

Best practices in plasma collection

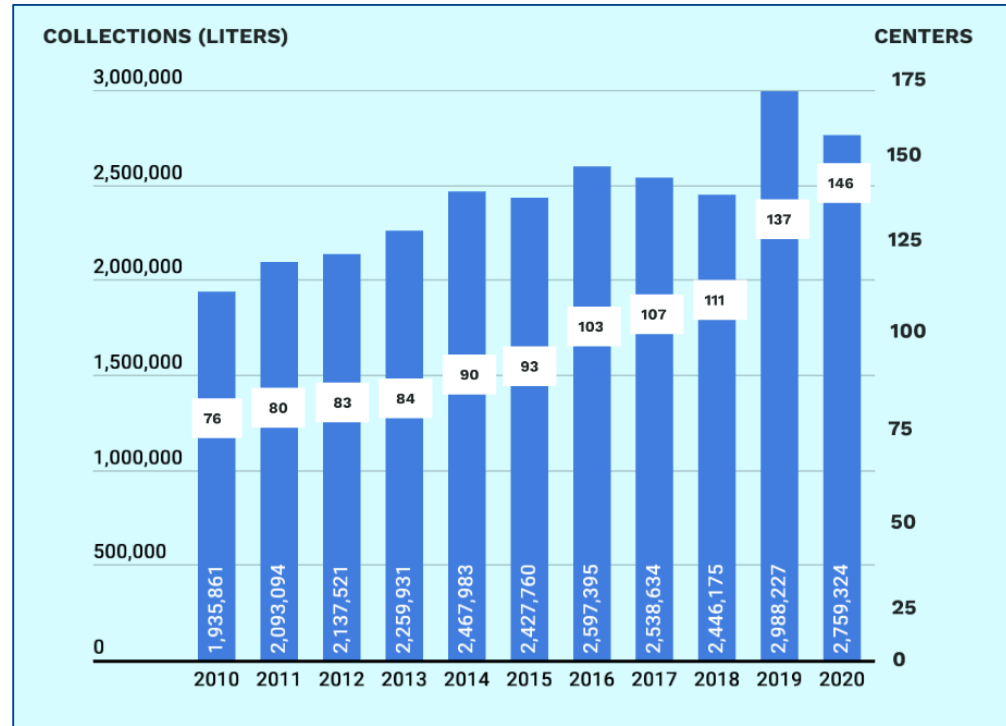
What can we learn from each other?

Matthias Gessner, EPA chair

About European Plasma Alliance (EPA)

- *Mission: Promote **safe plasma collection practices** in the EU with focus on **donor health** and **donor safety** to ensure **patients access to safe products***
- *Collected 2.8 million liters of source plasma in 4 countries in 2020*
- *146 centers (2021)*
 - *Germany: 79*
 - *Austria: 20*
 - *Czech Republic: 18*
 - *Hungary: 29*

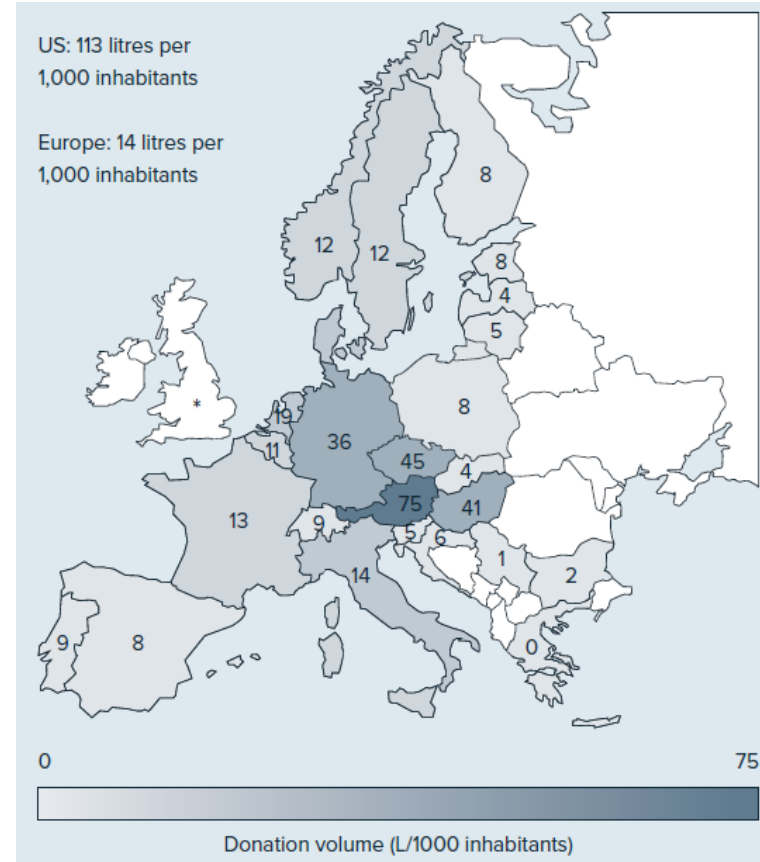
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Need to collect more plasma

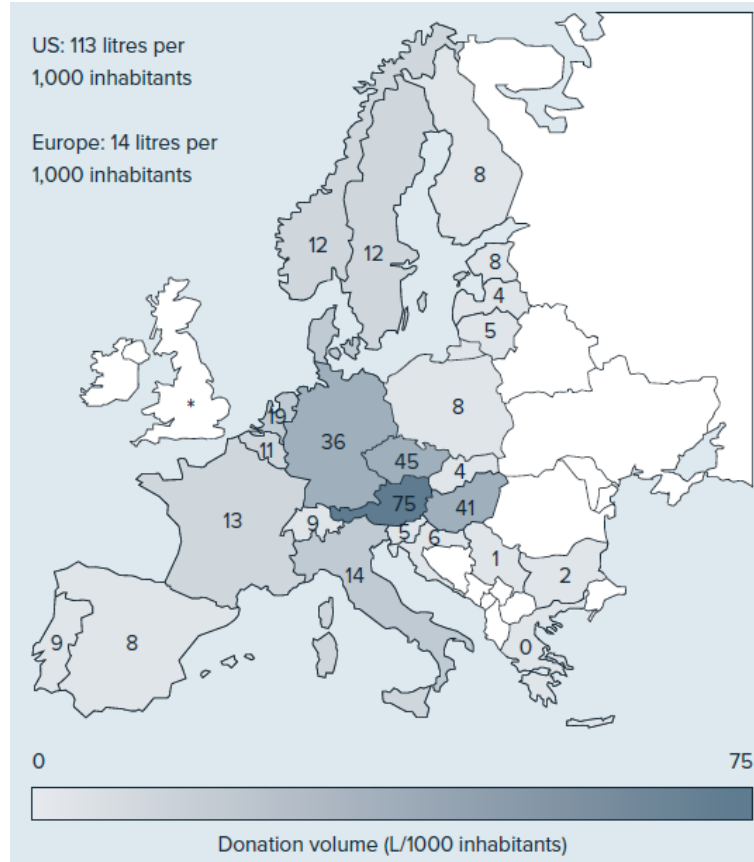
- Annual growth >7% of Immunoglobulin (IG) usage in EU over last years
 - More patients are receiving **valuable IG treatment!**
 - However, large **differences in IG usage** between EU countries
 - Median consumption in Bulgaria 4.6g & in Belgium 218g/1000 inhabitants (in 2020)
 - Europe Average 2020: 81 g
 - Significant number of **undiagnosed/untreated patients**
 - Need to address **health inequalities** between countries

References: Market Research Bureau and Vintura White Paper (2020) ([LINK](#))



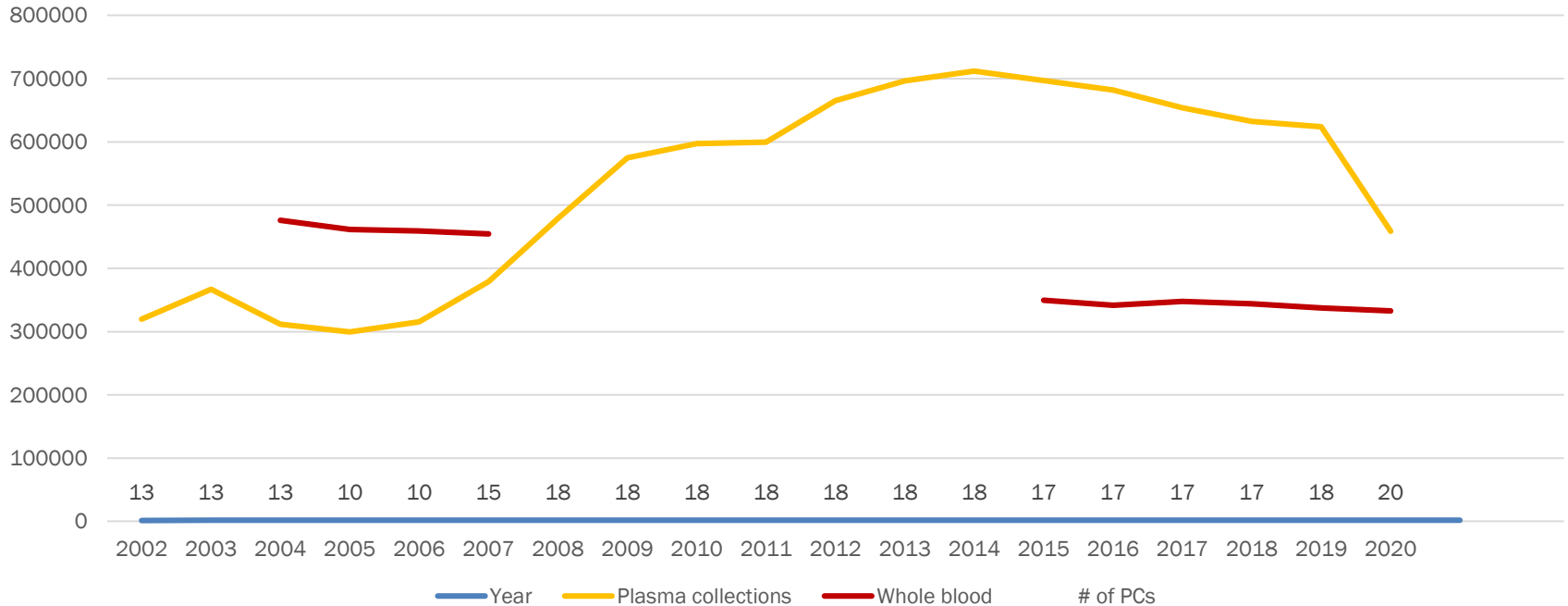
Learning on EU level

- Theoretical **IG sufficiency levels**
 - 120g/1000 = 30 liters/1000 inhabitants
 - 220g/1000 = 55 liters/1000 inhabitants
- Plasma collection in EU not keeping pace with EU patients' needs
 - **Dependency from US plasma of about 30%**
- Only **4 countries** provide sufficient plasma to cover the needs of their patients'
 - Austria, Czech Republic, Germany, Hungary
- **All European countries** need to contribute to plasma collection by apheresis



AT Blood & plasma collections 2002-2020

AT - development of blood and plasma collections 2002-2020



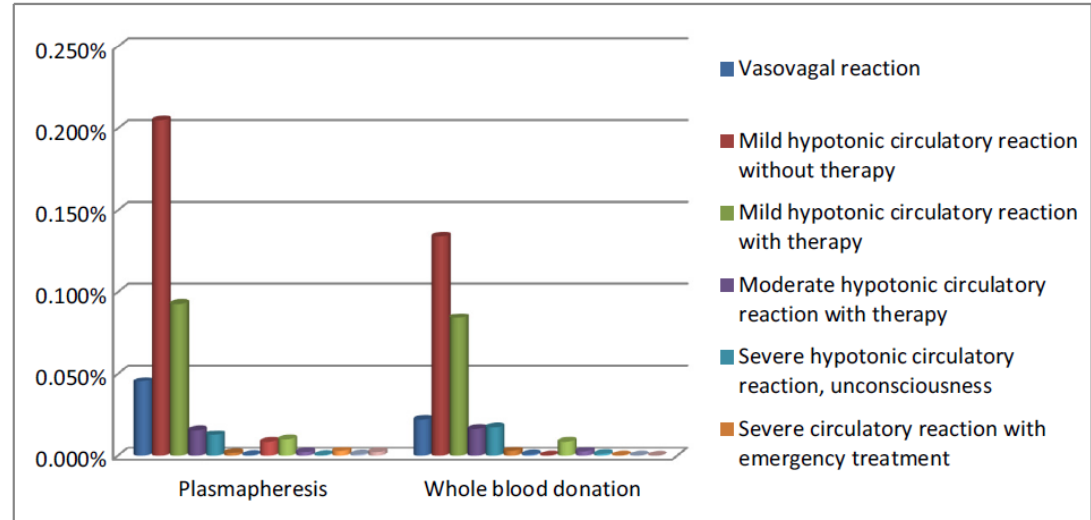
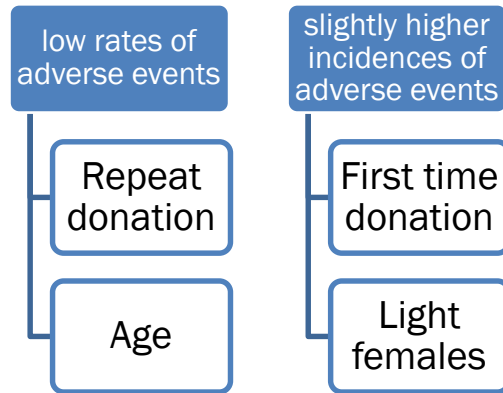
Learnings from AT

- Key plasma collection **regulation**
 - 72 hours between 2 donations
 - 50 donations/year
 - Donor Compensation not defined by law
- Blood collections declining over the last decade due to **Patient Blood Management** (PDM) with no indication of crowding-out
 - Down 36% from 58/1000 in 2004 to 37/1000 in 2020
 - No effect of COVID on blood collection
 - Volume of recovered plasma declining in parallel
- **Number of plasma centers** to support efficient plasma collection
 - New centers receive only temporary license
- Plasma collection of **50 donations** per year since 1964 safe for donors
 - SIPLA: demonstrating 60 donations/a are safe for donors (Germany)

Donor safety

Are compensated plasma donors at higher risk for adverse events? **NO**

Dr. Burkhardt in 2015 studied donor vigilance data on whole blood donation and plasmapheresis donation → very low incidences of adverse events.

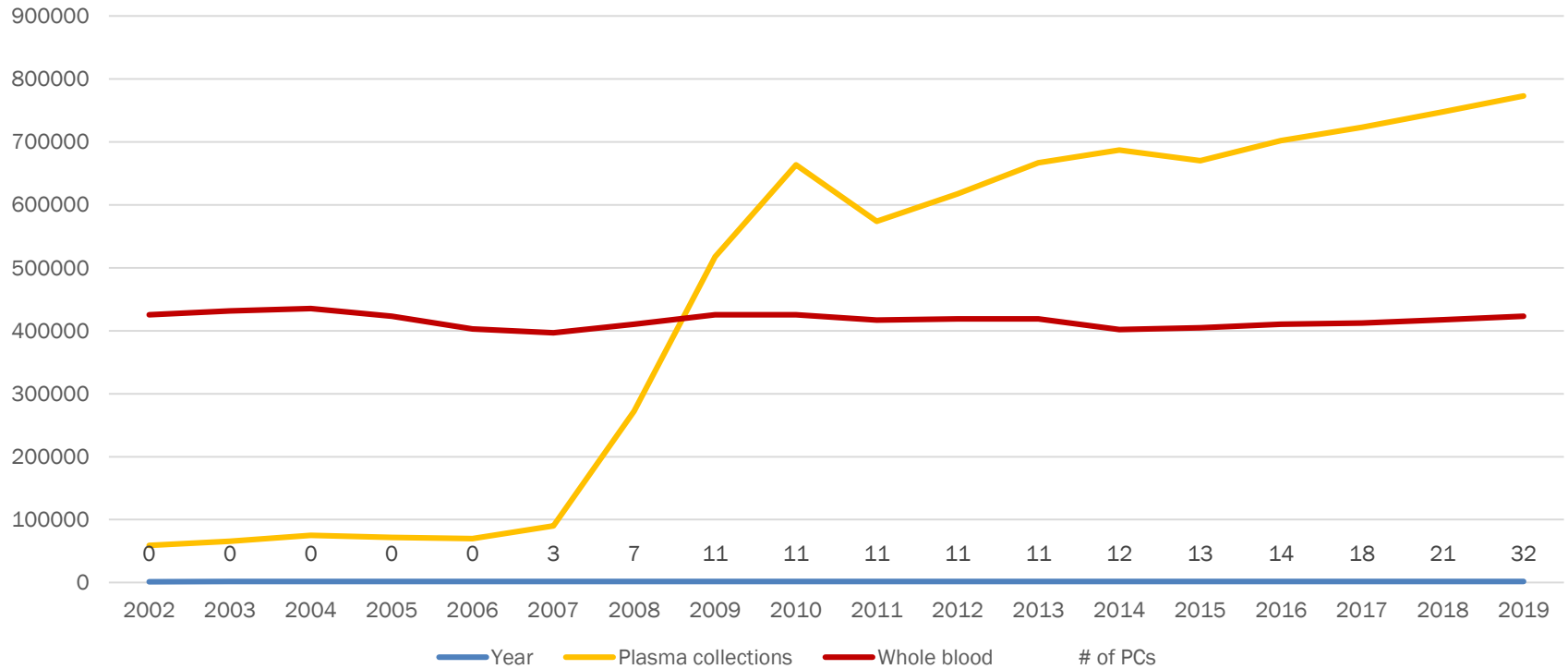


Burkhardt et. al (2015): donor vigilance data shows that both whole blood and plasmapheresis donations are safe with low incidences of adverse events ([LINK](#))

Hungary

- Key plasma collection **regulation**
 - 72 hours between 2 donations
 - 45 donations/year
 - Limit for Donor Compensation defined by law
- **Collection volumes not published**
- 2006 **1st plasma center**
- 2016 **Market liberalization** and entry of new players
- 2017 Annual **obligatory whole blood donation** for plasma donors

CZ Blood & plasma collections 2002-2019



Learnings from CZ

- Key plasma collection **regulation**
 - 2 weeks between 2 donations
 - 26 donations/year
 - Limit for Donor Compensation defined by law
- **Transparent** availability of collection information
- Blood and plasma donors are independent of each other - **no crowding-out** observed over >10 years
 - Blood collections remain flat at about 40/1000 per year
- Beyond a certain number **additional centers will not increase the overall plasma donation volume**
 - Maximum number to be limited?

No Crowding-out in coexistence



CZECHIA

- Blood collection numbers and rates have remained relatively stable over the past 10 years, with neither sharp upticks nor declines.
- This stability in blood collection has persisted despite the opening of 10 plasma collection centers between 2007 and 2010.
- This same stability in blood collection has persisted despite a dramatic increase in predominantly compensated source plasma collection during the same time frame, moving from 6.8/1000 donations per person in 2006 to 63.4/1000 donations per person in 2010

Professors Macis & Lacetera,
Johns Hopkins University and the University of Toronto (The Source Winter 2017)



GERMANY

“ ...blood and plasma donors are not part of the same donor population. We observed that blood donors are on average older than plasma donors. ...On average, a blood donor donates twice a year. A plasma donor donates on average 20 times a year. This is a whole different commitment and explains why it is more appealing to the younger population. ”

Dr. Franz Weinauer, Medical Director
Blood Donation Service of the Bavarian Red Cross (The Source Fall 2018)

Do compensated plasma donations reduce the donors giving uncompensated blood donations? NO

Assessments of the decreases in blood donation have been found to be primarily due to **Patient Blood Management**

No empirical evidence to support the idea that new plasma donation centers have a negative influence on traditional blood donations in a country

References ([LINK](#))

Summary - Best Practices

- Only **4 EU countries with plasma collection** have sufficient volumes of plasma for national patients and beyond
 - Transparent availability of collection data important
 - Blood is local - plasma is global, recovered plasma partially declining
 - Other EU MS need to contribute as well and initiate plasmapheresis programs
- **Coexistence of blood and plasma** collection is feasible
 - Over last 20 years no crowding out observed in Czechia and Austria
 - Cooperation of blood and plasma collection improves collaboration
 - Legal regulation of compensation aligns with VUD
- On average **1 donation/week** appears to be generally safe
 - AT, DE, HU: 45 - 60 donations
 - Plasma donor safety comparable to blood donation
- Alignment of **center-number per country** with donor-numbers



THANK YOU!



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