

# Plasmapheresis: Dutch experiences in an European context

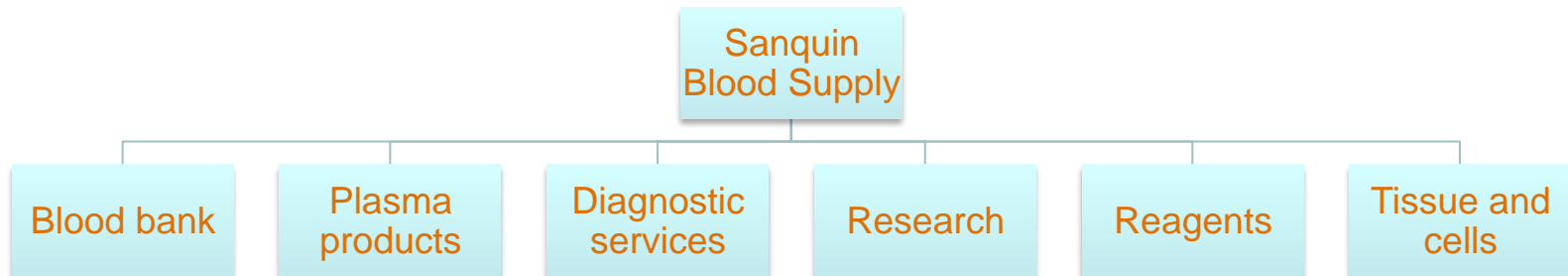
Arlinke Bokhorst, MD M&G

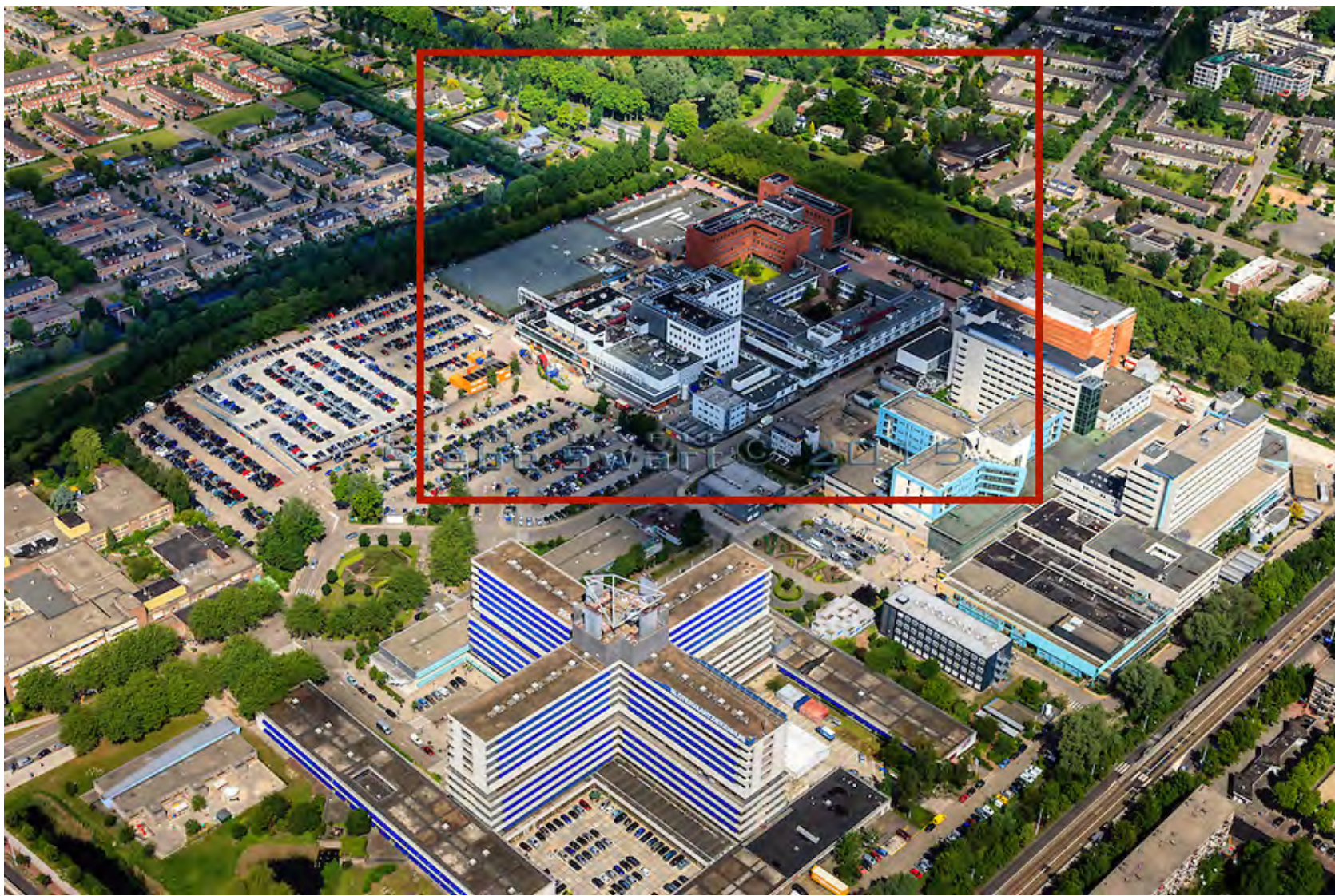
- manager medical donor affairs,

- Brief introduction of Sanquin Blood Supply
- Plasma collection in the Netherlands
  - Donor base
  - Collection centers
  - Donor Screening
- Pro's en con's of the Dutch approach
- European position
- Options for collaboration

## Sanquin : More than a blood bank.....

- Merge ( 1998) between all blood banks and blood related laboratories
- National facility, licensed as the only organization in the Netherlands to collect blood and provide (fresh) blood products
- Not-for-profit Foundation, but partly operating on a for-profit market
- All services are in house, plasma is only collected for the Division Plasma products





## Blood bank

### Short term preserved blood products

- Ery's, IUT, thrombocytes, FFP, serum, stem cells, mother milk,
- Whole blood, Plasmapheresis, therapeutic apheresis, Multi component, cytapheresis

	2015
Ery's	420.000 units
Thrombo's	56.000 units
Cytapheresis	1.900 procedures
FFP	55.000 units
PfF	320.000 Kg

## Plasmaferese Donors

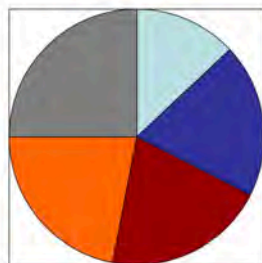
- Donors are recruited from Whole blood donors based on Blood group, medical indications ( hemoglobin, travel history, malaria etc.) and willingness
- Donors may also temporarily shift to plasmapheresis, MCC or thrombocytapheresis
- No remuneration; only travel costs compensation on request ( 0,19 ct/km)



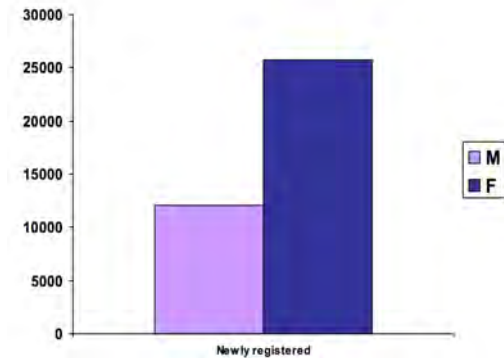
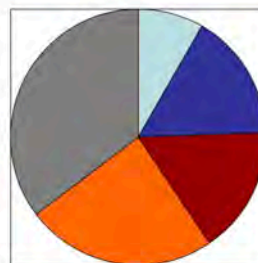
## Donor base

2014	WB Donors	Pf donors
#	318.000	59.000
Freq.	1.4	5.1
Mean Age	41 y	43 y
% female	58%	37%

Male Dutch Population



Male donors



## Plasma donors screening

- Donor history with an abbreviated Questionnaire by donor assistant
- Blood Pressure and Hemoglobin
  
- Donor Testing : HBV HCV, HIV, anti bodies, NAT, Lues (positive < 0,01%)
- Protein levels yearly
- Blood group and irregular antibodies







## Specific Ig donors

### Rhesus D donors

- 400 women en 15 men: provide half of the demand in the Netherlands
- Above 45 year boosted with 10 cc Red cells from selected donors

### Anti HBs, Anti Tetanus donors

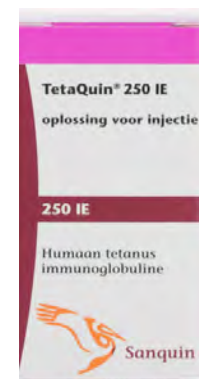
- 1500 donors with yearly Ig level tests and hyper immunization if needed

### Anti Varicella Zoster donors

- Found by donor history – immediate plasmapheresis for 2-3 x/3 weeks

### Anti Hepatitis A donors

- 600 donors ; hard to find because of low prevalence
- Immunisation does not lead to adequate levels
- To improve Gamma globulin products





## Collections

- XL centers (8) all collections
- L, M fixed centers WB and apheresis (31)
- 62 mobile sites (WB)



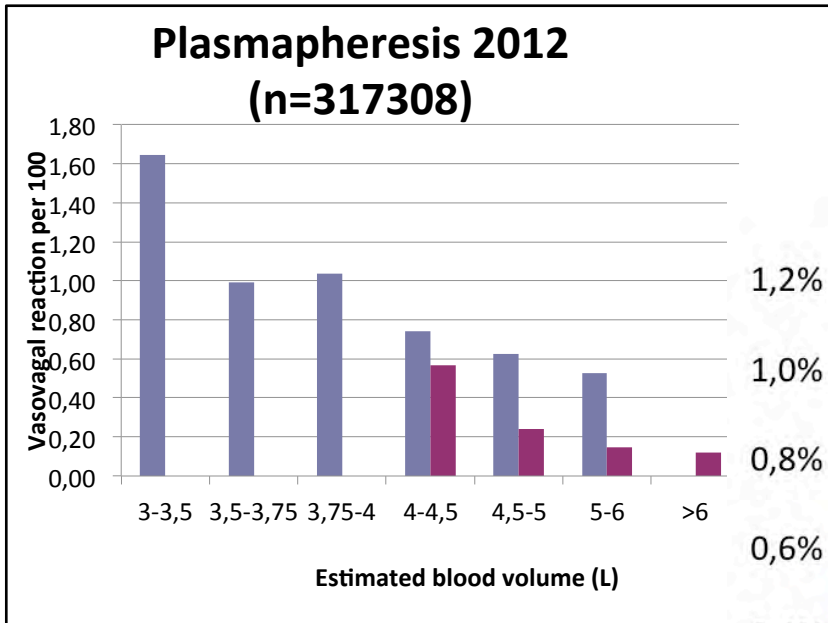
## Plasma collection

Collection center varies from 5- 14 apheresis beds, besides 4-10 WB beds

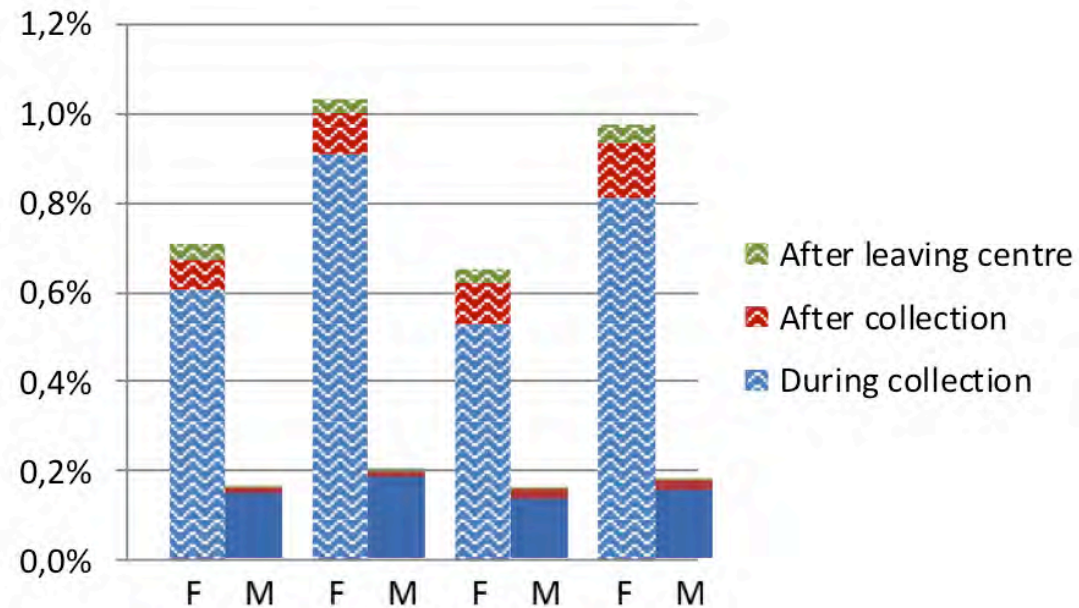
- 2 type of machines Fresenius and Haemonetics
- Standard collection volume is 650 ml including ac, lower based on BMI
- Average collection time 37-49 minutes (Fresenius) 31-39 minutes (Haemonetics express software) no NaCL.
- Centralized freezing units in Amsterdam, Nijmegen ( within 1 hour < -30 °C)



# Donor complications VVR



Implementation express software  
2013-2014 H versus Fresenius



## Dutch plasmapheresis organisation

### Pro's

- Loyal donor base through shared recruitments efforts
- Flexible donor exchange between donation types – direct donors where needed
- Maximal use of the available plasma
- Low on VVR and Infection rate
- Technical expertise to perform all type of cellular and Multi component apheresis

### Con's

- Plasma donor handling derived from the whole blood approach
- Interdependency between donation types – less freedom to act
- Many different procedures to manage
- Collection centre is located close to donors but fragmented: too little volume per site

To summarize :

**Not efficient enough!**

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# Costs of plasma through apheresis

Bloodtransfusion

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Blood Transfusion - 1 2015

Plasma for fractionation in a public setting: cost analysis from the perspective of the third-party payer

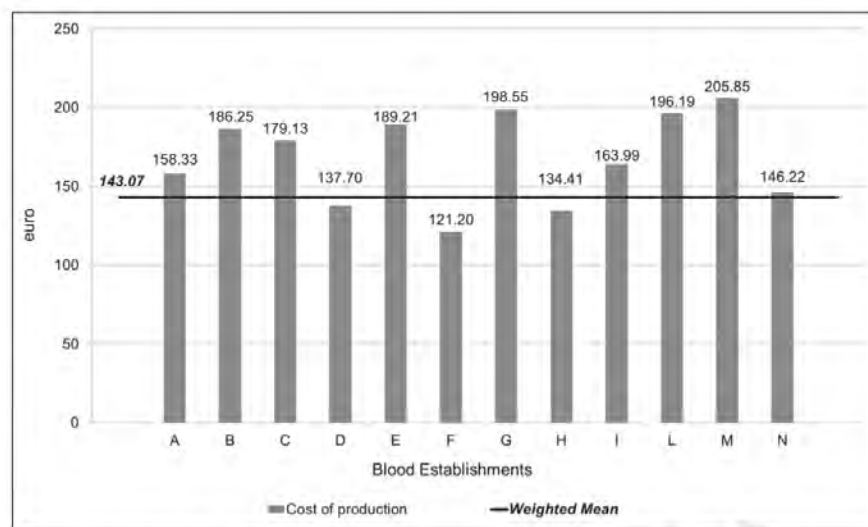
Mario Eandi, Giorgio Gandini, Massimiliano Povero, Orietta Zaniolo, Lorenzo Pradelli, Giuseppe Aprili

Blood Transfus 2015; 13: 37-45

**Table IV**

Total cost per valid plasma bag and per litre arriving for industrial processing - local analysis.

Plasma unit from	PA	M	WB
Bag+instrument rental	32.24	34.77	1.61
Donor test	28.01	5.99	5.15
Validation tests	20.83	3.80	3.77
Plasma freezing	0.36	0.36	0.36
Office supplies	1.04	1.03	1.03
<i>Total materials</i>	<i>82.47</i>	<i>45.95</i>	<i>11.91</i>
Selection/management	21.07	3.88	3.90
Output	17.78	6.70	4.97
Distribution	1.72	1.72	1.72
<i>Total working time</i>	<i>40.57</i>	<i>12.30</i>	<i>10.59</i>
<i>Indemnities</i>	<i>28.82</i>	<i>6.06</i>	<i>4.57</i>
<i>Overhead expenses</i>	<i>18.46</i>	<i>8.74</i>	<i>3.37</i>
<b>Total cost/valid unit</b>	<b>170.32</b>	<b>73.04</b>	<b>30.44</b>
Mean yield/donation	600 mL	399 mL	270 mL
<b>Cost/litre of plasma (€)</b>	<b>283.87</b>	<b>183.05</b>	<b>112.75</b>
Frequency adjustment (% PA on total apheresis)	92.2		
<b>Cost/litre of plasma (€)</b>	<b>A: 276.24</b>	<b>B/C: 112.75</b>	



**Figure 8** - Standardised cost of production of a unit of plasmapheresis plasma (average weight 559 g) in 12 Blood Establishments (A-N) (year 2009).

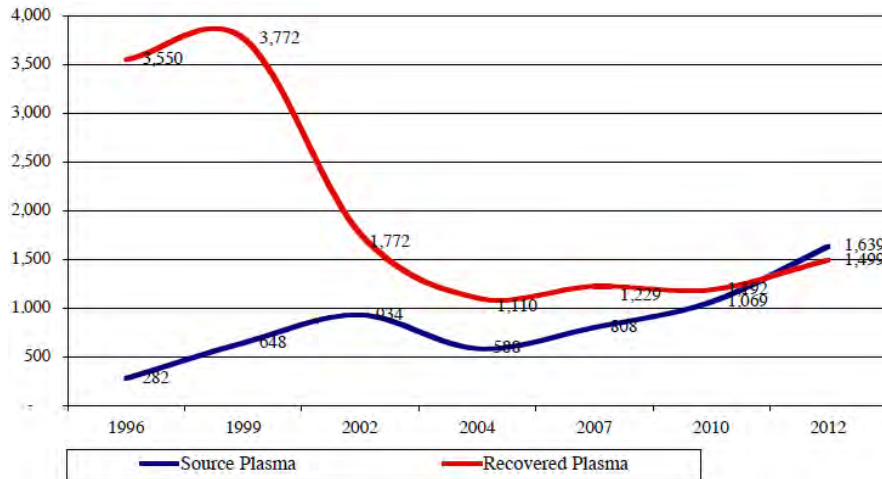
Grazzini e.a.2013

Eandi e.a. 2015

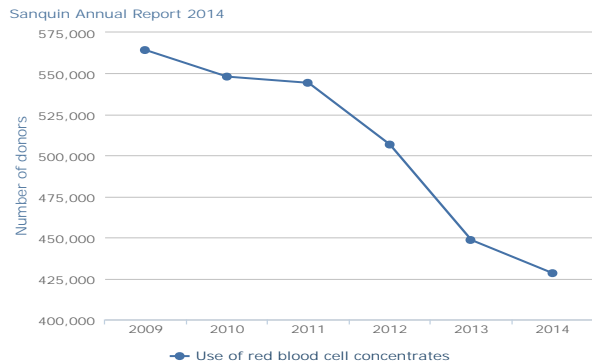
## Improve or redesign current processes

Improvement	Redesign
PfF specific selection criteria and Questionnaire	Electronic Questionnaire and agenda
Simply collection bag ( no sample pouch)	Plasma collection only
Reduce Hb measures	Dedicated software including logistics
BMI derived collection volumes	On-side freezing unit
No blood groups; less labeling	
Higher collection speed	

## Other reasons to become more efficient



- Use of red blood cells is decreasing
- Less recovered plasma available
- More apheresis have to be performed
- Demand for Ivlg is increasing worldwide
- Europe still depends for 70-75 % on US import of PDMP





## Self sufficiency in Europe\*

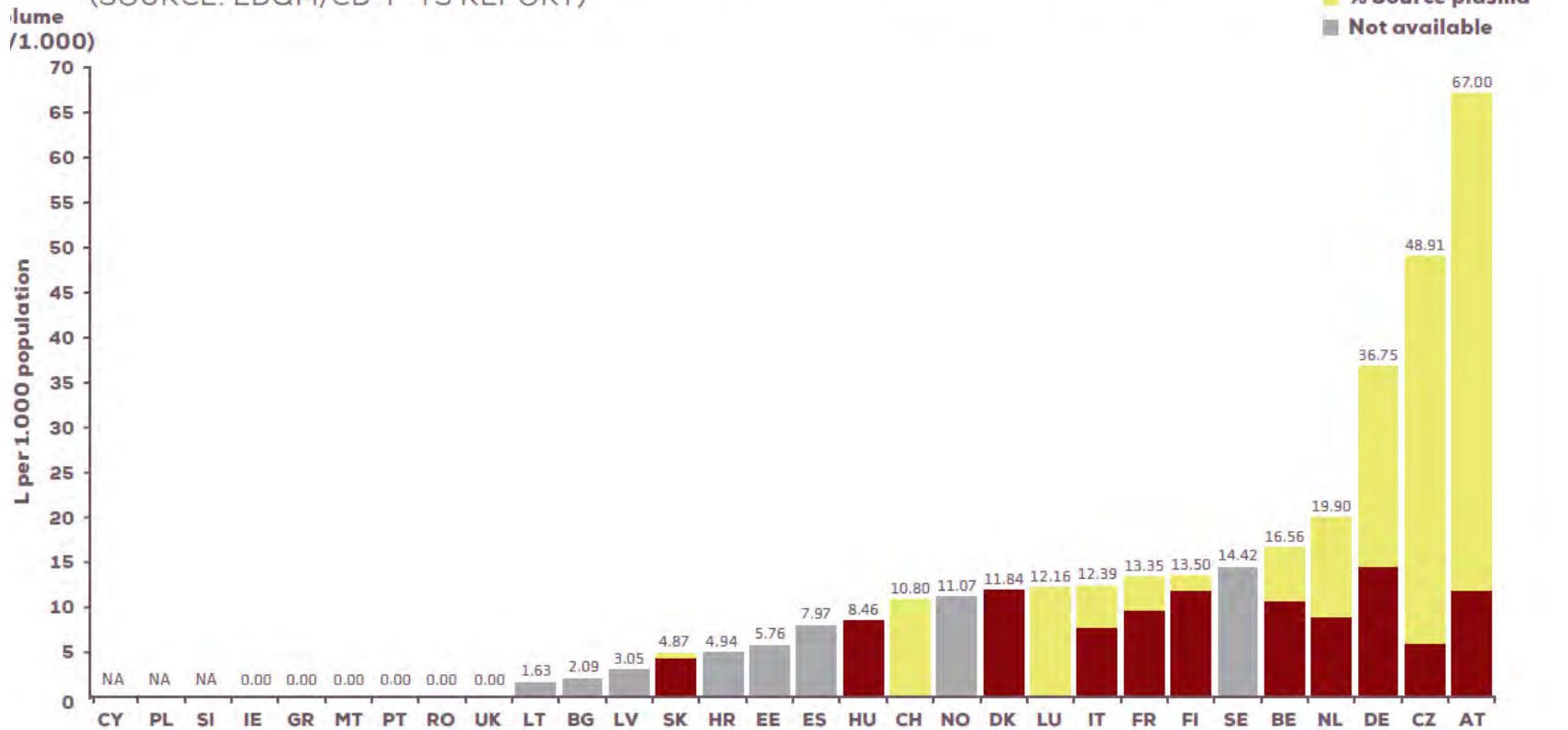
Plasma derived medicinal products made from both non-remunerated and remunerated donations are currently essential to meet global health requirements and in this respect, cooperation between blood establishments and the plasma industry is important to ensure that the best community outcomes are achieved including sufficiency of supply for patients

A de Angelis on Dublin consensus meeting 2011 *Blood Transfus* 2013; **11** Suppl 4: s132-7

\* *Sufficient supply of PDMP to fulfil the need of patients, derived from by donors from the same area and in line with state of the health care system*

# Plasma (L) collected per 1000 inhabitants (2011)

**PLASMA FOR FRACTIONATION COLLECTED IN EU AND EFTA COUNTRIES IN 2011**  
(SOURCE: EDQM/CD-P-TS REPORT)



## Need for collaboration

- Collecting and providing evidence to support working methods and preserve the public trust
- Defining donor selection and protection criteria that are
  - evidence based and
  - Cost effective
- Exchanging best practices
- Advocate the use and need for PDMP : support public awareness
- Program to enhance to European self sufficiency

Danke für Ihre Aufmerksamkeit!

