

Donor injuries

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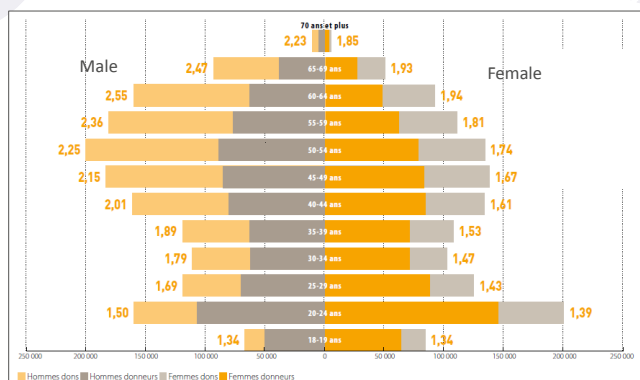
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 France



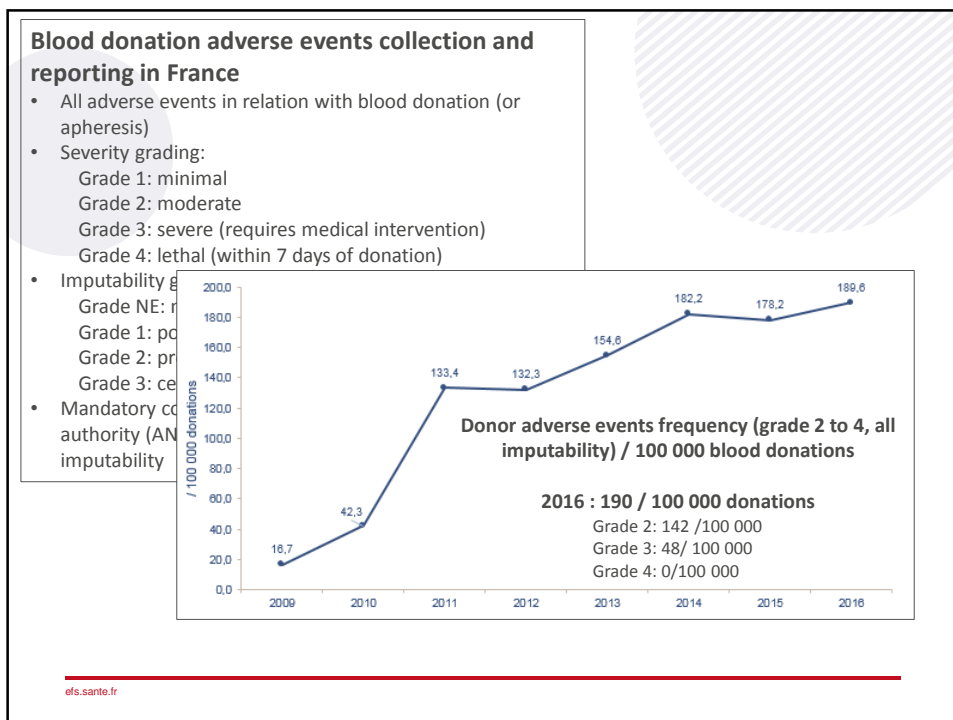
Blood donors: a large, healthy population exposing themselves voluntarily for altruistic motives to potential complications and risks.

In France (2016):

- 2 876 062 donations by 1 597 458 donors
- 84,7% whole blood donations and 13,4% apheresis donations



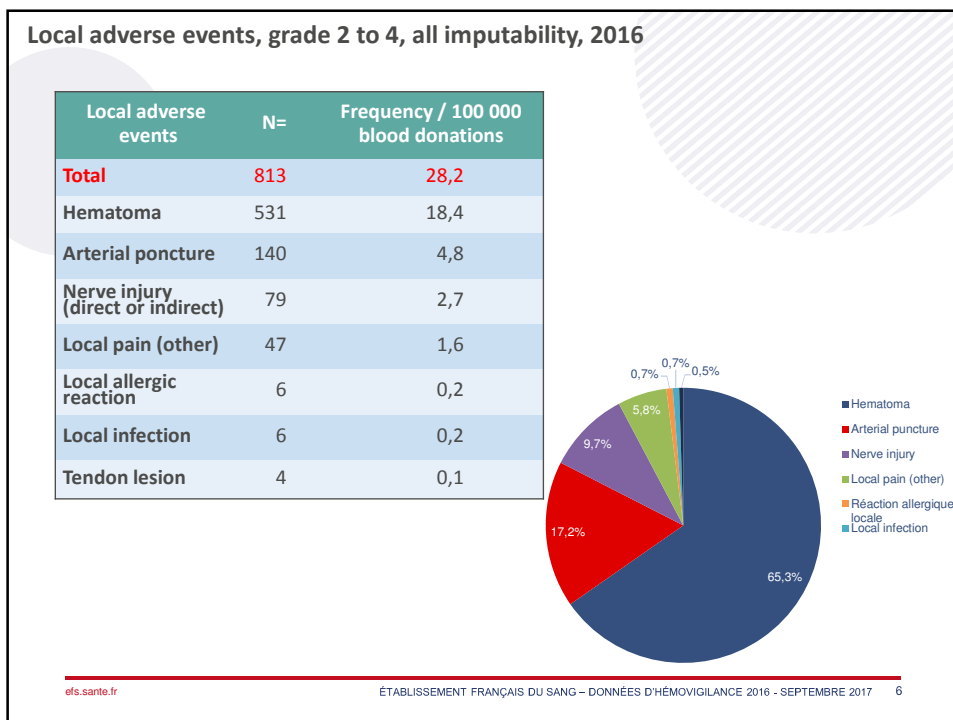
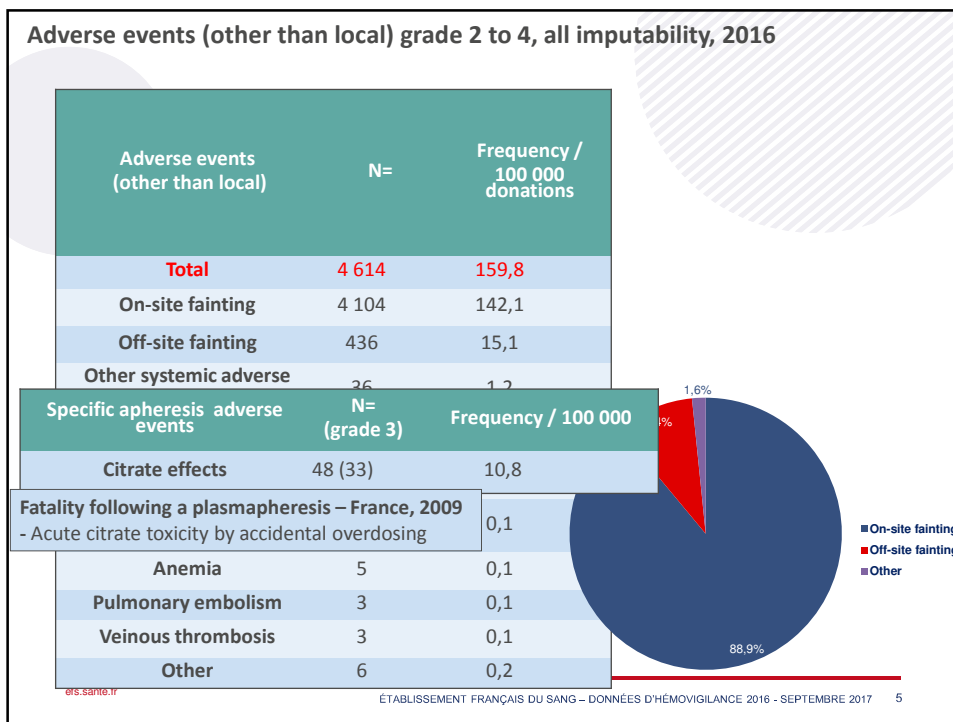
Number of donors and donations



Donor adverse events frequency, grades 2 to 4, all imputability, Etablissement Français du Sang, 2016

Imputability and severity	Grade 2		Grade 3		Grade 4		Total	
	N	%	N	%	N	%	N	%
Possible	27	0,7%	54	3,9%	0	0%	81	1,5%
Probable	211	5,1%	186	13,6%	0	0%	397	7,3%
Certain								
Not evaluable								
Total								
		Adverse events		Donations	Fréquence / 100 000		p	
	Male	2 375		1 552 484	152,9			
	Female	3 100		1 335 003	232,2			
								<0,0001
	1st donation	1 595		353 099	451,7			
	Prior donation	3 880		2 522 963	153,8			
								<0,0001
	Whole blood	4 259		2 444 449	174,2			
	Apheresis	1 216		443 038	274,5			
								<0,0001

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Adverse event (other than iron deficiency)	Total	10	0,3
On-site fainting			
Off-site fainting			
Other systemic events			
Thrombophlebitis			
Stroke			
Acute mountain syndrome			
Pulmonary embolism			
Vein thrombosis			
Other			

Iron deficiency

- A frequent and underreported blood donation adverse event
- May preexist to blood donation, in particular in pre-menopausal women, but is significantly aggravated by blood donation
- If not prevented/treated will result in anemia
- Even in the absence of anemia, is associated with:
 - Fatigue and decreased exercise endurance
 - Cognitive dysfunction
 - Pregnancy-related complications
 - Pica and restless legs syndrome

Anemia among repeat donors in continental France
Fillet AM et al, AABB 2017

- Deferral for low pre-donation Hb (< 12 g / 100ml in females, < 13 g/100 ml in males)
 - 2,9% female donors
 - 0,8% male donors
- 100% Hb recovery since previous donation (median: 30 weeks in females donors, 21 weeks in male donors):
 - 48,5% female donors
 - 49,8% male donors
- % Hb recovery increases with increasing interval between donations

*Iron depletion-related anemia
Iron depletion is not reported*

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Moving forward (1)

Evaluate novel strategies to prevent and treat known donation-related injuries/adverse events

Iron depletion and anemia

- Increased donation interval
- Ferritin-guided increased donation interval and/or iron supplementation
- Iron supplementation

Fainting reactions

- Hydration (isotonic / plain water)
- Increased salt intake
- Applied muscle tension

Further identify donor injury risk factors that may allow for risk-factor guided prevention strategies

- Population and occupation level
- Genomic level tomorrow

Prevention of fainting reactions and/or tiredness after whole blood donation: a randomized trial assessing hydration and/or muscle tension exercises (Evasion study, Morand et al, Transfusion, 2016)

- Factorial design, cluster randomization (1 cluster = 1 blood donation unit)
- Comparison of 6 strategies regarding **hydration**:
 - ✓ 500mL of an **isotonic drink** (two tablets of Isostar power Tabs, lemon flavor) in slightly mineralized water
 - ✓ 500mL of **slightly mineralized water**
 - ✓ **advice to drink** a glass of slightly mineralized water or fruit juice with or without :
 - ✓ **muscle tensing exercises**
- Donor phone interview one week after donation



Fainting reactions occurrence

Fainting reactions in the Evasion study:

- At the donation unit: the need to lie down in the “Trendelenburg” position.
- After leaving the donation unit: the need to sit or lie down, up to 48 hours after donation.

Fainting reactions	All donors (n=4576)	Female donors (n=2302)	Male donors (n=2274)	OR
Overall	5,5% (n=253)	8,1% (n=187)	2,9% (n=66)	3,0 p<0,01
On-site	3,0% (n=136)	3,7% (n=86)	2,2% (n=50)	1,7 p<0,01
Off-site	3,0% (n=137)	5,1% (n=117)	0,9% (n=20)	6,0 p<0,01
Both on-site and off-site	0,4% (n=20)	0,7% (n=16)	0,2% (n=4)	4,0 p=0,014

Evasion study results

- Overall fainting incidence can be reduced by drinking 500mL of an isotonic solution or water during donation.
- Fainting during blood donation can be reduced by muscle tensing exercises (30% reduction when compared to no exercises).
- Off-site fainting after blood donation and unusual tiredness can be reduced by isotonic hydration during donation (30% reduction when compared to «advised to drink»).

ISBT 2018:

- Effectiveness of water and salted snacks administration at time of blood donation on rates of vasovagal reactions. Robillard P et al, Canada
- To study the effect of pre-donation salt loading on vasovagal reactions in college-going students . Kumar K et al, India
Randomized study in 3060 young donors. Salt loading decreases fainting frequency, in particular off-site fainting.

ECDHM 2018

- Reducing the risk of vasovagal reactions: implementation applied muscle tension and water loading into routine whole blood collection. Thijsen A, Australia
- Can we prevent vasoagal reactions in our young inexperienced whole blood donors. A placebo controlled study comparing effects of a 330 vs 500 ml water drink prior to donation. Wiersum-Ossleto J et al, Netherlands

beneficial effect.

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Risk factors for fainting reactions in whole blood donors

Evasion study findings

- **Female donors** are at a higher risk of fainting reactions (OR: 3), especially for off-site fainting reactions (OR: 6).

Multivariate analysis in male and female (n=2298) donors:

- **Young age / student status**, as well as **reduced physical status** are associated with an increased risk of fainting reactions in female donors (OR: 3,2 and 1,3 / reduced grade from 1 to 10, respectively) and not in male donors.
- **1st time donation** is associated with an increased risk of fainting reactions in male donors (OR: 3,8) and not in female donors.
- **Increasing hemoglobin levels** is associated with an increased risk of (off-site) fainting reactions both in male and female donors (OR: 1,6 and 1,29 / increase per g / 100 ml).
- **Stress related to donation** is associated with an increased risk of (on-site) fainting reactions in male and female donors, but perhaps more so in male donors (OR: 1,8 and 2,6).
- **Pain at venipuncture and during donation** is associated with an increased risk of (on-site) fainting reactions, especially in male donors (OR: 1,2 / increased grade from 1 to 10).
- **Fainting reaction** is associated with higher risk of fainting at a subsequent donation (OR:6,5).

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Moving forward (2)

Develop prospective long-term surveillance programs combining donor registries and health data bases

- To investigate putative or poorly characterized donor injury risk factors
- To characterize potential long-term donation adverse events

The case for a special focus on plasma apheresis donors

- Increasing need in plasma for PDMP world-wide / self-sufficiency issue in Europe
- Depending on jurisdictions, plasma apheresis frequency up to twice a week (US)
- Several unresolved safety issues in high frequency plasma donors, such as:
 - Protein depletion and associated immuno-modulation
 - Hypocalcemia-induced disruption of bone metabolism
 - Exposure to plasticizers (DEHP)
- Overall insufficient long term surveillance data

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