

Transfusion: Practical Aspects & Hemovigilance

BHS 02/03/2024



Plan

> Transfusion of blood components

- > Transfusion of packed red blood cells (PRBC)
 - Description of component
 - > Pretransfusion Compatibility testing
- > Transfusion of fresh frozen plasma (FFP)
 - Description of component
 - > Pretransfusion Compatibility testing
- > Transfusion of platelets
 - Description of component
 - > Pretransfusion Compatibility testing
- > Hemovigilance



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> Hemovigilance



Transfusion of packed red blood cells (PRBC) Description of component

- Centrifugation of whole blood (removal of plasma and buffy-coat) or red cell apheresis
- Primary citrated anticoagulant (red cells shelf life \pm 21 days)
- Additive solutions (extension of shelf life to 42-49 days)
- PRBC volume is depending on the method of preparation
- PRBC (Council of Europe)
 - HCT of 0,50-0,70
 - Hb of minimum 40g/unit
 - Haemolysis at the end of the storage <0,8% of red cell mass
 - Leucocyte count $< 1 \times 10^6$ per unit
- Conservation at $+2^{\circ}$ C to $+6^{\circ}$ C
- Administration through a 170-200µm filter





Transfusion of packed red blood cells (PRBC) Description of component

- PRBC
- PRBC Irradiated
- PRBC CMV negative

- PRBC cryopreserved (-60°C to -80°C)
- PRBC washed
- PRBC for neonates or baby packs (O-; CMV-)
- PRBC for intra-uterine transfusion (O-; CMV-; irradiated; <7days; HCT: 0,75-0,85)





Transfusion of packed red blood cells (PRBC) Description of component

- Irradiation of PRBC:
 - TA-GVHD (Transfusion-associated graft-versus-host disease) is a very rare complication following transfusion of viable allogeneic lymphocytes into immunosuppressed recipients
 - Irradiation of PRBC for the prevention of TA-GVHD by inactivating residual lymphocytes with gamma rays or X-rays at a minimum dose of 25 Gy

bih guidelines

Guidelines on the use of irradiated blood components

Theodora Foukaneli,^{1,2} Paula HLB. Bolton-Maggs,^{1,4} Rebecca Cardigan,⁶ Alasdair Coles,⁷ Andrew Gennery,⁴ Avid Jane,⁹ Dinkantha Kumararatae,¹⁰ Ania Manson,¹⁰ Hein V. New,^{11,12} Nicholas Torpey¹³ and on behalf of the British Society for Haematology Guidelines Transfusion Task Force

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BSH updated UK guidelines 2020

bih guideline

Guideline development for prevention of transfusionassociated graft-*versus*-host disease: reduction of indications for irradiated blood components after prestorage leukodepletion of blood components

Johanna C. Wiersum-Osselton, ¹ . Hans L. P. van Duijnhoven,⁵ Tanja Netelenbos⁶ and Martin R. Schipperus⁷

¹TRIP (Transfusion and Transplantation Reactions in Patients) Hemorigilance and Biovigilance Office, Leiden, ²Medlon-Medisch Spectrum Twente, Enschede, ³Department of Hematology, Leiden University Medical Center, Leiden, ⁴Knowledge Institute of Medical Specialists, Utrecht, ⁴Elkerliek Ziekenhuis, Helmond, ⁴Haga Teaching Hospital, The Hague, and ⁷Department of Hematology, University Medical Center UMCG, Groningen, The Netherlands

Dutch updated guidelines 2021



Transfusion of PRBC

Description of component

BSH updated UK guidelines 2020 ²	Dutch updated guidelines 20211
Hodgkin lymphoma at any stage of the disease should receive irradiated components indefinitely	Hodgkin lymphoma stage III or IV (with bone marrow infiltration) not routinely required (depends on medications)
All patients treated with purine analogue drugs should receive	Use of purine/pyrimidine agonists
irradiated components indefinitely	Patients with long-lasting T-cell suppression after medication: fludarabine or other T-cell-depleting medication if the approved product information warns of TA-GVHD risk, for six months after cessation of the therapy
Stem cell transplants	Stem cell transplants (time increased from earlier guidelines)
Allografts : to receive irradiated components from start of conditioning and be continued until defined criteria are met ² rather than a fixed	Allogeneic stem cell transplantation: until one year after last medication/intervention
time.	Autologous stem cell transplantation: until six months after
Autografts for three months (six months if total body irradiation was part of conditioning)	transplantation
Irradiation required from seven days before and during bone marrow/stem cell harvest	Peripheral blood stem cell apheresis and bone marrow collection: no longer required
Patients with aplastic anaemia undergoing treatment with antithymocyte globulin or alemtuzumab (anti-CD52) should receive irradiated components duration not defined	Medication which in combination with patient's illness gives a long-lasting T-cell suppression, such as anti-CD52 treatments for haematological diseases and antithymocyte treatment for aplastic anaemia: from the initiation of treatment till six months after completing treatment
Routine irradiation of red cells to preterm or term infants not required unless there was a previous intrauterine transfusion Both: Intra-uterine transfusions (IUT), thereafter until six months after :	Premature babies and/or pregnancy <32 weeks (previously up to six months after due date) No longer required

bjh commentary

not

Guidelines: the same evidence but different conclusions — relaxation of indications for irradiation of cellular blood components?

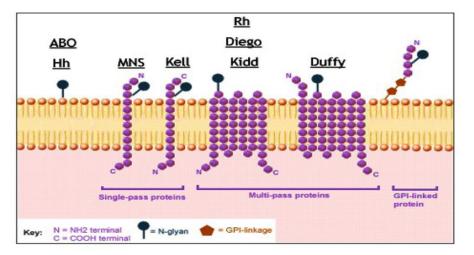
Paula H. B. Bolton-Maggs

Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK

Commentary on Wiersum-Osselton et al, Guideline development for prevention of transfusion-associated graft-versus-host disease: reduction of indications for irradiated blood components after prestorage leukodepletion of blood components. Brit J Haematol. 2021;195:681-688.





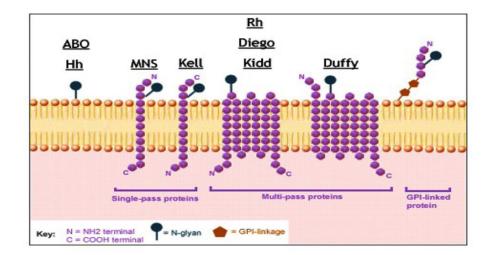


Currently recognized antigens classification:

- Systems
- Collections
- Low incidence antigens
- High incidence antigens

http://www.isbtweb.org/working-parties/red-cell-immunogenetics-and-blood-group-terminology/





Patient antibodies:

- Natural antibodies
- Immune antibodies
- Auto-antibodies

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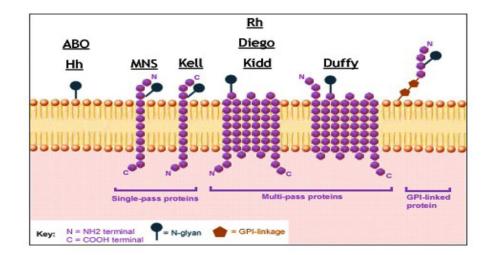


- Pre-transfusion tests:
 - Major Crossmatch
 - Patient's ABO/Rh types (2x) and crossreaction of serum's patient with ABO compatible PRBC
 - If negative: PRBC are reserved to the patient
 - If positive: red cell antibody identification and major crossmatch; information of the physician in case of short blood supply
 - Type and Screen
 - Patient's ABO/Rh types (2x) and Indirect Antiglobulin Test (IAT)
 - If positive IAT: Antibody identification and Crossmatch of antigennegative PRBC; information of the physician in case of short blood supply
 - If negative IAT: labelling of the ABO compatible PRBC at the moment of the blood order



TRANSFUS MEDICINE	SION Official Journal of the British Blood Transfusion Society	
Transfusion Medicine	GUIDELINES	
	pre-transfusion compatibility fusion laboratories*	procedures
British Committee for Stand C. Milkins, ¹ J. Berryman, ² C.	ards in Haematology . Cantwell, ³ C. Elliott, ⁴ R. Haggas, ⁵ J. Jones, ⁶ M. Rowley, ^{3,7} M.	Williams ⁸ & N. Win ⁹
Hospitals, NHS Foundation Tr UK, ⁴ Department of Blood Tr teaching Hospital NHS Trust,	erts Hospitals NHS Trust, Watford, UK, ² Department of Blood Tr rust, London, UK, ³ Department of Blood Transfusion, Imperial C ansfusion, South Tees Healthcare Trust, Middlesborough, UK, ⁵ D Leeds, UK, ⁶ Welsh Blood Service, Cardiff, UK, ⁷ Colindale Centr oting Centre, NHSBT, Tooting, UK	College Healthcare NHS Trust, London, Department of Blood Transfusion, Leeds
Received 18 July 2012; accepted for	publication 27 September 2012	
Key	Recommandation 12:	
Unless secure el	lectronic patient identifi	cation systems are in
place, <u>a second</u>	sample should be reque	sted for confirmation
of the ABO grou	up of a first time patien	<u>t prior to transfusio</u> n,
where this not in	npede the delivery of urg	gent red cells or other
components	-	





Alloimmunization through transfusion or pregnancy

Incidence of alloimmunization in the general population: 2% to 5% Incidence alloimmunization in patients with SCD: 30% to 40%





- □ Alloimmunization to red blood cell remains a serious complication
- □ Risk factors associated with alloimunization:
 - □ Antigenic differences between donors and SCD patients
 - HLA II genotype influence predisposition to the RBC antibody responder status
 - □ Inflammatory state of SCD patients





Antigenic differences between donors and SCD patients

- Polymorphic differences in immunogenic RBC antigens between caucasian donors and african transfusion recipients
 - I. Significantly different RBC antigen frequencies of some common blood groups (RH, KEL, FY, JK, MNS,...)
 - II. RH variants
 - III. Loss of High-incidence antigens \rightarrow Rare blood groups
 - IV. Low-incidence antigens → Alloimmunization in intra-ethnic transfusions





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Antigenic differences between donors and SCD patients

	Caucasian frequency %	African frequency %	BRU+HUDE %
Fya —	34	90	92
Fy(a –b –)	Very rare	68	92
Jkb -	26	50	67
S -	45	70	67
Kell 6 ou Jsa	< 1	20	NT

Phenotype C-,E-,K-, Fy^a-, Jk^b-: 26% of Africans; <2% of Caucasians





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Antigenic differences between donors and SCD patients

- Loss of a High-incidence antigens:
- > RH:-18, RH:-34, RH:-46 \rightarrow 0,1% in Africans
- → KEL:-7 → 1% in Africans
- > MNS:-5 \rightarrow 1% in Africans

▶

Short blood supply in Europe





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HLA II genotype influence predisposition to the RBC antibody responder status

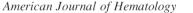
Some patients develop alloantibodies following initial RBC transfusions while others do not even after multiple transfusions

RBC antibody responder and RBC antibody non-responder

HLA type and risk of alloimmunization in sickle cell disease

Carolyn Hoppe,1* William Klitz,2,3 Elliott Vichinsky,1 and Lori Styles1

Red blood cell (RBC) transfusions are frequently required to treat patients with sickle cell disease (SCD) [1]. One of the most serious complications of repeat transfusion is alloimmunization to RBC antigens [2]. Because human leukocyte antigen (HLA) genes mediate the response to foreign antigens, particular HLA alleles may predispose to the development of alloimmunization in patients with SCD who receive multiple transfusions. We conducted a case-control study to determine if particular HLA alleles are associated with alloimmunization and whether HLA homozygosity influences the risk of developing RBC alloantibodies. High-resolution HLA genotyping was performed on DNA samples from 159 multiply transfused patients with SCD. HLA allele frequencies were compared between alloantibody-positive and alloantibody-negative groups. The HLA-DRB1*1503 allele was associated with an increased risk (P = 0.039), while HLA-DRB1*0901 conferred protection from alloimmunization (P = 0.008). HLA Class II locus homozygosity was more frequently observed in the alloantibody-negative group (P = 0.01). These preliminary findings suggest that particular HLA-DRB1 alleles and overall homozygosity at HLA class II loci are associated with alloimmunization risk in SCD. If confirmed, HLA type may serve as a useful genetic predictor of alloimmunization risk, and permit a targeted approach to the use of phenotypically matched blood.







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□ SCD is characterized by chronic inflammation

□ Hypothesis: "Inflammation may play a role in the high rate of alloimmunization"

pin research paper

Prevalence and risk factors for red blood cell alloimmunization in 175 children with sickle cell disease in a French university hospital reference centre

Summary

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de Montalembert^{1,2}

Department of Paediatrics, Necker Hospital for Sick Children, Paris Descartes University, ²Laboratory of Excellence GR-Ex, ³Département Centre National de Référence pour les Groupes Sanguins (CNRGS), Institut National de la Transfusion Sanguine (INTS), ⁴Inserm UMR_S1134, Paris Diderot University, ⁵Etablissement Français du Sang (EFS), Necker Hospital for Sick Children, and 6Obstetrical, Perinatal and Paediatric Epidemiology Research Team (EPOPé), Inserm UMR1153, Paris, France

Received 13 November 2016; accepted for publication 27 December 2016 Correspondence: Slimane Allali, Department of Paediatrics, Hôpital universitaire Necker-Enfants malades, 149 rue de Sèvres, 75015, Paris, France. E-mail: slimane.allali@aphp.fr

Patients with sickle cell disease (SCD) show a high prevalence of red blood cell (RBC) alloimmunization, but few studies have focused on children. We aimed to study the prevalence and risk factors of RBC alloimmunization in SCD children. We retrospectively analysed the medical and transfusion files for 245 SCD children hospitalized in our centre in 2014 and included 175 patients who had received at least one RBC unit in their lifetime. The main clinical and immuno-haematological characteristics of alloimmunized and non-alloimmunized patients were compared. The prevalence of alloimmunization was 13.7% [95% confidence interval (CI) (8.6-18.6)], and 7.4% [95% CI (3.5-11.3)] after excluding the probable irregular natural antibodies (anti-M, anti-Le^a, anti-Le^b, anti-Le^x). Main risk factors for alloimmunization were increased number of RBC units received (median of 65 vs.

10 units per patient; P = 0.01) and the presence of one or more red cell autoantibodies (46.2% vs. 4.7%; P < 0.0001). The alloimmunization rate was higher for episodically transfused than chronically transfused patients (1.43 vs. 0.24/100 units received; P < 0.001). The presence of red cell autoantibodies appears to be a major risk factor for alloimmunization in SCD children and could justify specific transfusion guidelines.

Keywords: sickle cell disease, children, blood transfusion, red blood cell alloimmunization, immunohaematology.



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 - Pretransfusion Compatibility testing

> Hemovigilance





Transfusion of fresh frozen plasma (FFP) Description of component

- Prepared from whole blood or from plasma collected by apheresis
 Contains normal plasma levels of stable coagulation factors, albumin and immunoglobulins
- $\Box \ge 70$ IU Factor VIIIc level per 100ml and at least similar amounts of the other labile coagulation factors and naturally occurring inhibitors
- □ Conservation at -30°C or lower
- \Box Administration through a 170-200µm filter







Transfusion of fresh frozen plasma (FFP)

□ Pathogen reduction treatment

- Active on known viruses, bacteria, protozoa and contaminating leukocytes but also on unknown transfusion-transmissible agents, they are not active on prions
- Current methods: solvent-detergent, methylene blue, amotosalen, and riboflavin
- □ Pretransfusion Compatibility testing
 - Patient's ABO blood group determined on two different blood samples collected at different times



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Transfusion of platelet concentrates (PCs) Description of component

- PCs
 - Apheresis platelets (prepared by apheresis from single donors)
 - Recovered platelets (prepared by separation and pooling of units of platelets from whole blood of multiple donors)
- No difference in haemostatic effect; platelet survival and post-transfusion increment for both preparations
- Storage: max 5 days after collection at 22±2°C
- Specific preservative solutions bags permitting O₂ and CO₂ so that the pH during storage stays continuously between 6.4 and 7.4







Transfusion of platelet concentrates (PCs)

- Leukodepleted: decreased incidence of alloantibody mediated refractoriness to PC transfusion, CMV transmission and FNHTRs
- Pathogen reduction treatment
 - Maximum storage time could be extended to 7 days with equivalent safety and clinical efficacy (*Lozano et al, 2011; Schlenke et al, 2011*)

 \rightarrow prevention of RhD immunisation by the use of RhD-immune globulin if RhD+

PC are transfused to RhD- patients of child-bearing age or younger

- But belgian law 6/2/2018: 5 days
- Pretransfusion Compatibility testing:
 - Patient's ABO/ RhD blood groups
 - Contamination of PCs by red cells

Platelet express on their surface:

- ABO antigens
- Class I HLA antigens
- HPA antigens





Transfusion of platelet concentrates (PCs) Response to platelet transfusion

- Platelet recovery or CCI
- <u>Absolute Increment</u> =

(Post-transfusion platelet count) – (pre-transfusion platelet count)

• <u>Corrected Count Increment (CCI)</u> =

Absolute Increment X Body surface area / number of platelets transfused (10^{11})

CCI: 10-60 minutes after transfusion (Mc Farland, AABB, 2008)



Transfusion of PCs: Response to platelet transfusion

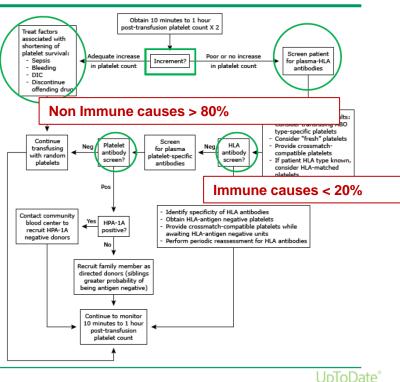
□ Transfusion platelet refractoriness

- Only when at least two ABO-compatible transfusions, stored for <72 hours result in poor increments
- Defined in a clinically stable patient when two sequential platelet transfusions lead to 1 hour post-transfusion CCIs of less than 5000 platelets x m2 per µl
- ✓ If \downarrow 1h and 24h: Immune cause (antibodies against HLA class I and/or HPA antigens)
- ✓ If N 1h and ↓ 24h: Non immune cause (sepsis, splenomegaly, DIC, GvHD, bleeding, medications,...)
- « Non immune causes are the most likely and the first that should be explored in the diagnosis of platelet refractoriness »
 Management of the platelet refractory patient. S.K.Forest, E.A.Hod.



Transfusion of platelet concentrates (PCs)

Diagnosis and management of platelet refractoriness





Hemovigilance

- Hemovigilance = Hema (blood in Greek) + Vigilans (watchful in Latin)
- Hemovigilance system improve the safety of blood transfusion by applying a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence.

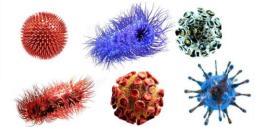


Early 1980s...



Mistransfusions





Infectious diseases







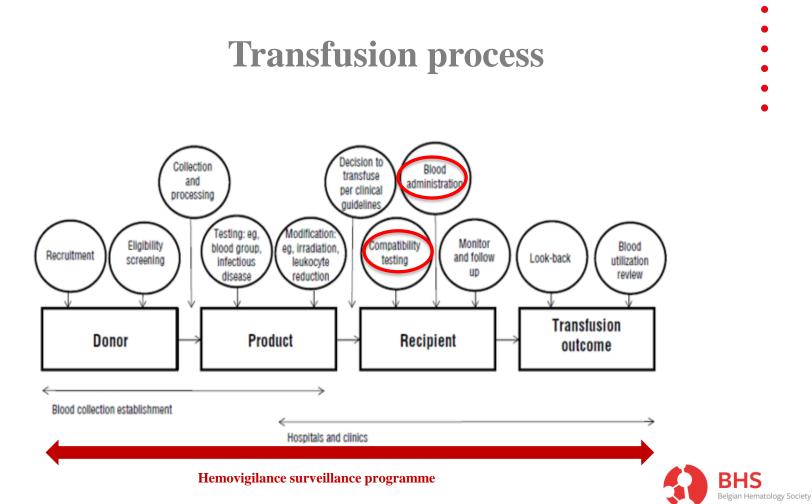
Infectious diseases





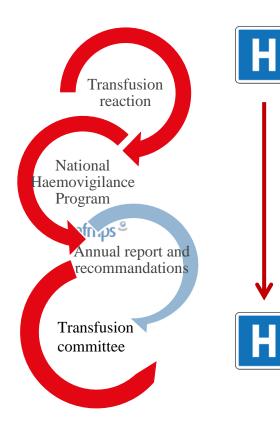
Mistransfusions





http://www.aabb.org/tm/Pages/default.aspx

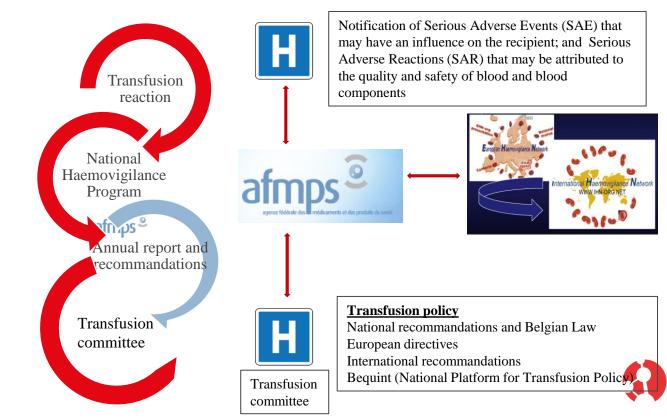
Hemovigilance (recipient)



Goal of Hemovigilance: Improve blood transfusion safety



Hemovigilance (recipient)



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Hemovigilance: notification form

APMPS

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APMPS	
	Département Vigilance
Agence Fédérale des Médicaments	Centre d'hémovigilance
et Produits de Santé	
FORMULAIRE DE NOTIFICATION/CONFIRMATION D'UNE REACTION TRANS	
D'UN INCIDENT INDESIRABLE GRAVE EN RAPPORT AVEC U	UN COMPUSANT SANGUIN
Code Höpital Nom Höpital	_
Année Numéro d'ordre Notificati	tion Confirmation
A. NOTIFICATION	
I. Patient 1.1. date de naissance: 1.2. sexe : H	0 F0
2. Composant sanguin transfusé	_
Concentré érythrocytaire (CE) ; numéro d'unité: Allogéniq	ave 🗆 Autologue
Concentré plaquettaire (CP) ; numéro d'unité:	hérèse (donneur unique) 🔲 CP standard
Plasma frais congelé, viro-inactivé (PFCVI) ; numéro d'unité:	
Plasma nais conjune, viro-maceive (PPCVI), numero e brina.	
Autre: plusieurs/différents composants; n	numéro(s) d'unité: .
 Réaction transfusionnelle Date et heure : Date et heure du début de la transfusion (en cas de réaction transfusionn) 	nelle): à (hr:min)
Date et neure : Date et neure du decut de la transfusion (en cas de reaction transfusionn) Date et heure de la réaction ou de l'incident :	a (nrmin)
I.2. Lieu de la transfusion : Deloc opératoire Soins intensifs Chirurgie	Hémato-oncologie
Médecine interne Pédiatrie Hôpital de jour	nur 🗋 Autre : .
3.3. Symptômes	
malaise tachycardie	oligurie, anurio
frissons hypertension	hypotension
fièvre arythmie cardiaque	C choc
démangeaison	perte de connaissance
urticaire douleur thoracique/abdominale	hémorragie diffuse
rougeur nausées/vomissements	eutre:
éruption dyspnée	autre:
ictère hémoglobinurie	autre:
I. Diagnostic ou syndrome/incident	
4.2. Heindyse immundegises due à une incompatibilité AID 10 11	CNV Autre paratitaire stransfusion: fa Autre: purimonaire sigu (sfelailiance cardiaque, surcharge e) alcinos indéleinables graves: tassi la section 10. tasion encrée d'un composant sanguín (veuillez
Laboras de contect de l'hópial pour l'hómo subrer; Vaddage en ja personne de contect (claux e le den subrer)	teux ré lient après l'incident (si connue) compiet compiet se, lesquelles: s, lesquelles:
Laboras de contect de l'hópial pour l'hómo subrer; Vaddage en ja personne de contect (claux e le den subrer)	e Ista 4 6 6 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7

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Hemovigilance: AFMPS annual reports



Rapport de la première concertation annuelle du 10 décembre 2019 sur les critères d'exclusion temporaire, et les périodes d'exclusion connexes, pour les donneurs concernant le comportement sexuel.

Rapport annuel Hémovigilance

Rapport annuel 2019

Rapport annuel 2018 (corrections 26/11/2021: pages 23 et 28)

Rapport annuel 2017

Rapport annuel 2016

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2019 AFMPS Annual Report

4.2. Composants sanguins distribués et administrés

La figure 4 montre l'évolution du nombre de composants sanguins distribués et administrés sur la période 2015-2019. La distribution et l'administration globales des composants sanguins en 2019 sont similaires à l'année précédente.

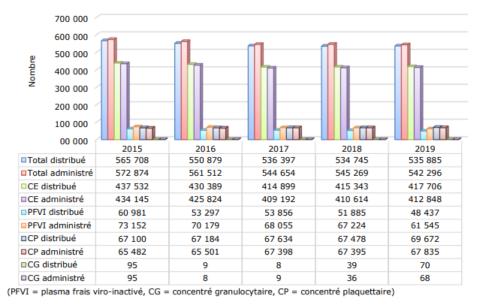
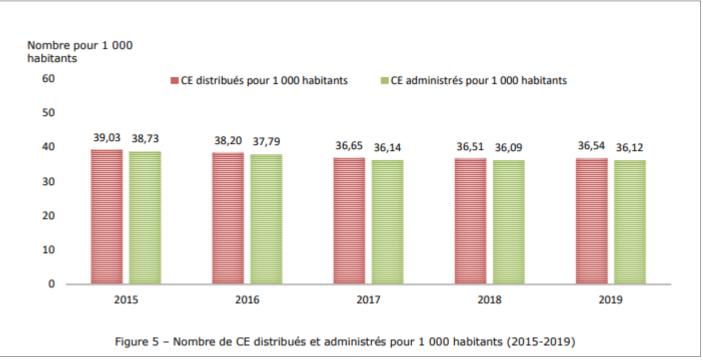


Figure 4 – Nombre de composants sanguins distribués et administrés (2015-2019)

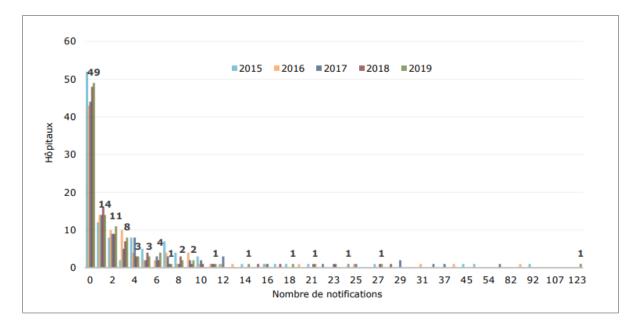


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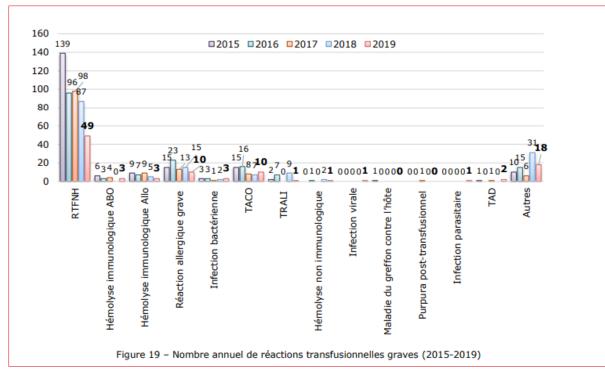




En 2019, 55 hôpitaux ont notifié au moins 1 incident ou réaction indésirable grave et 49 hôpitaux n'ont notifié aucun incident ou réaction. Le nombre de notifications par hôpital varie de 0 à 123 et le nombre total de notifications par hôpital pour 1 000 composants sanguins administrés varie de 0 à 5,05 (médiane : 0,15).



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Thank you for your attention





References

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