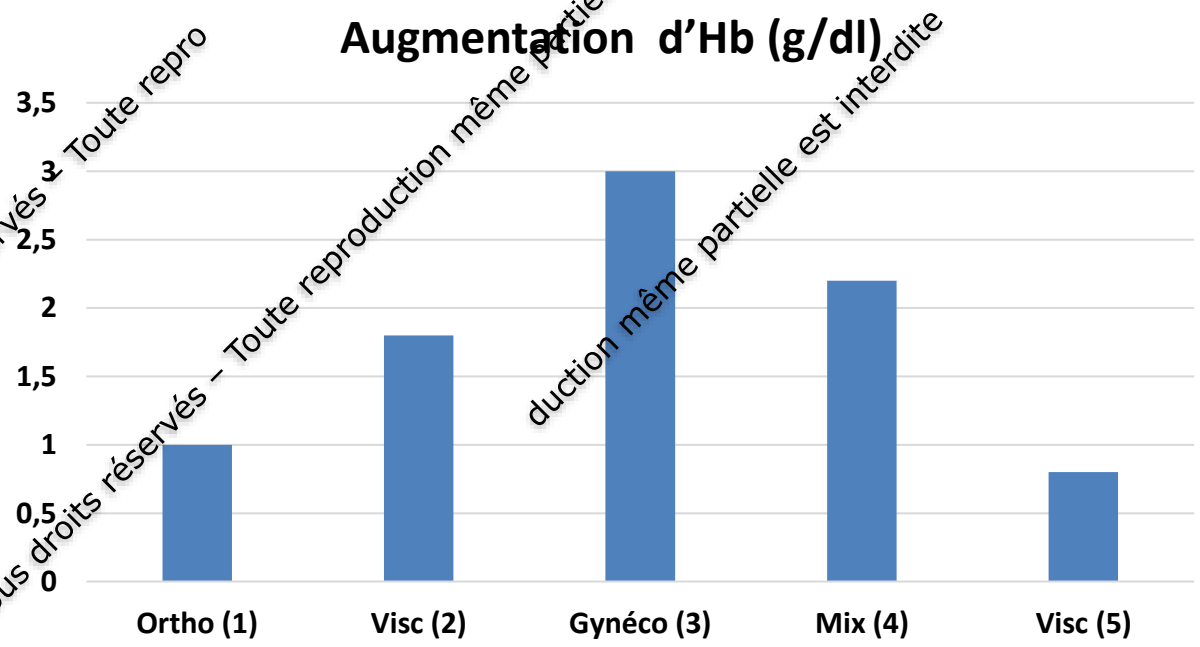


Le fer IV est efficace en pré-opératoire

Traitement pré-op, de 4 à 21 jours
Doses entre 900 mg et 1,2g



Hb t_0 :	*12*	*9,8*	*7,5*	*10,4*	*10,7 g/dl*

1. *Theusinger Anesthesiology 2007*
2. *Keeler Colorectal Dis 2014*
3. *Kim Acta Haematol 2009*
4. *Bisbe BJA 2011*
5. *Froessler Ann Surg 2016*

La dose compte!

Table 3: Average calculated iron deficit dose in clinical Studies 1–5.

Study	Patient population	Calculated mean iron deficit based on the modified Ganzoni formula* (mg)	Standard deviation	Number of patients
(1) van Wyck et al., 2007 [38]	Postpartum	1458	33	182
(2) van Wyck et al., 2009 [39]	Heavy uterine bleeding	1608	383	251
(3) Seid et al., 2008 [40]	Postpartum	1539	351	143
(4) Barish et al., 2012 [41]	IDA various etiologies	1520	342	348
(5) Hussain et al., 2013 [42]	IDA various etiologies	1508**	359	161
Overall mean		1531	NC	1085

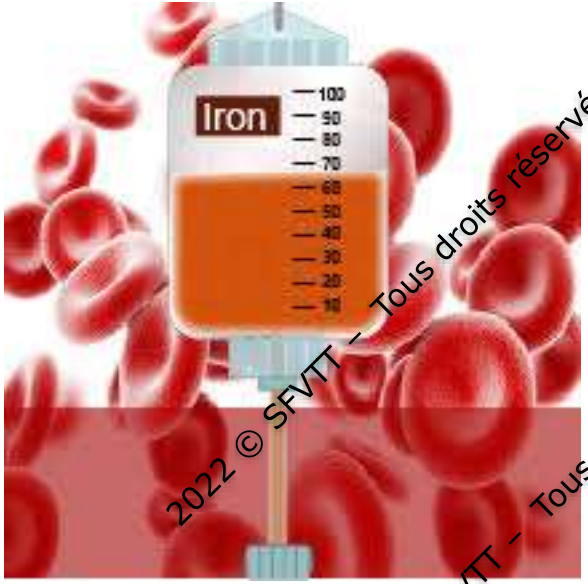
IDA = iron deficiency anemia; NC = not calculated.

Analyse de 5 études randomisées contrôlées

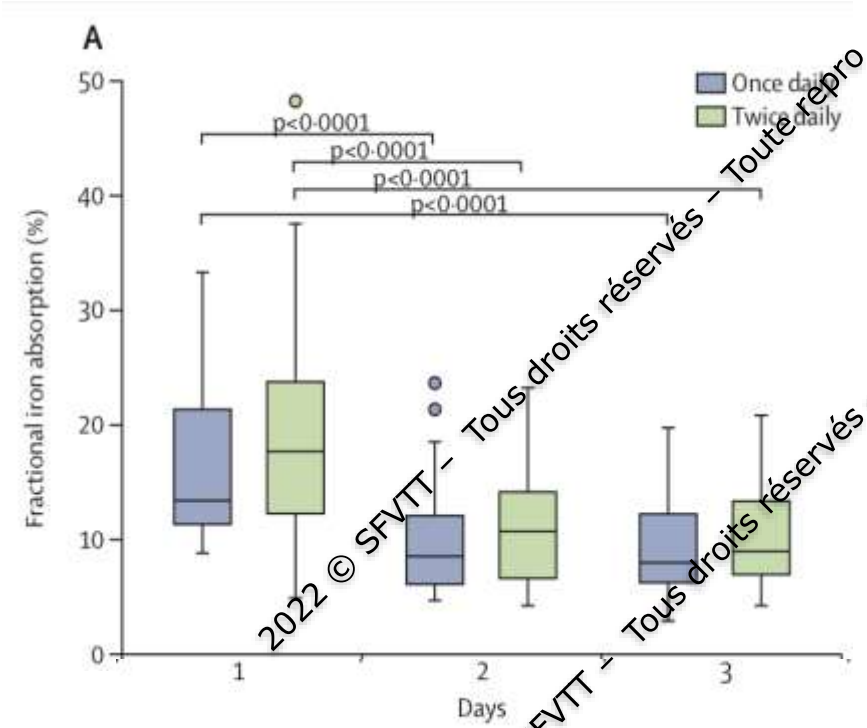
Déficit moyen calculé = **1531 mg !**

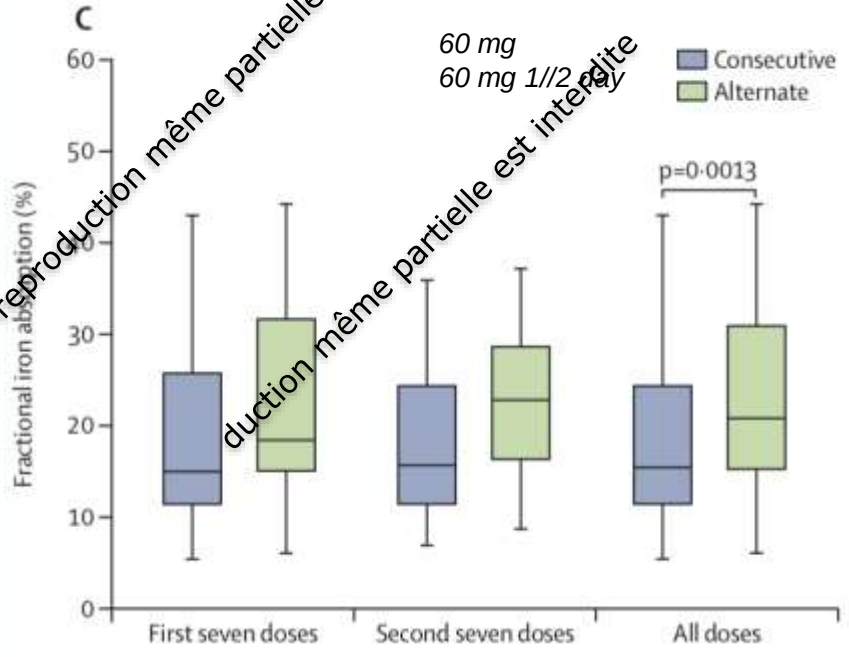
Koch *Anemia* 2015

IV ou per OS ?



120 mg
60mgx2

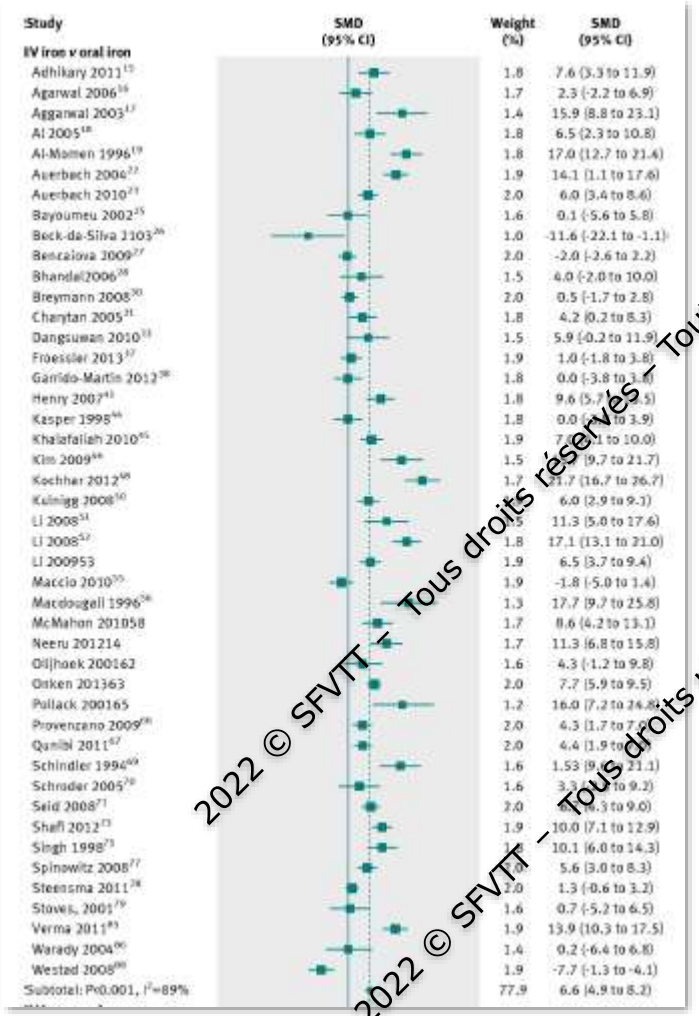




Total iron dose absorbed after 28 days:
131 mg (71·4, 240·5) versus **175·3 mg** (110·3, 278·5; p=0·0010)

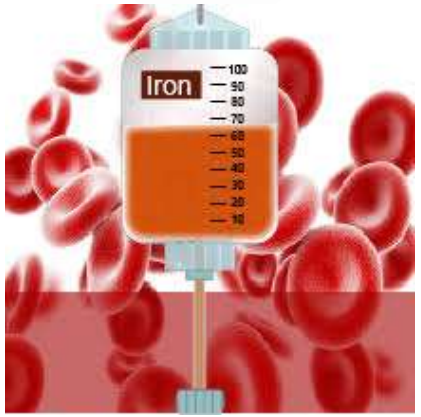
Absorption <10% !

Stoffel *Lancet Haematology* 2017



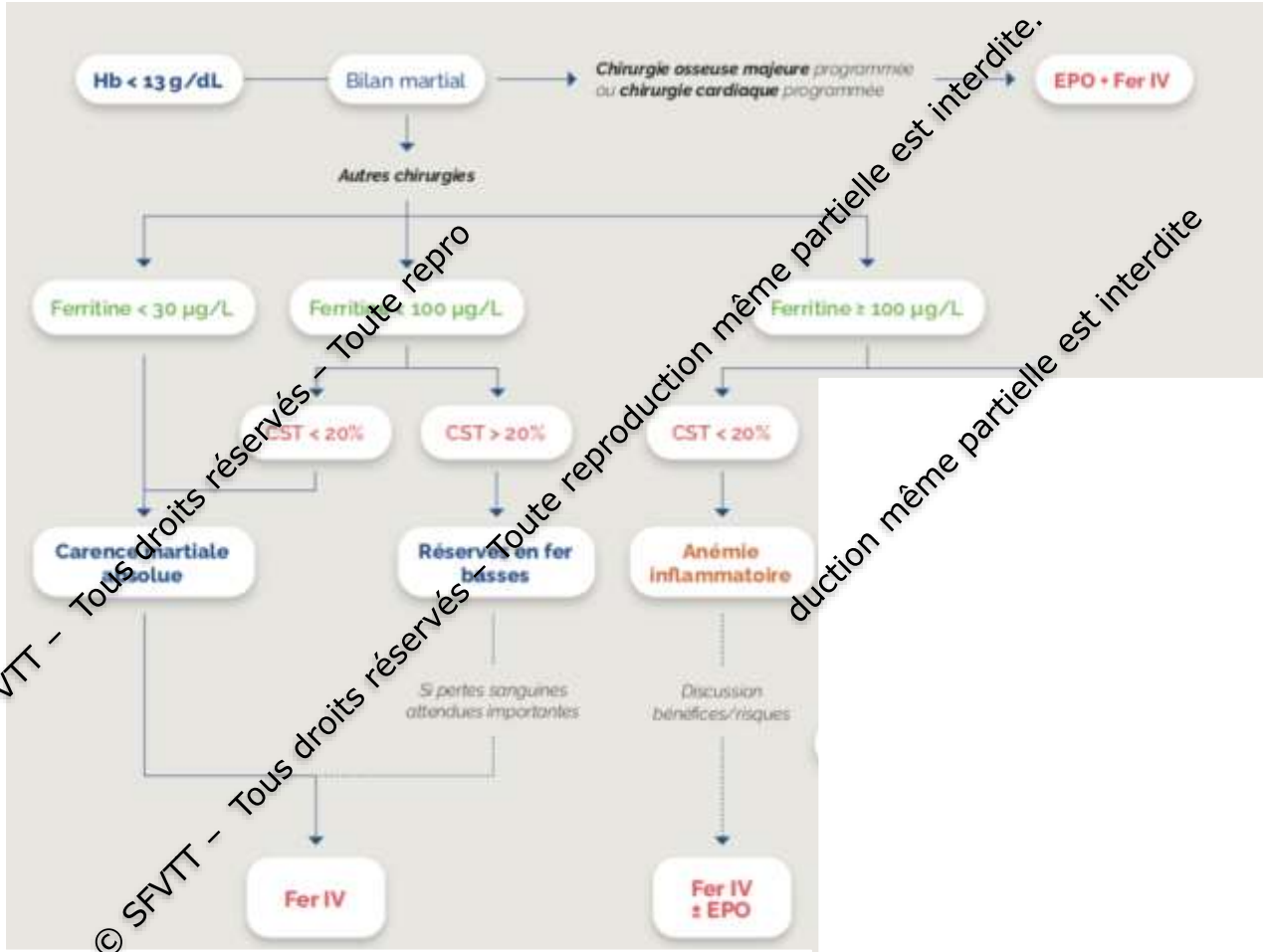
Fer IV vs Oral

72 études
10.605 patients
-**Delta Hb 6,5[4,9-8,2] g/L**
-**Transfusion 0,74[0,62-0,88]**



Litton *BMJ* 2013

HAS
HAUTE AUTORITÉ DE SANTÉ



Anémie inflammatoire: EPO ?

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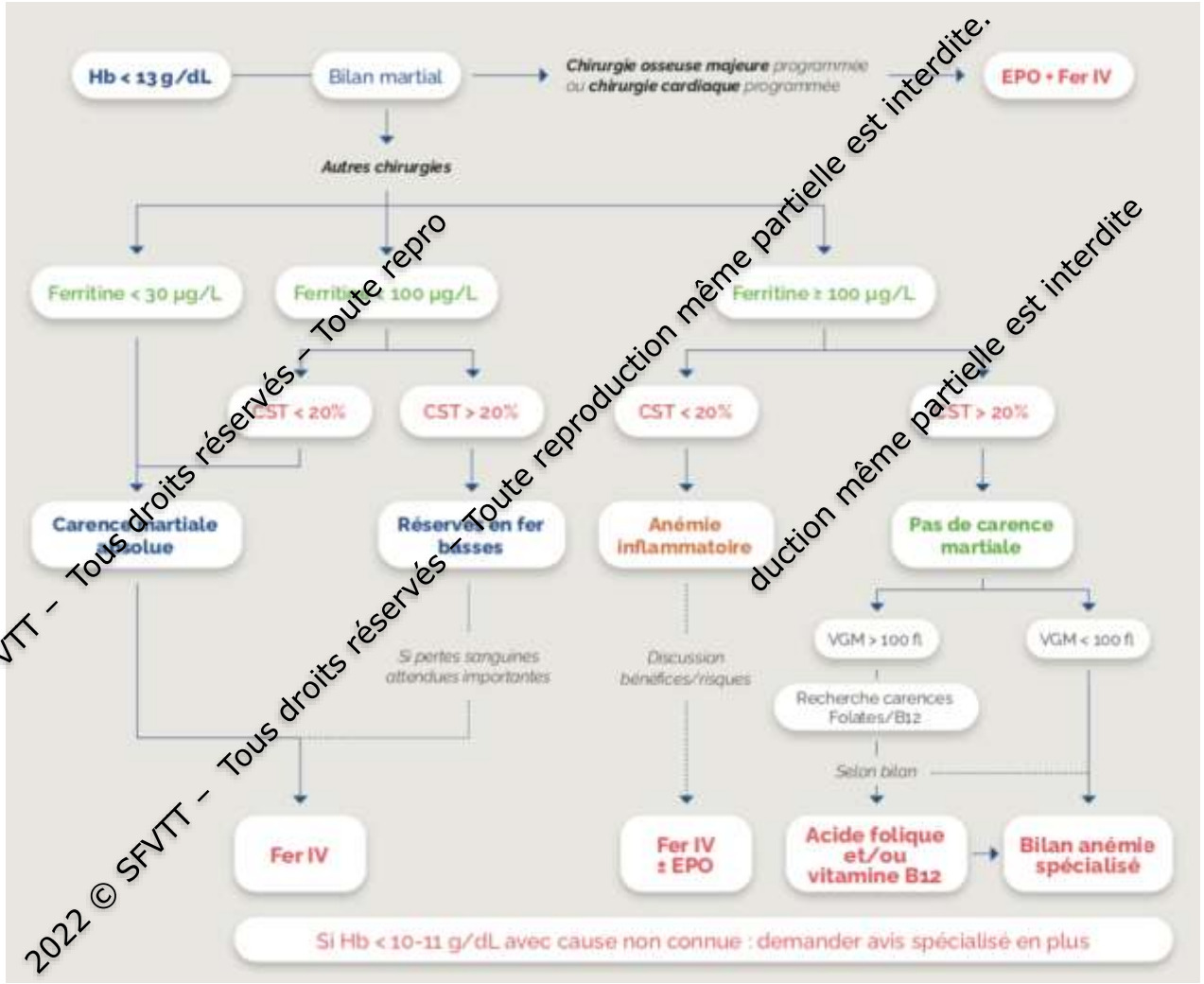

Gestion PER-opératoire

- **Acide Tranexamique prophylactique orthopédie et chirurgie cardiaque (A)** *(1g IVL incision ± 1g IVSE)*
- **Acide tranéxamique en cas d'hémorragie** (A)
- Hémostase chirurgicale
- Pas de garrot pour la chirurgie du genou (A)
- Cell Saver pour chirurgie cardiaque, Aortique, Rachis, reprise (B) discuter en en cas de cancer (AE)
- Limiter les drainages (sauf chirurgie cardiaque)
- Normothermie (B)
- Monitorage pertes

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Tranexamic Acid in Patients Undergoing Noncardiac Surgery

P.J. Devereaux, M. Marcucci, T.W. Painter, D. Conen, V. Lomivorotov,

Devereaux (POISE-3) *NEJM* 2022

Table 1. Baseline Characteristics of the Patients, Type of Surgery, and Medications.*

Characteristics	Tranexamic Acid (N=4757)	Placebo (N=4778)
Age — yr	69.5±9.5	69.3±9.4
Surgery — no./total no. (%)		
Any procedure	4729/4757 (99.4)	4740/4778 (99.2)
General‡	1769/4729 (37.4)	1773/4740 (37.4)
Orthopedic	1083/4729 (22.9)	1063/4740 (22.4)
Vascular	699/4729 (14.8)	700/4740 (14.8)
Urologic	598/4729 (12.6)	624/4740 (13.2)
Spinal	237/4729 (5.0)	206/4740 (4.3)
Gynecologic	162/4729 (3.4)	171/4740 (3.6)
Thoracic	127/4729 (2.7)	146/4740 (3.1)
Low-risk	39/4729 (0.8)	34/4740 (0.7)
Plastic	14/4729 (0.3)	23/4740 (0.5)

Devereaux (POISE-3) *NEJM* 2022

Table 2. Effects of Tranexamic Acid on 30-Day Outcomes.*

Outcome	Tranexamic Acid (N=4757)	Placebo (N=4778)	Hazard Ratio (95% CI)†	P Value
Primary efficacy outcome: composite bleeding outcome — no. (%)‡	433 (9.1)	561 (11.7)	0.76 (0.67–0.87)	<0.001§
Individual components of composite bleeding outcome — no. (%)				
Life-threatening bleeding¶	78 (1.6)	79 (1.7)	0.99 (0.73–1.36)	
Major bleeding¶	363 (7.6)	496 (10.4)	0.72 (0.63–0.83)	
Bleeding into a critical organ¶	12 (0.3)	21 (0.4)	0.57 (0.28–1.16)	
Primary safety outcome: composite cardiovascular outcome — no./total no. (%)‖	649/4581 (14.2)	639/4601 (13.9)	1.02 (0.92–1.14)	0.04**
Individual components of composite cardiovascular outcome — no. (%)				
MINS¶	608 (12.8)	602 (12.6)	1.02 (0.91–1.14)	

TXA 1 g + 1g

Devereaux (POISE-3) *NEJM* 2022

JAMA Surgery | Original Investigation

Association of Intravenous Tranexamic Acid With Thromboembolic Events and Mortality

A Systematic Review, Meta-analysis, and Meta-regression

Isabel Taeuber; Stephanie Weibel, PhD; Eva Herrmann, PhD; Vanessa Neef, MD; Tobias Schlesinger, MD; Peter Kranke, MD; Leila Messroghli, MD; Kai Zacharowski, MD, PhD; Suma Choorapoikayil, PhD; Patrick Meybohm, MD

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216 études, 125 550 patients

Pas plus de complications thromboemboliques

Table 1. TXA and Total Thromboembolic Events

Medical discipline	No. of included studies	TXA Events	TXA No. of included patients	Control Events	Control No. of included patients	Model	Risk difference (95% CI)	*P* value	I^2, %
Cardiothoracic	16	72	3171	74	3009	Fixed effect	−0.001 (−0.009 to 0.007)	.83	0
						Random effects	−0.001 (−0.007 to 0.[illegible])	.91	
Neurological	12	282	20[illegible]	230	2000	Fixed effect	0.026 (0.007 to 0.[illegible]45)	.01	57
						Random effects	0.018 (−0.01[illegible] to 0.048)	.26	
Gynecological	26	35	12 356	41	12 286	Fixed effect	−0.001 (−0.002 to 0.001)	.53	0
						Random effects	−0.001 (−0.002 to 0.001)	.50	
Orthopedic	101	172	4787	113	4149	Fixed effect	0.[illegible]1 (−0.007 to 0.009)	.79	0
						Random effects	0.001 (−0.004 to 0.007)	.64	
Major trauma	1	204	10 060	233	10 067	Fixed effect	−0.003 (−0.007 to 0.001)	.16	NA
						Random effects	−0.003 (−0.007 to 0.001)	.16	
Maxillofacial	6	0	265	0	192	Fixed effect	0.000 (−0.023 to 0.023)	>.99	0
						Random effects	0.000 (−0.019 to 0.019)	>.99	
Pediatric	2	0	42[illegible]	0	40	Fixed effect	0.000 (−0.067 to 0.067)	>.99	0
						Random effects	0.000 (−0.064 to 0.064)	>.99	
Other	12	14	799	15	670	Fixed effect	−0.004 (−0.021 to 0.013)	.62	0
						Random effects	−0.004 (−0.018 to 0.011)	.63	
Total	176	779	33 487	706	32 413	Fixed effect	0.001 (−0.002 to 0.003)	.66	0
						Random effects	−0.001 (−0.002 to 0.001)	.39	

Tauber *JAMA Surgery* 2021

Baisse de la mortalité par saignement

Table 3. TXA and Bleeding Mortality

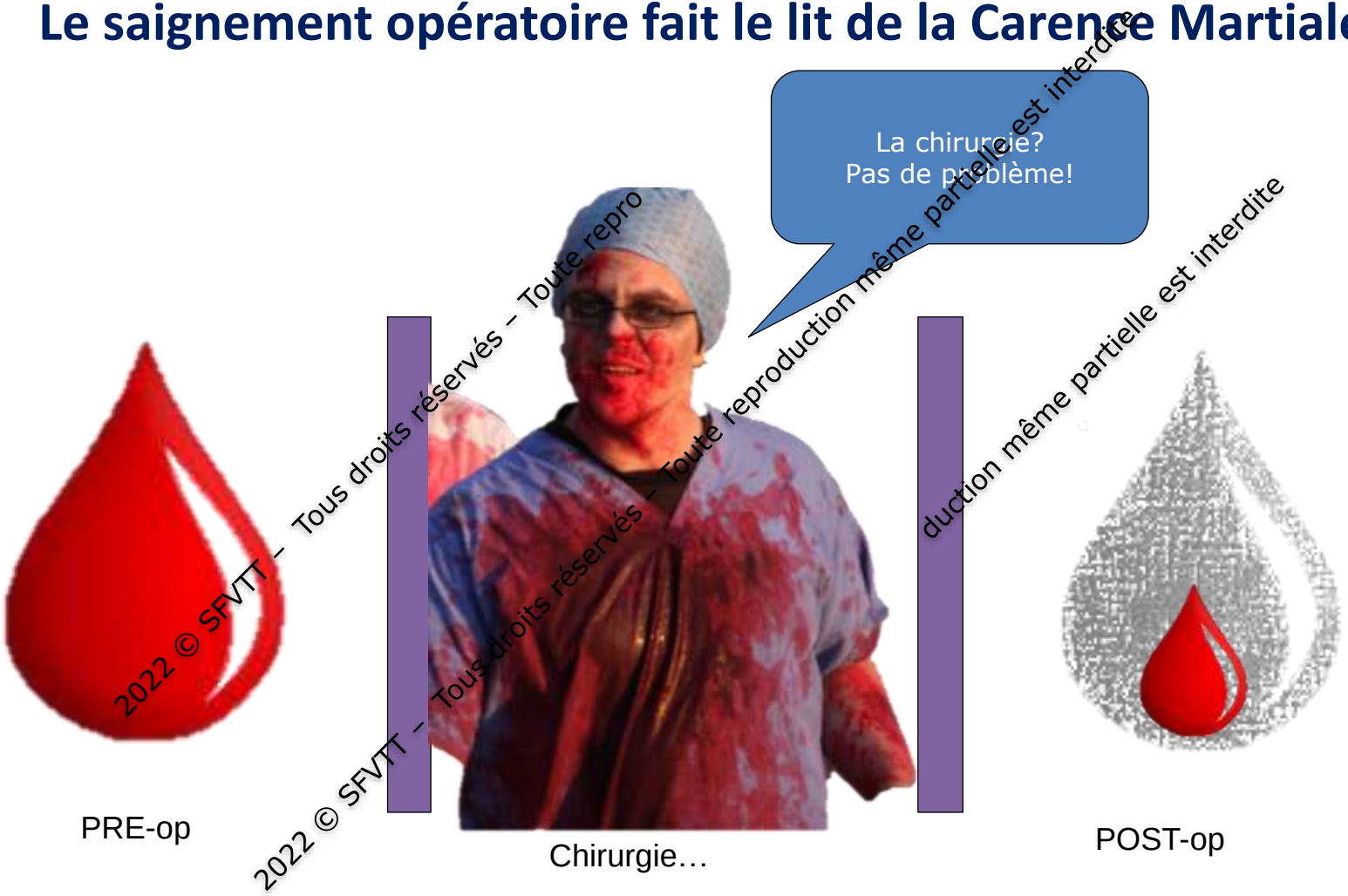
Medical discipline	No. of included studies	TXA		Control		Model	Risk difference (95% CI)	*P* value	I^2, %
		Events	No. of included patients	Events	No. of included patients				
Cardiothoracic	12	0	543	1	478	Fixed effect	−0.002 (−0.016 to 0.012)	.77	0
						Random effects	−0.004 (−0.01 to 0.011)	.94	
Neurological	8	43	6[illegible]	91	678	Fixed effect	−0.071 (−0.102 to −0.041)	<.001	60
						Random effects	−0.05[illegible] (−0.11 to −0.002)	.04	
Gynecological	8	155	10 871	191	10 [illegible]4	Fixed effect	−0.003 (−0.007 to −0.000)	.05	0
						Random effects	−0.002 (−0.005 to 0.001)	.12	
Orthopedic	13	0	647	0	461	Fixed effect	0.000 (−0.014 to 0.014)	.77	0
						Random effects	0.000 (−0.013 to 0.013)	>.99	
Major trauma	1	489	10 060	574	10 067	Fixed effect	−0.008 (−0.015 to −0.002)	.01	NA
						Random effects	−0.008 (−0.015 to −0.002)	.01	
Pediatric	1	0	40	0	42	Fixed effect	0.000 (−0.046 to 0.046)	>.99	NA
						Random effects	0.000 (−0.046 to 0.046)	>.99	
Other	6	5	655	17	661	Fixed effect	−0.018 (−0.033 to −0.004)	.02	53
						Random effects	−0.01 (−0.028 to −0.009)	.30	
Total	49	6[illegible]	23 501	874	23 201	Fixed effect	−0.008 (−0.011 to −0.005)	<.001	9
						Random effects	−0.004 (−0.008 to −0.001)	.02	

Tauber *JAMA Surgery* 2021

Gestion POST-opératoire

- Surveillance saignement et anémie post-op (AE)
- Faire un bilan à 4 semaines post-op (médecin traitant)(AE)
- **Anémie post-op (Hb<12 g/dl) = apport de FER (IV) (B)**
- Transfusion
  - Seuils restrictifs (7-8 g/dL) selon tolérance
  - Transfusion unitaire

Le saignement opératoire fait le lit de la Carence Martiale



Un exemple de Fer IV en post-opératoire

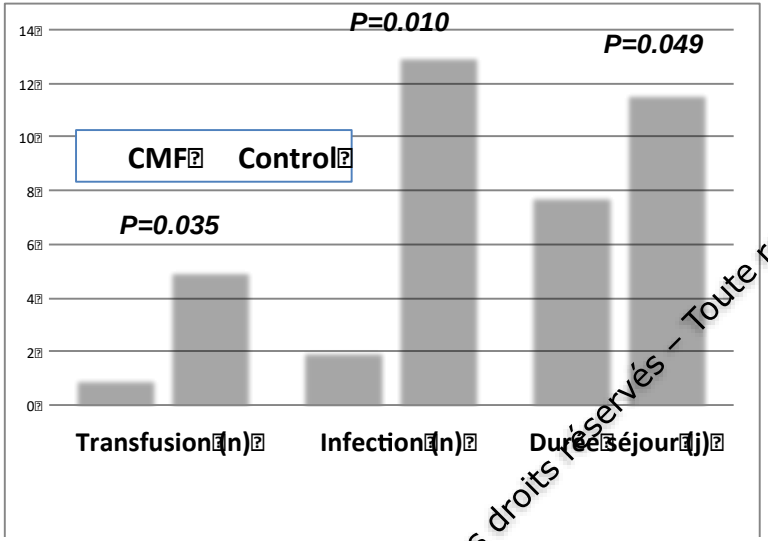
- Etude randomisée, ouverte, bi-centrique
- J1 post op (ortho++, Visc, Uro, gyneco)
  - Chirurgie réglée
  - Séjour≥ 2 nuits
  - Hb [7 – 12 g/dl]
  - CMF Ferritine<100 ou TSAT<20%
- Randomisation CMF 1g vs standard of care

Khallafallah *Lancet Haematol* 2016

	Standard care (control; n=98)	Intravenous ferric carboxymaltose (intervention; n=103)	Treatment effect*	p value
Haemoglobin (g/L)				
Preoperative	134·40 (13·10)	134·50 (11·10)	−0·61 (−4·31 to 3·09)	0·094
Postoperative (day 1)	105·50 (13·80)	106·20 (11·90)	0·00	
4 weeks	121·50 (14·50)	130·10 (11·30)	7·84 (3·79 to 11·9)	<0·0001
12 weeks	133·60 (11·30)	137·50 (11·10)	3·07 (−0·99 to 7·14)	0·24
Iron saturation (%)				
Preoperative	22·60 (6·70)	22·30 (4·70)	0·01 (−2·82 to 2·83)	0·82
Postoperative (day 1)	12·00 (5·60)	11·70 (6·60)	0·00	
4 weeks	19·70 (10·70)	30·90 (11·70)	11·40 (8·33 to 14·50)	<0·0001
12 weeks	25·30 (13·10)	31·70 (8·50)	6·62 (2·78 to 10·50)	0·0026
Serum ferritin (µg/L)				
Preoperative	188·00 (103·00)	188·00 (185·00)	−45·20 (−148·00 to 57·50)	0·18
Postoperative (day 1)	329·00 (335·00)	304·00 (423·00)	0·00	
4 weeks	274·00 (296·00)	717·00 (410·00)	468·00 (355·00 to 582·00)	<0·0001
12 weeks	196·00 (231·00)	481·00 (611·00)	309·00 (159·00 to 460·00)	0·0026

Baisse Hb
=
CM post opératoire

Khallafallah *Lancet Haematol* 2016



- **Transfusion** *(IRR 0.10 [0.01-0.85])*
- **Infection** *(IRR 0.14 [0.03-0.63])*
- **Durée de séjour** *(-3.8] [-7.7 - -0.02])*

	Standard care (control; n=73)	Intravenous ferric carboxymaltose (intervention; n=97)	Treatment effect	p value
Physical scales				
Physical functioning				
Postoperative (day 1)	45·7 (31·4)	45·7 (29·6)	0·00	
4 weeks	33·6 (23·5)	42·1 (28·9)	8·47 (−3·50 to 20·40)	0·17
12 weeks	53·4 (27·6)	55·9 (26·7)	2·45 (−9·90 to 14·80)	0·70
Role physical†				
Postoperative (day 1)	52·8 (27·0)	41·2 (31·3)	0·00	
4 weeks	27·6 (25·6)	30·0 (26·8)	14·00 (0·18 to 27·80)	0·047
12 weeks	52·4 (28·6)	58·4 (27·5)	17·60 (4·37 to 30·90)	0·0092

- **Fatigue physique**

Khallafallah *Lancet Haematol* 2016

HAS
HAUTE AUTORITÉ DE SANTÉ

5. Recommandations organisationnelles

Le diagnostic et le traitement d'une anémie et/ou d'une carence martiale doivent s'intégrer dans le parcours de soins périopératoires (depuis l'indication chirurgicale posée jusqu'au rétablissement complet du patient) (AE).

Une concertation multidisciplinaire est recommandée en cas de report nécessaire de la chirurgie pour le traitement d'une anémie préopératoire, afin d'évaluer le bénéfice et les risques associés à ce report (AE).

Il est recommandé de mettre en place une stratégie et un programme de gestion du capital sanguin en périopératoire dans les établissements de santé pour réduire la transfusion et les durées de séjour (Grade B).

Cette démarche peut s'appuyer sur la création d'un comité « gestion du capital sanguin » en lien avec le comité de sécurité transfusionnelle et d'hémovigilance de l'établissement (AE).

Il est recommandé que les établissements de santé mettent en place des indicateurs de suivi des mesures de la gestion du capital sanguin[3] (Grade C).

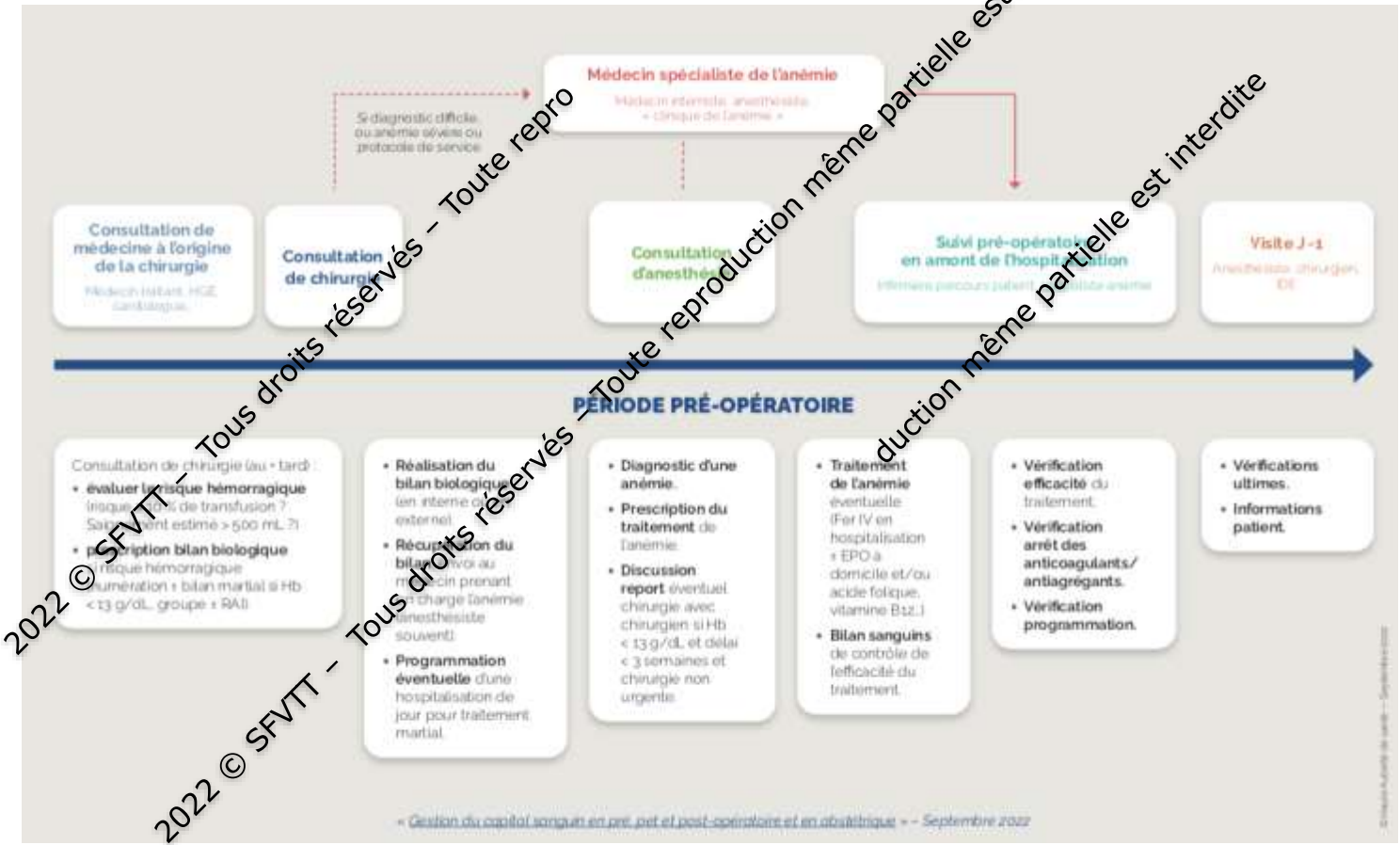
Il est recommandé en chirurgie majeure qu'un programme de réhabilitation améliorée après chirurgie (RAAC) intègre la gestion périopératoire du capital sanguin (Grade C).

Il est recommandé que les infirmier(e)s coordinateur(rice)s de RAAC, dans le cadre d'un protocole national de coopération, soient des acteurs (actrices) important(e)s dans ce type de programme (AE).

Il est recommandé d'informer le médecin traitant du diagnostic et du traitement d'une anémie préopératoire en vue de la réalisation d'un bilan étiologique le cas échéant et du suivi de cette anémie (AE).

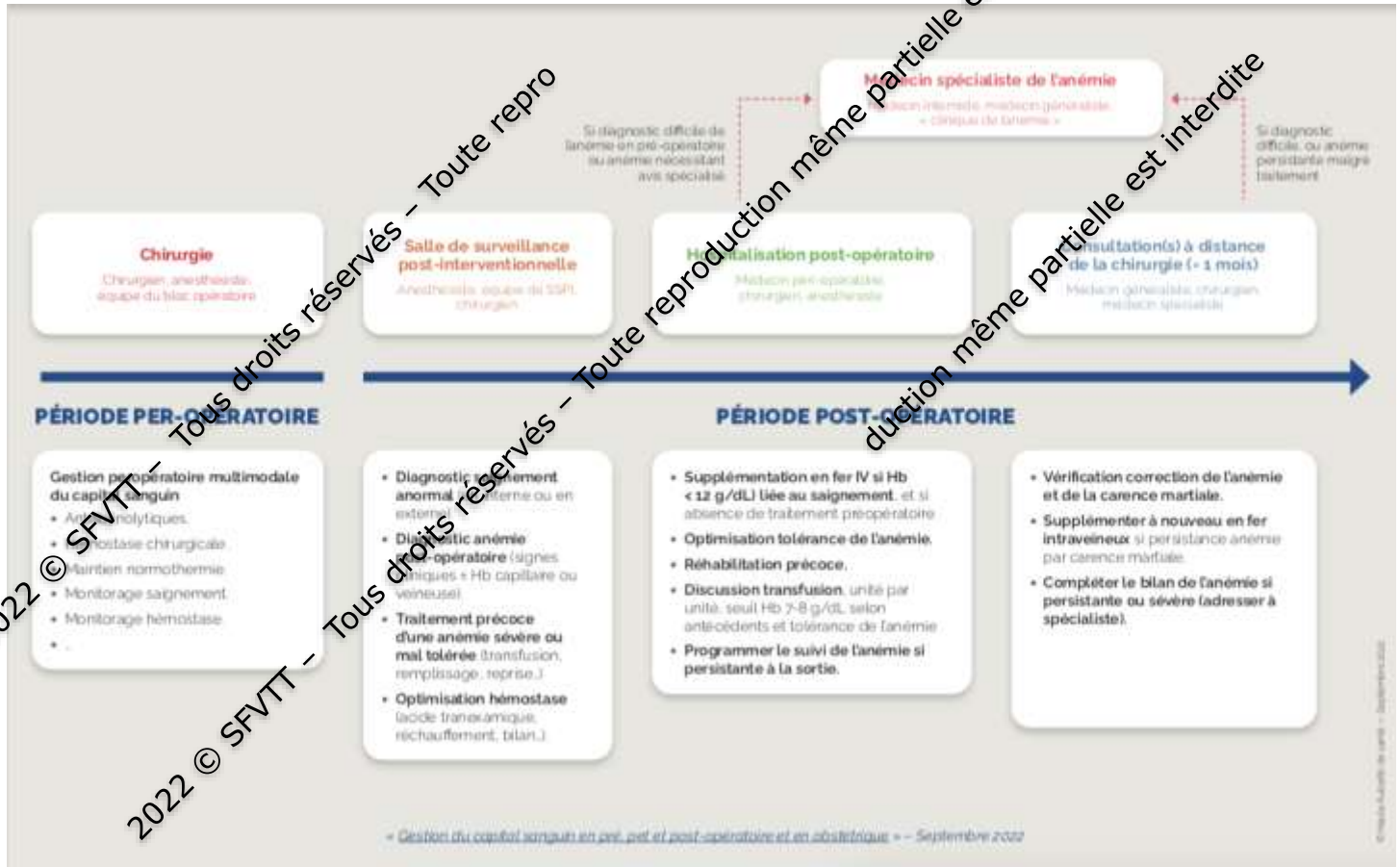
HAS
HAUTE AUTORITÉ DE SANTÉ

PBM = parcours de soin



HAUTE AUTORITÉ DE SANTÉ

PRE – PER – POST opératoire



Projet « article 51 »

Résumé du projet

Cette expérimentation propose d'améliorer le devenir des patients chirurgicaux en luttant contre l'anémie et la carence martiale tout en limitant les transfusions peri-opératoires. Elle repose sur la mise en place d'un parcours coordonné de prise en charge sous la forme d'un modèle nommé PBM, Patient Blood Management proposant :

Un **forfait d'ingénierie et de pilotage** permettant la mise en place de l'expérimentation article 51 au sein des établissements.

Une **rémunération spécifique à la pratique du PBM** décomposée en deux sources de financement :

- Une **part fixe** permettant aux établissements d'investir dans le système d'information et dans la formation du personnel soignant qui n'a pas vocation à perdurer au-delà des premières années de mise en place (T0, année 1 et année2).

- Une **part variable** sous forme d'**incitation financière inspirée du modèle IFAQ** (Incitation Financière A la Qualité) et reposant sur l'utilisation d'indicateurs spécifiques à l'image des IQSS (Indicateurs à la Qualité et Sécurité des Soins).

Conclusions

Le PBM est un enjeu MONDIAL

Evolution d'un concept centré sur les produits sanguins vers une amélioration du capital sanguin pour un meilleur devenir.

PBM = Changement des pratiques

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