

Development of: Competence Framework for Specialist nurses in plasma collection centers

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Collaboration

Why ESNO,

ESNO is the association of European Specialist Nurses to raise their profile and position of the Nurses in advanced position

About FoNSE

FoNSE is the ESNO foundation, where activities and projects are facilitated, by their members and associate nurses from Europe and beyond

About Plasma Protein Therapeutics Association (PPTA)

PPTAs mission is to promote safe plasma collection practices in the EU with focus on donor health and donor safety to ensure patients access to safe products

About EDTNA/ERCA

EDTNA/ERCA is a multidisciplinary organisation working in renal care and blood filtration.



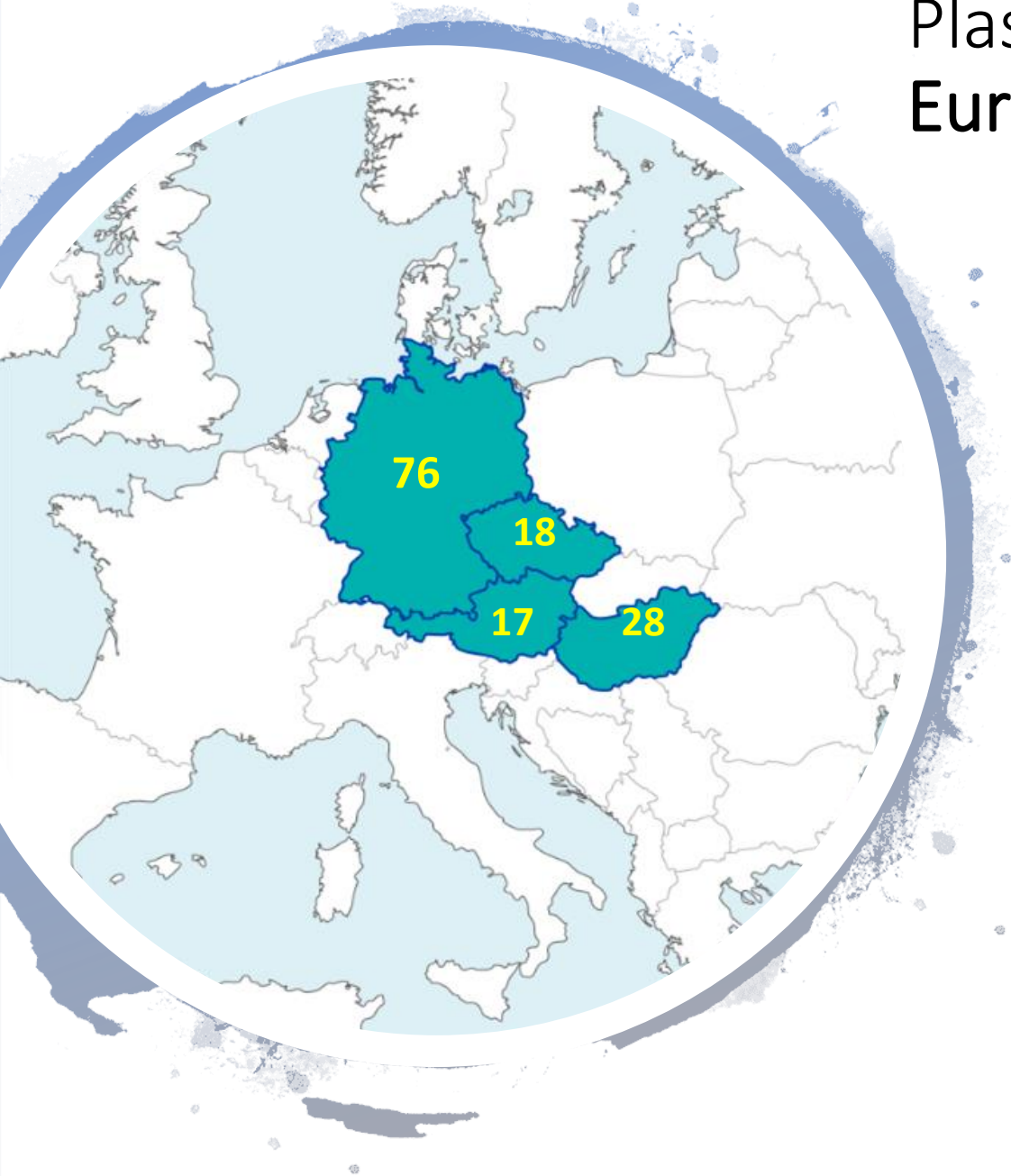
Profiling Competence Nurses in Plasma Collection Centers

Nurses ----- Specialization

- Classic development specialization: e.g., intensive care – operating
- Disease specific: cancer, rheumatology, respiratory
- Leadership: directors, management and education
- Per health spectrum: infection, heart failure, blood and plasma



Plasma and Plasma Protein Therapies (PPT) European Context



- Diagnosis of life-threatening plasma protein related disorders.
- PPT are often the primary or only treatment option for these patients.
- In Europe, 55% of the plasma is collected in 4 countries where private and public collectors coexist and work together: Austria – Czechia- Germany – Hungary
- Collecting sufficient plasma for the manufacturing of therapies for patients is only possible with healthy plasma donors
- Most European countries do not have dedicated plasma collection programs in place



The Power of Plasma Donation Animation



À regarder ...



Partager



About plasma

<https://www.youtube.com/watch?v=08Pb-UZPLiU&feature=youtu.be>

Current challenges



- Plasma is donated from healthy people either through a whole blood donation or a plasmapheresis
- In Europe, 38% of the plasma need is collected by public collection services and 24% by private collectors. Europe is reliant on US plasma imports
- Many EU countries = physical presence of a *physician*
- EU legislation = *qualified healthcare professional*.
- Challenges to fill these positions:
 - Shortened center opening hours
 - Difficulties opening new centers
 - COVID-19 increased staffing problems and reduced center capacities
- The lack of physicians will eventually have consequences on the availability of European plasma.

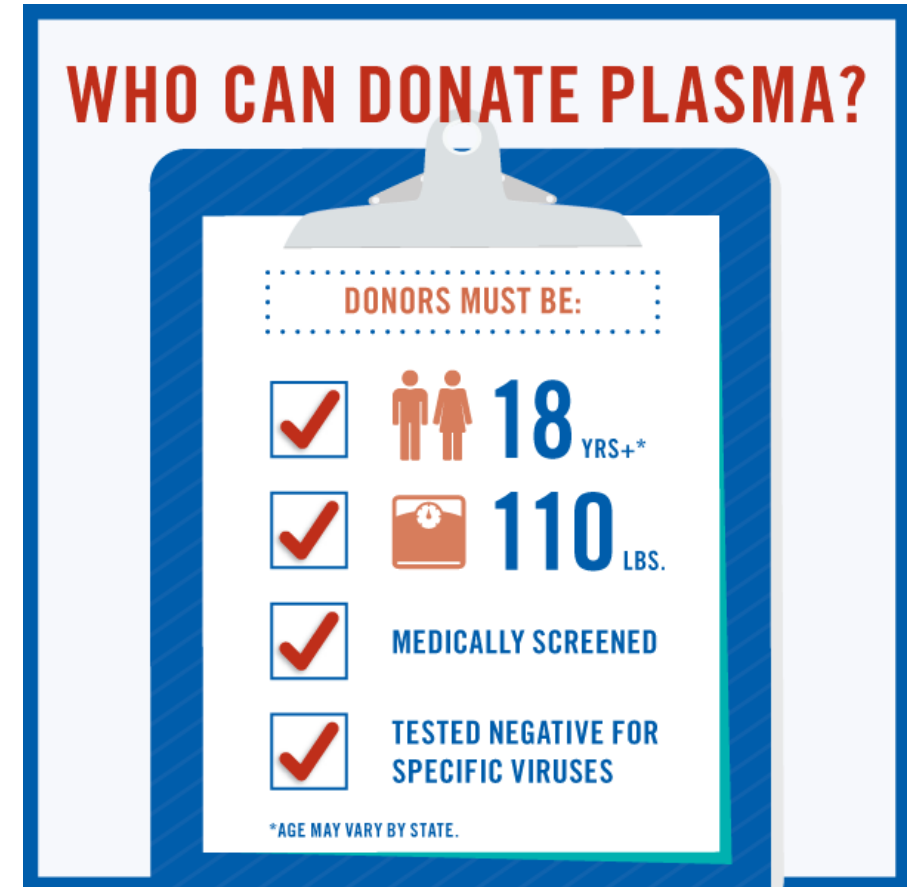
EU regulatory background

- Potential donors need to be examined and interviewed before donation by a qualified healthcare professional
 - *DIRECTIVE 2002/98/EC*
- Some Members States (Austria, Czechia, Germany and Hungary) have determined that the qualified healthcare professional needs to be a medical doctor and need to be present at all times
- However, to our perspective, this could also fit the profile of a registered nurse



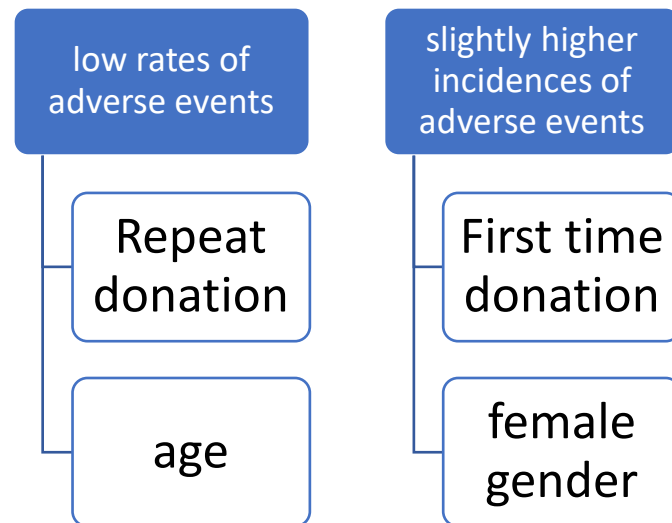
Donor health and safety is paramount

- The delegation of medical tasks in the field of blood and plasma donation to qualified health care professionals
→ safe !
- Adverse events during donation are quite rare and they are usually mild in nature
- Regulations should be changed to reflect more modern practices that are widely accepted elsewhere
- Studies show that screening of regular plasmapheresis donors by qualified health professionals is safe and effective

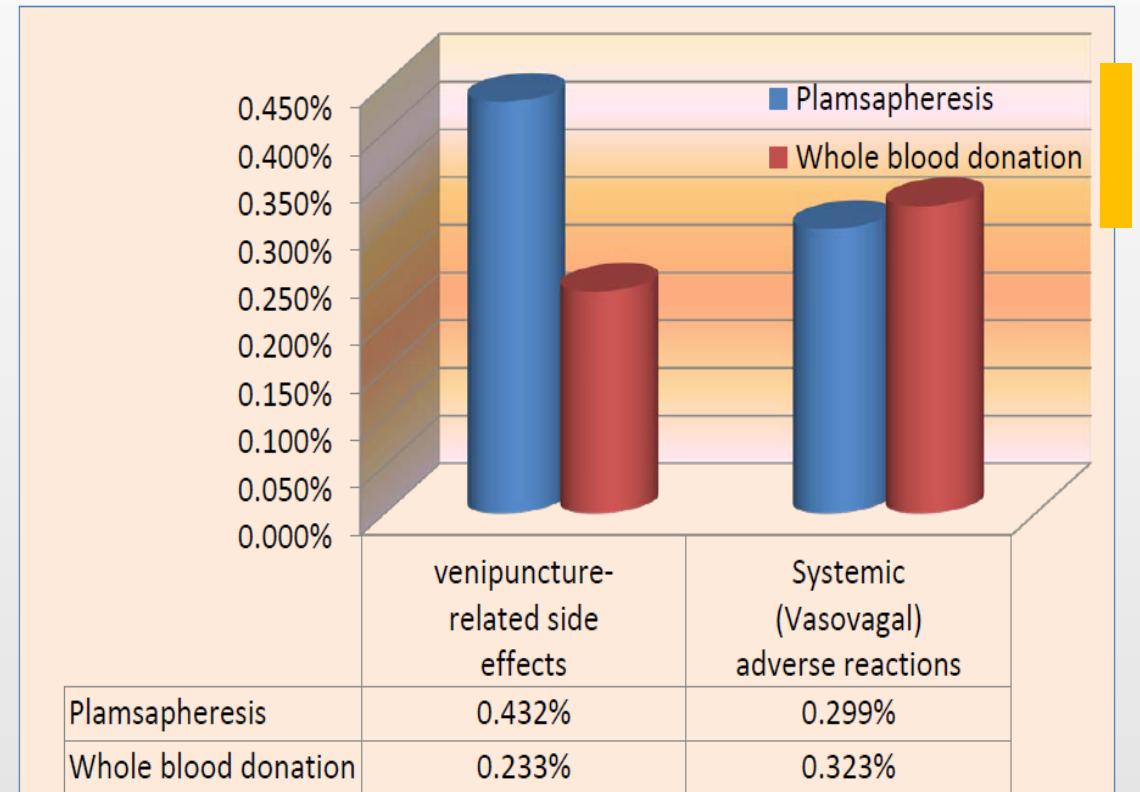


Adverse Events

Dr. Burkhardt in 2019 studied donor vigilance data → whole blood donation and plasmapheresis donation → very low incidences of adverse events.



Overview of adverse reactions to whole blood and plasma donations (multiple donors)



Dr. med. Thomas Burkhardt

* Dr. Burkhardt – Presented at EQDM Workshop on Plasma Supply Management 29-30 January 2019

PPTA Data Collection Study on Adverse Events

- PPTA analyzed millions of plasma donations from member companies
- Most observed donor adverse events were vasovagal events
- The need for medical intervention was rare

2016 Data Collection Study Highlights	
Data collection period	3 months in 2016
Total plasma donations	7,6 million (79% of industry)
DAE recorded	15.300
Overall DAE rate	2,09 per 1.000 donations
Top 2 DAE Categories (over 75% of all AEs)	Hypotensive/vasovagal prefaint with no loss of consciousness (57% of all AEs) Local injury (hematoma/bruise) related to phlebotomy (18% of all AEs)
Most rare DAE Categories	Severe hypotensive events (0,06 per 1.000 donations) Hypotensive events with prolonged loss of consciousness (0,01 per 1.000 donations) Hypotensive injury (0,007 per 1.000 donations)
2018 Data Collection Study Highlights (soon to be published)	
Data collection period	4 months in 2018
Total plasma donations	12,5 million donations
Overall DAE rate	1,58 per 1.000 donations
Top DAE Categories	Vasovagal
Rare occurrences	Medical intervention Donors needing transportation to the hospital within 24 hours, including donors who have AEs after they left the donation center (0,04 per 1.000 donations)



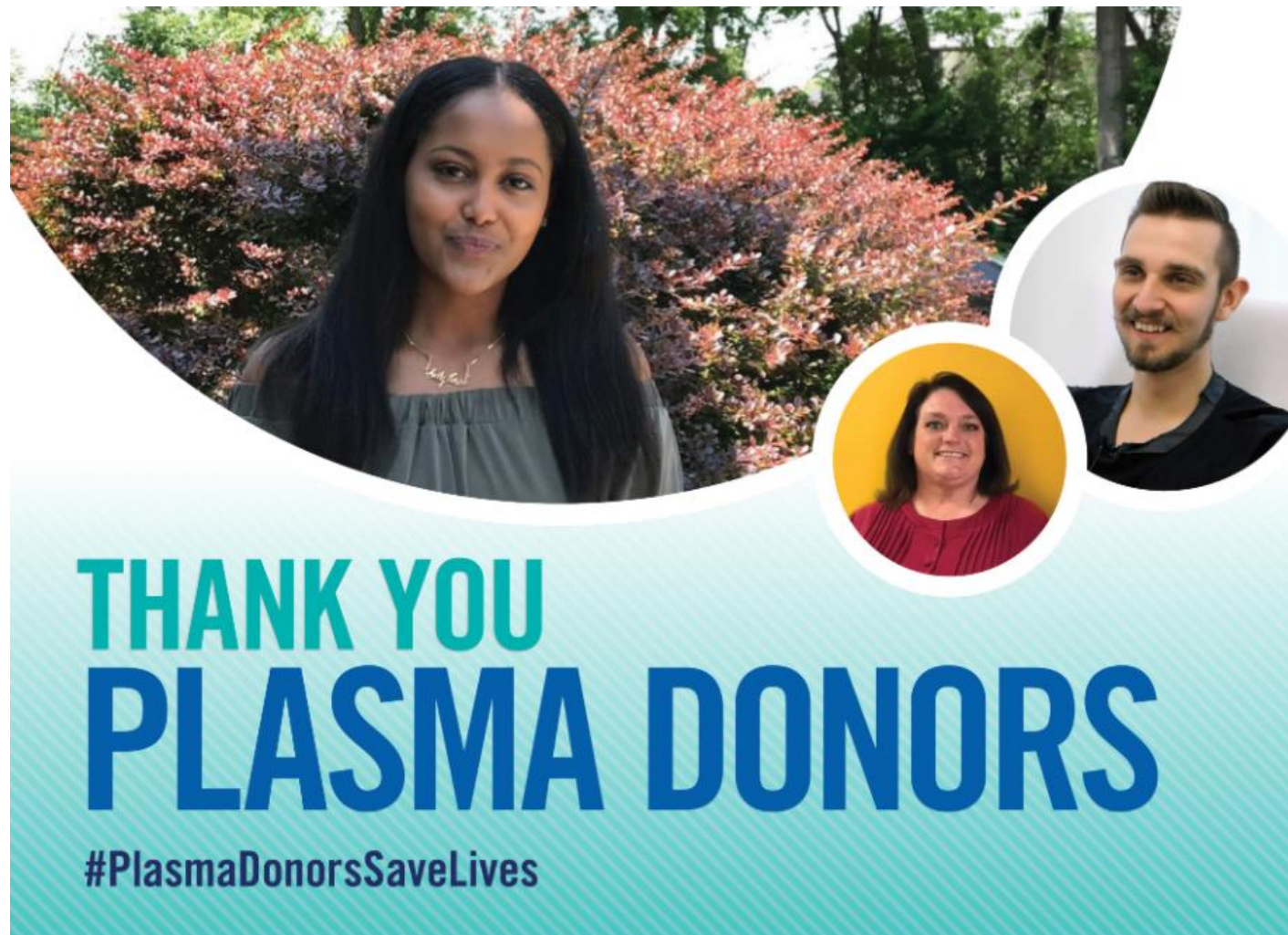
Specialist Nurses roles and recognition

- Raising awareness for plasma donation and the diseases that are treated with plasma therapies
- Curriculum for nurses in plasma collection centers
 - Physicians define criteria for donor assessment
 - Delegate donor examination to trained health professionals
 - Physician available on call instead of present
- Political willingness to make legislative changes and more regulatory flexibility
- Calling policymaker at national and EU level to initiate an inclusive dialogue and to put in place an appropriate legislative framework
- Increase plasma collection through plasmapheresis in Europe and decrease the reliance from third countries.

Career opportunities for Plasma Collection Specialised Nurses

- ✓ Lifetime career
- ✓ From novice to expert
- ✓ Contribute to novel therapeutic environment
- ✓ Working with experts: medical, pharma industry
- ✓ European nurse minded profession
- ✓ Contribution to clinical research
- ✓ Reliable timetable
- ✓ Different fields of nursing. Promoting education, health promotion.





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