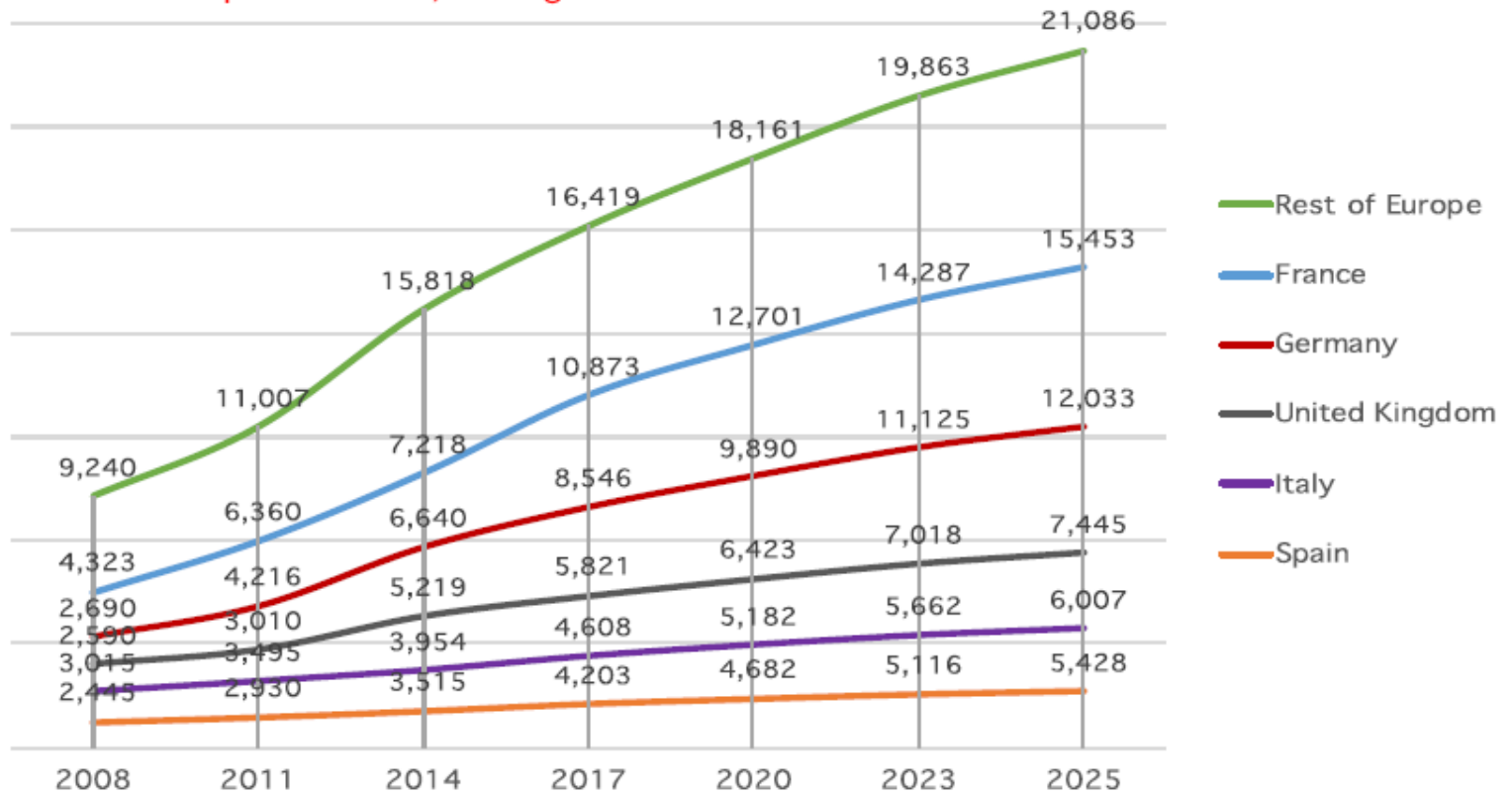


Personnel requirements in European plasma centers – revisited

Dr. Matthias Gessner
European Plasma Alliance
IPFA/EBA workshop on plasma collection, Amsterdam
January 2020

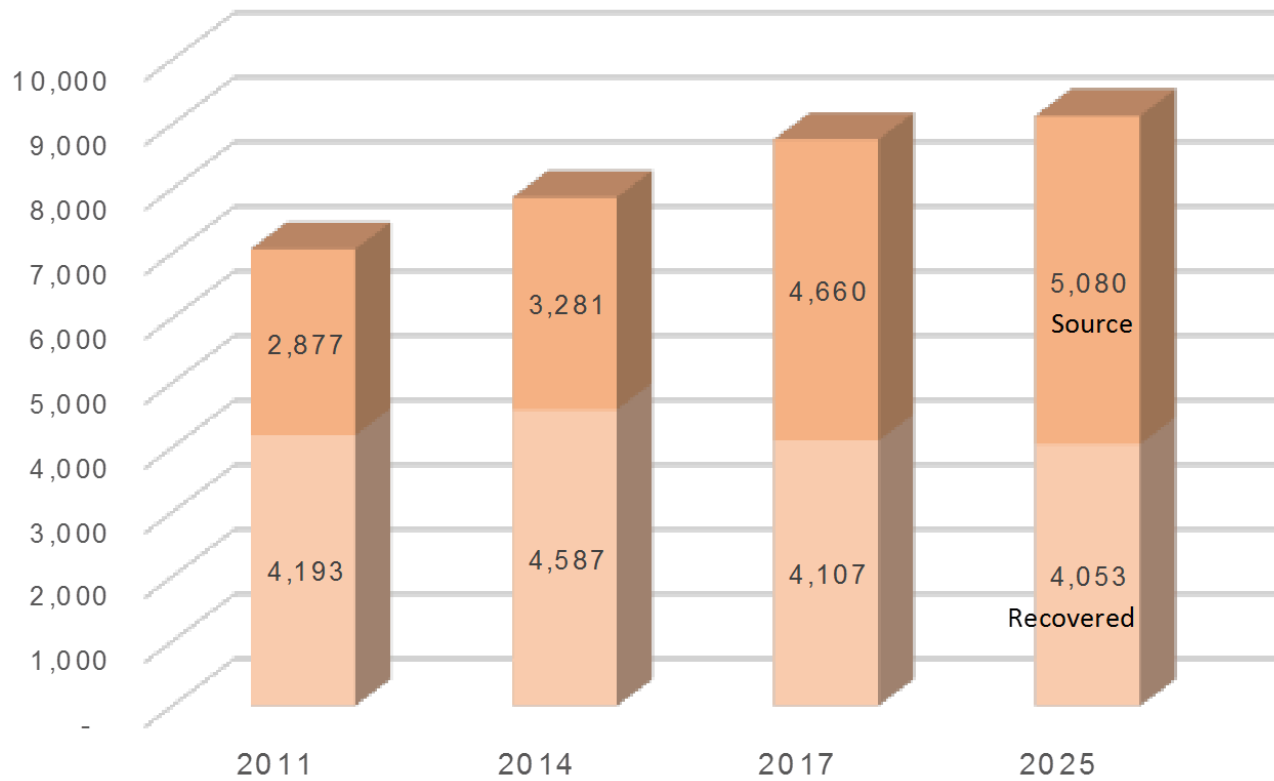
IVIG & SCIG CONSUMPTION BY COUNTRY IN EUROPE 2008 - 2025 - Kilograms

Total Europe 2025: 67,368 Kg.

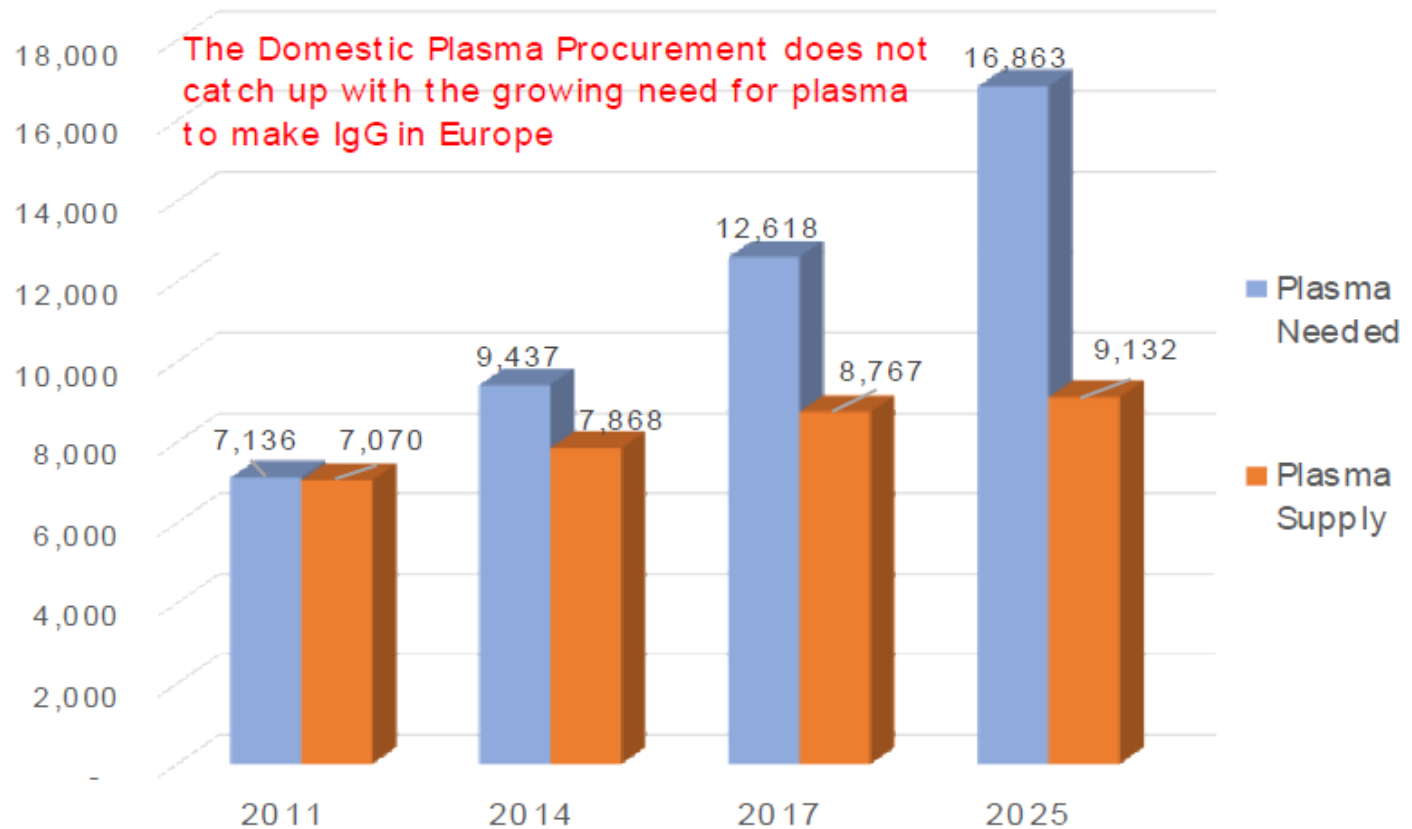


The Growing Discrepancy between Recovered and Source Plasma in the Domestic Supply from 2011 and 2025

The share of source plasma increases while recovered plasma's declines



The Growing Discrepancy between the Domestic Supply of Plasma and the Needs to meet IgG Demand from 2011 to 2025



- Plasmapheresis will be the main source to meet growing demand for plasma in the EU
- Blood and plasma collection rely on physicians for oversight, donor qualification, and donor management



Ref. <https://www.boardvitals.com/blog/physician-shortages/>

- Health workforce imbalances and shortages are a major concern in the European Region. Although the number of physicians and nurses has increased in general in the region by approximately 10% over the past 10 years, it is unlikely that this increase will be stable and sufficient to cover the needs of ageing populations.
 - Physicians are getting older, and nearly one out of three physicians is more than 55 years old.*
-
- Lack of physician has consequences for Europe's plasma supply
 - Physicians are needed for blood and plasma collection
 - Positions are generally difficult to fill due to low attractiveness
 - National regulations differ concerning physicians' involvement in blood and plasma donation

 - Consequence: opening hours have to be adapted, reducing time available for donors to donate

*Ref.: <http://www.euro.who.int/en/health-topics/Health-systems/health-workforce/data-and-statistics> (accessed Dec. 20, 2019)

- Article 9 Responsible person
 - 1. Blood establishments shall designate a person (responsible person), [...]
 - 2. The responsible person shall fulfil the following minimum conditions of qualification:
 - (a) he/she shall possess a diploma, certificate or other evidence of formal qualifications in the field of **medical or biological sciences** awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned; [...]
 - Article 19 Examination of donors
 - An examination of the donor, including an interview, shall be carried out before any donation of blood or blood components. A **qualified health professional** shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.
-

Physician Requirements in European National Legislation

- German Transfusion Act
 - § 4 (3) A donation facility may only be operated **if a medical doctor is present** during the blood withdrawal on humans.
 - § 5 (1) Authorized to donate are only persons who have been declared suitable under the responsibility of a medical doctor according to the state of medical science and technology and the **suitability has been determined by a medical doctor**. [...]
- Czech Ordinance 143/2008 laying down more detailed requirements for the quality and safety of human blood and blood components
 - §14 6.1.3. **The doctor is responsible** for carrying out the procedures for assessing eligibility and donor selection, procurement and procedures related to collection.
- Hungarian Decree 3/2005. (II. 10.) on quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components and on certain technical requirements thereof
 - §13 (4) **Specially trained health care professional decides on suitability** according to the instructions for operation. If you notice a condition that is not covered by the operating instructions, the doctor will decide on the suitability of the donor.
- Hungarian Decree 60/2003. (X. 20.) The minimum professional conditions for providing health services
 - **1 physician per plasma center**
- Austrian Blood Safety Act
 - §7 (6) The operation of a blood donation institution is **only permissible in the presence of a medical doctor** authorized to work independently in Austria, who has the necessary knowledge and skills.

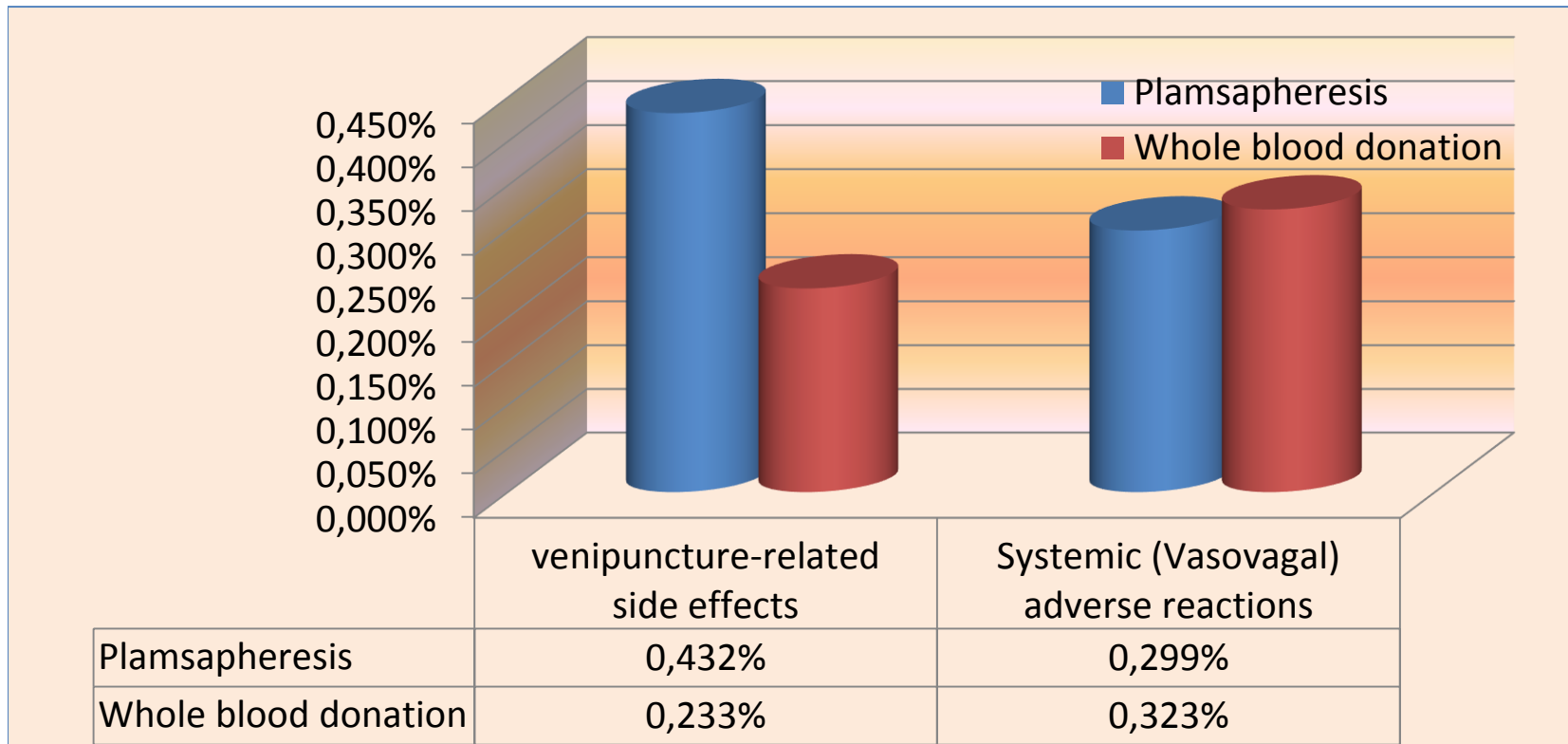
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- Austrian Blood Safety Act
 - §7 (6) The operation of a blood donation institution is **only permissible in the presence of a medical doctor** authorized to work independently in Austria, who has the necessary knowledge and skills. Deviating from this, **whole blood donations in mobile blood drives are permitted without the presence of a doctor** [...] provided that direct consultation with a suitably trained doctor is possible.

- Legislation allowing blood donation without presence of a physician
 - Denmark
 - United Kingdom
 - Switzerland
 - Quebec
 - United States
 - Austria (mobile whole blood donation only)

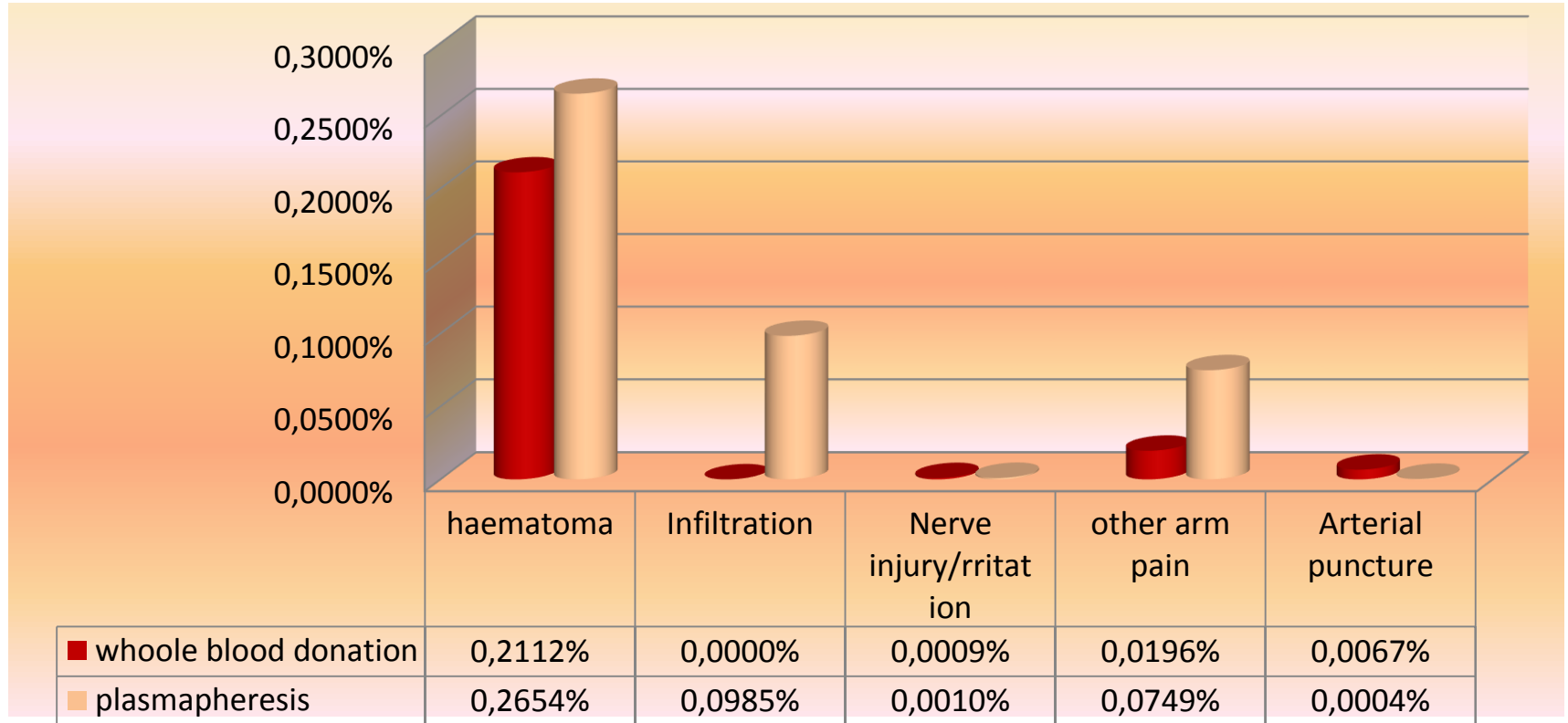
- Donor Qualification
 - Medical expertise to define standardized criteria for donor acceptance
 - Decision in case of new facts, exceptional cases
- Donor Safety
 - Assurance that processes follows approved Standard Operation Procedures
 - Assurance that processes are performed by trained qualified health professionals
 - Medical responsibility to assure donor safety

Adverse events in whole blood and plasma donations (multiple donors)



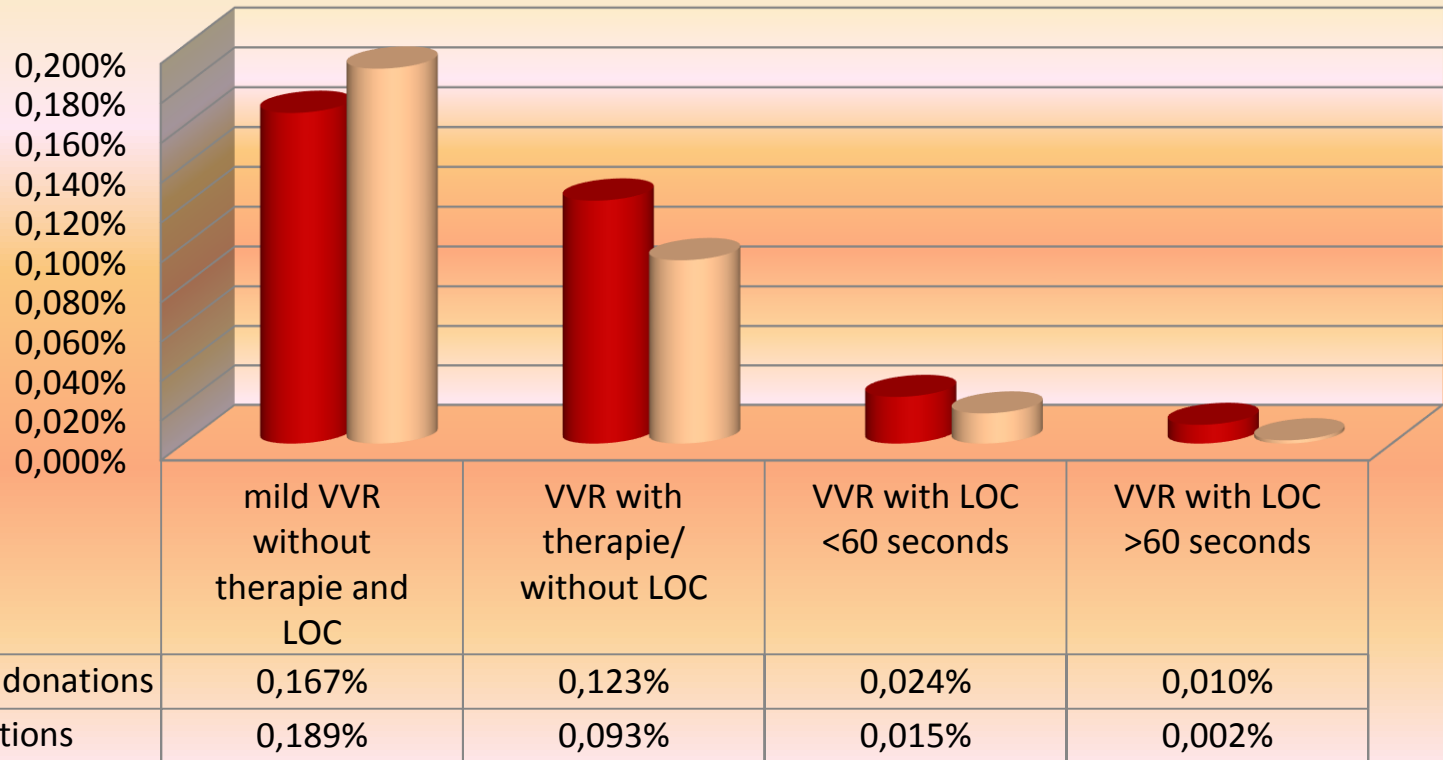
Ref.: Dr. med. Thomas Burkhardt, DRK-Blutspendedienst Nord-Ost; EDQM/EU Commission Symposium, January 29-30, 2019, Strasbourg

Most frequent local side effects in comparison



Ref.: Dr. med. Thomas Burkhardt, DRK-Blutspendedienst Nord-Ost; EDQM/EU Commission Symposium, January 29-30, 2019, Strasbourg

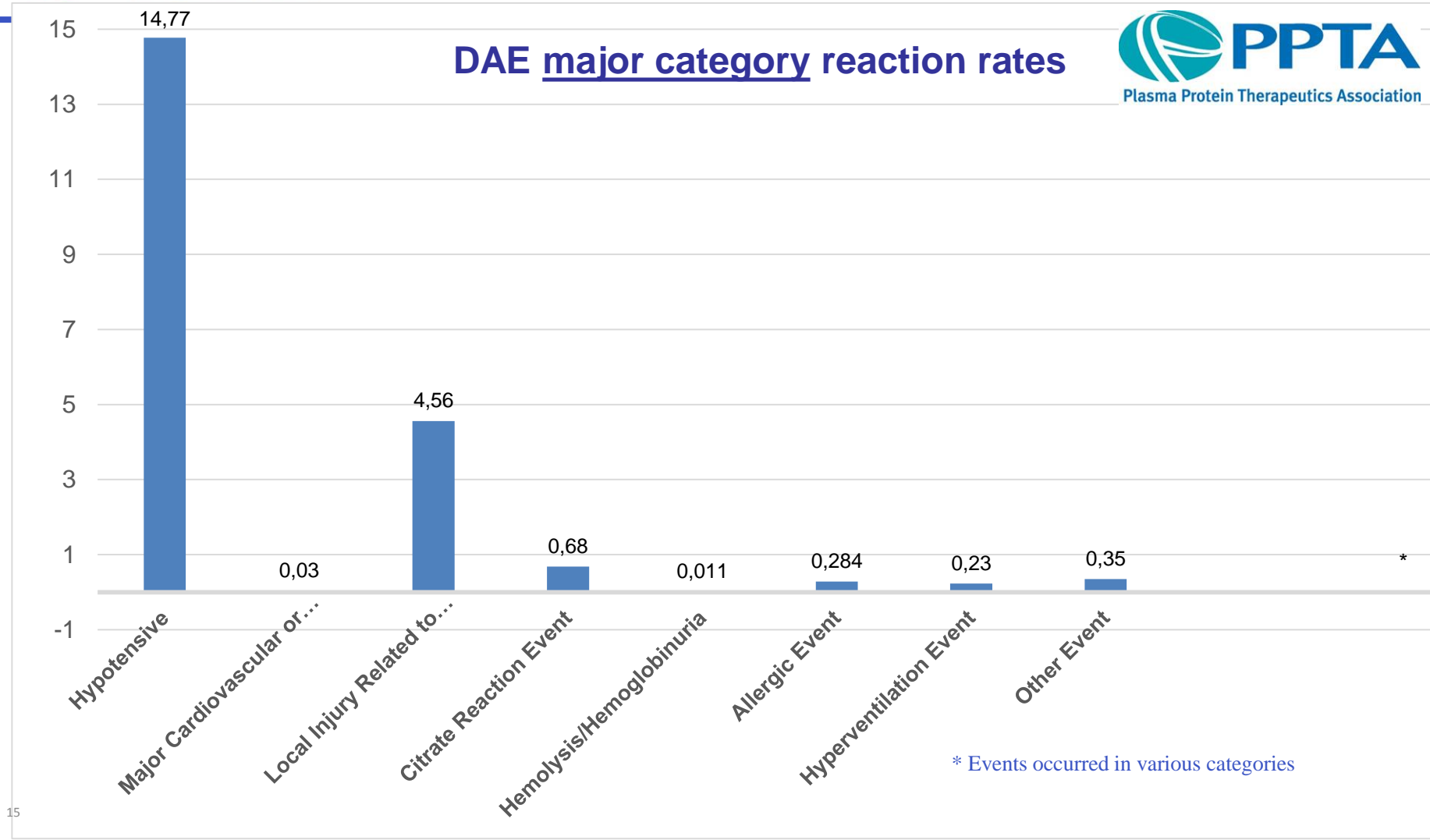
Frequency and severity of vasovagal reactions in whole blood donation and plasmapheresis



Ref.: Dr. med. Thomas Burkhardt, DRK-Blutspendedienst Nord-Ost; EDQM/EU Commission Symposium, January 29-30, 2019, Strasbourg

DAE major category reaction rates

Events per 10,000 donations



Ref.: Mary Gustafson, PPTA; EDQM/EU Commission Symposium, January 29-30, 2019, Strasbourg

Adverse Events in Blood and Plasma Donors

- In blood and plasma donation events are rare and usually mild
- Young, lower-weight, female, and first-time donors most at risk for hypotensive reactions
 - Most serious loss of consciousness outside of center
- In case of more severe adverse events the center physicians provide first aid and call emergency medical services
 - Plasma collection is done in cities where emergency medical services are available within minutes

So what to do?

- Shortage of physicians changes the job profile and requires re-evaluation of medical tasks previously limited to physicians in all areas of medicinal practice - this must include blood and plasma collection
 - Employment of physicians maximizing value to society
- We need to assure medical oversight for existing and additionally required European plasma collection with less physicians available on the job market
 - We need to define new medical job profiles for plasma center staff to relieve strong reliance on physicians
- We need national regulations and processes allowing appropriately trained qualified health professionals performing donor qualification and overseeing plasma collection under a physician's supervision who is not necessarily constantly present in the center during operation
- **Perform source plasma collection in all EU member states to distribute need for healthcare personnel (and donors) over maximum number of countries**



THANK YOU