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Blood Service

PLASMA SUPPLY MANAGEMENT IN THE COUNCIL OF EUROPE

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Plasma supply management in CoE

- Introduction
- Ad hoc WG TS093 Plasma supply management
- Surveys on plasma for fractionation (PfF) in the CoE
- Plasma symposium 2019

Introduction_CoE_EDQM_Transfusion

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Home > About us > About EDQM > Vision, Mission & Values

Vision, Mission & Values

Our Vision

The EDQM is a leading organisation that protects public health by:

- enabling the development,
- supporting the implementation, and
- monitoring the application

of quality standards for safe medicines and their safe use which are recognised as a scientific benchmark and applied world-wide.

The guidance and standards developed by the EDQM in the areas of blood transfusion, organ, cell and tissue transplantation and consumer health issues have a positive impact on public health in Europe and beyond.

Videos

Presentation of the EDQM and its activities

The 9th Edition European Pharmacopoeia: Maintaining high quality standards in a dynamic global environment

EDQM_Blood Transfusion

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Home > Transfusion & Transplantation > Blood Transfusion > Organisation & Work Programme

Organisation & Work Programme

Organisation

The Steering Committee (CD-P-TS)

Its primary responsibilities, according to the terms of reference, are to:

- examine questions related to human blood transfusion, with regards to quality and safety standards and their implementation, including collection, preparation, storage, distribution and appropriate use;
- assist members states in improving, and if needed, in restructuring their blood transfusion services by promoting principles of voluntary non-remunerated donations;
- define and promote the implementation of quality and safety standards in blood and blood components collection, storage, distribution and usage;
- taking into account ethical aspects propose safety and quality standards on professional practices and on product specifications;
- ensure the transfer of knowledge and expertise through training and networking;
- monitor practices in Europe and assess epidemiological risks, in particular of the emergence of new transmissible diseases;

Recent updates

Terms of reference of the European Committee on Blood Transfusion (CD-P-TS)
Valid from 01 Jan 2018 to 31 Dec 2019

Latest Publications

Guide to the Preparation, Use and Quality Assurance of Blood Components - 19th Edition

Projects coordinated by CD-P-TS

Project TS093
Plasma Supply Management

Mandate of the TS093 Working Group

A subordinate working group has been appointed by the CD-P-TS to focus on issues with plasma supply management (PSM, project TS093). A core working group was set up with members nominated by the CD-P-TS upon proposal by national Delegations.

Project TS100 - follow-up to TS057
Risk Behaviours having an impact on Blood Donor Management and Transfusion Safety

TS 093 Plasma supply management

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- An ad hoc working group (WG) under the European transfusion committee (CD-P-TS) since 2014
- Meeting(s) of core (members proposed by national CD-P-TS Delegations) and extended WG (Stakeholders)
- Annual reports to CD-P-TS

Tasks

- To develop tools to assess self-sufficiency in member states leading to a clear landscape
- To achieve sustainable and safe plasmapheresis collection with a focus on donor protection
- To provide evidence based data to support the revision of the *"Guide to the preparation, use and quality assurance of blood components".*

Collected data and surveys

Annual data collection by CD-P-TS: PfF 2001-2014 in CoE and L/1000 inh

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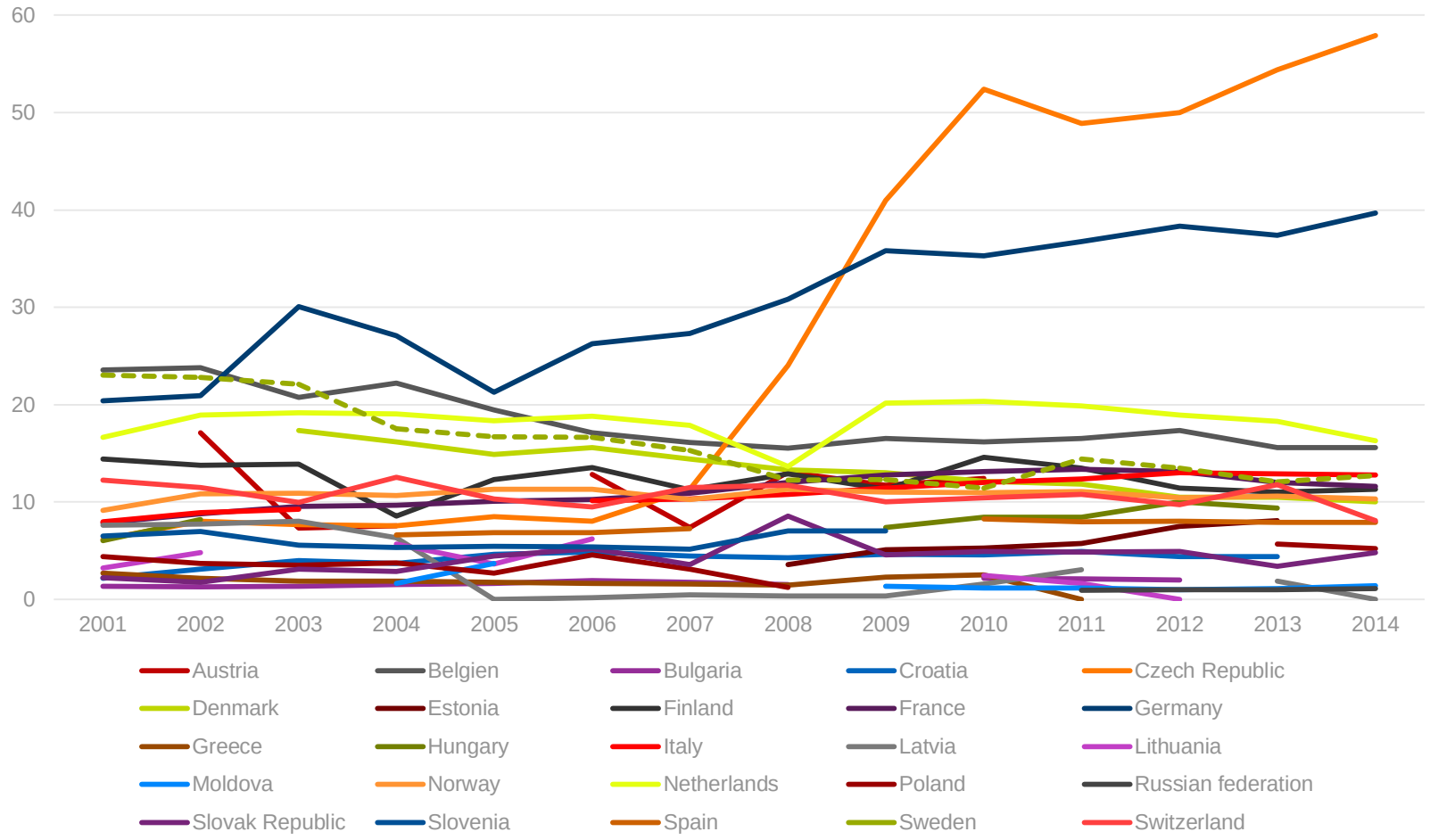

Table 3.14 Trends in Blood Transfusion in Europe (2001-2014), table 4.1 Collection, testing and use of blood components in Europe 2012 - 2014.

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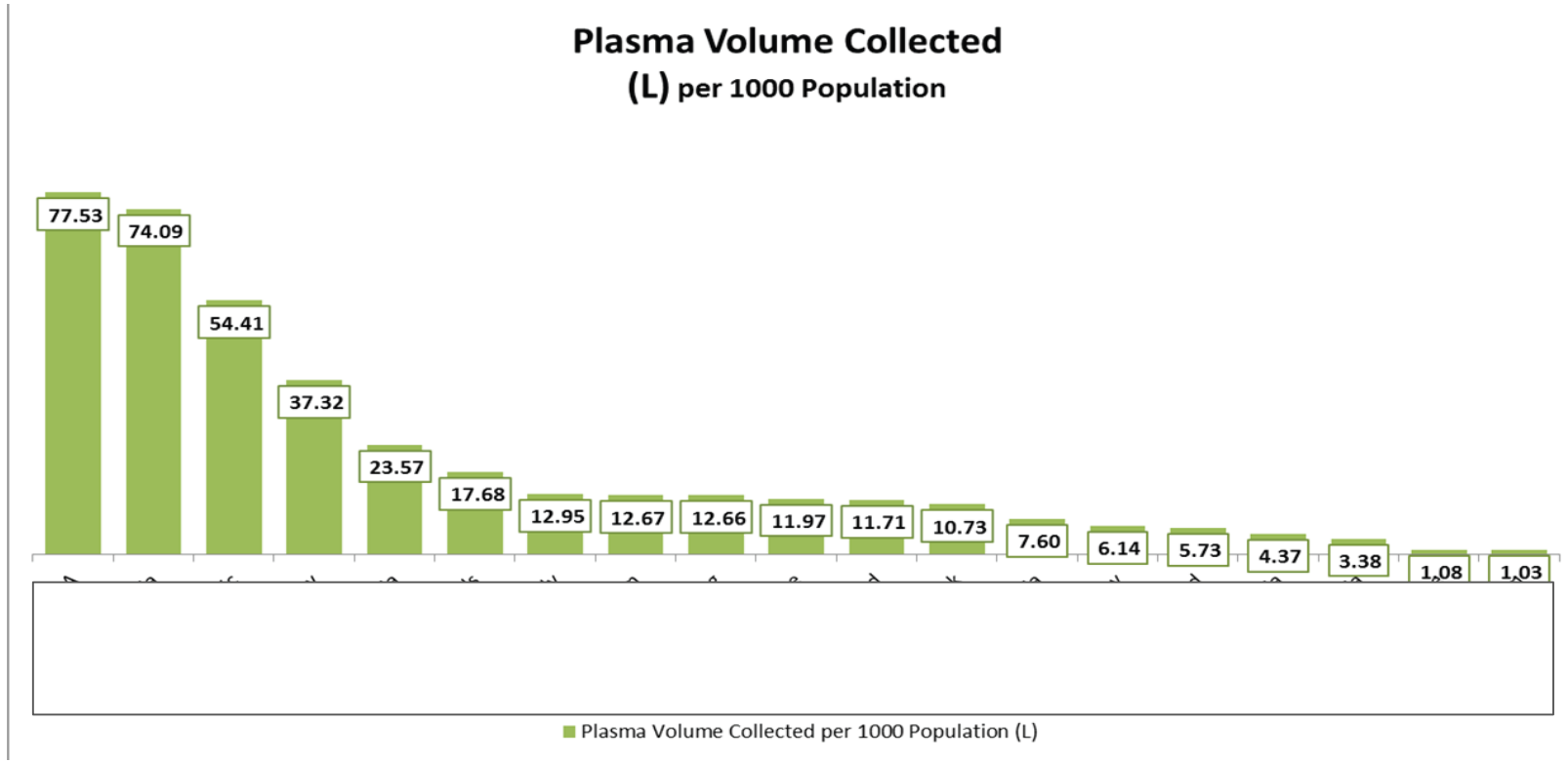
TS093 Survey 1 (2013) outcomes (17 MS and 2 OS)



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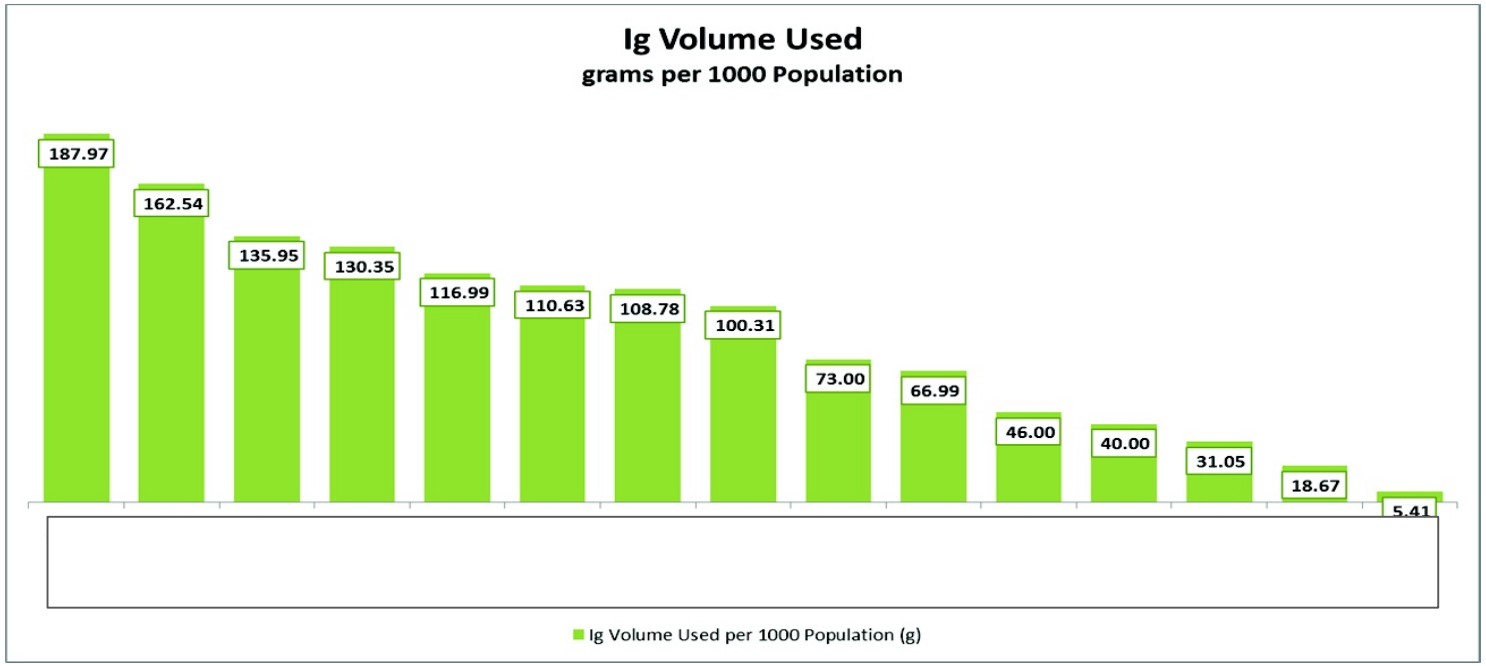

Summary / Survey 1

- Range L plasma/ per 1000 population: 1.0 - 77.5
- Higher volume = more apheresis
- Higher volume = more likely to pay or compensate
- IgG use: range 5.41 – 187.97 g/1000 population
- For one responder (OS); highest use of IgG + highest plasma supply – for all other countries weak correlation within IgG use and plasma collection

TS093 Survey 2 (2016)

65 initial and 38 complete responses

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	BE	MS/OS
Blood establishments which do not supply plasma for fractionation	5	5
Blood establishments which only supply recovered plasma for fractionation	12	8
Blood establishments which only supply apheresis plasma for fractionation	0	0
Blood sstablishments which supply both recovered and apheresis plasma for fractionation	21	17
**Main barrier preventing investment in plasmapheresis is financial:collection cost higher than selling price / lack of funding*		

Recommendations, Survey 2

- CD-P-TS should inform their Ministry of Health /government about current difficulties in collecting enough PfF
- Evidence based recommendations for plasmapheresis should be updated in the CoE Guide to support safe and sustainable plasmapheresis

Survey 3 (2017)
Safe and sustainable plasmapheresis – survey of current practices

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Survey with 49 questions; covering

- Eligibility criteria and medical assessment
- Collection volume and frequency
- Blood tests (e.g. Hb, Hct, plasma proteins)
- Management of red cell loss
- Donor panel demographics
- Capture and recording of adverse events
- Equipment used
- Staff qualification and supervision
- Site requirements
- Productivity measures and key performance indicators

TS093: Safe and sustainable plasmapheresis – survey of current practices

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- 36 BE from 25 countries responded
- 24 BE in 16 countries collected PfF by plasmapheresis (of these, 17 BE in 9 MS of CoE)
- Plasmapheresis collections last Fiscal Year (LFY)
- 2 888 390 donations (data provided by 22 of 24)
- 652 379 donors (data provided by 16 of 24)
- 61% male donors (min-max: 40 – 97, data provided by 19 of 24)

Practice versus recommendations (1)

Norda et al, ISBT 2018

CoE Guide recommendations for plasmapheresis:
- max 750 mL excluding anti-coagulants

Collection volume / plasmapheresis	lower	aligned	higher
Practice as reported by BE's	8	7	9
Collections LFY	804 574	776 548	1 307 268
Donors LFY	260 230	210 216	181 993

Practice versus recommendations (2)

Norda et al, ISBT 2018

CoE Guide recommendations: max 33 plasmapheresis collections per year

Frequency	lower	aligned	higher
Practice as reported by BE's	13	2	8
Collections LFY	2 093 187	81 126	763 705
Donors LFY Data on donors submitted by	552 285	9 108	40 546

Norda et al, ISBT 2018

Practice versus recommendation (3): donation frequency LFY

CoE Guide recommendations: max 33 plasmapheresis collections per year

Number of donations by donors	1-5	6-10	11-15	16-20	21-25	> 25
Aligned/lower frequency (611 833 donors, 2 062 034 collections)	82%	16%	4%	1%	1%	0%
Higher frequency (40 456 donors, 561 622 collections)	39%	15%	11%	7%	7%	21%

Summary and conclusions

Norda et al, ISBT 2018

- Most donors have a limited donation activity in the LFY.
- Less than 30% of the donors experience higher collection volumes than recommended by the Guide
- Further analysis of survey data will be undertaken for a correlation between collection practices, PfF supply and donor safety
- Questions and conclusions will enter into a scientific discussion at EDQM *-> Plasma Symposium Jan 2019*
- Evidence-based recommendations on plasmapheresis will be used for revision of the 20th edition of the Guide to promote a more robust supply of PfF while safeguarding donor health.

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International Symposium on 'Plasma Supply Management'

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TRANSFUSION | SYMPOSIUM | 29 JANUARY 2019 TO 30 JANUARY 2019 | STRASBOURG, FRANCE

Background

Human plasma is the critical component of numerous therapeutic products used in the treatment of life-threatening diseases, including bleeding disorders, immune system disorders and several other severe pathologies. In recent years, the global use of and demand for plasma for fractionation has grown and this trend is expected to continue.

European patients are highly dependent on USA collected plasma, which puts Europe at risk in case of any sudden supply interruptions. It is therefore important that plasma collection by blood services is intensified within Europe while protecting donors' rights.

Programme Overview

This symposium will discuss the facts and scientific evidence surrounding the collection of plasma for fractionation and the elaboration of donor eligibility criteria to ensure donor protection. Evidence-based data will be used to revise the text of the next edition of the 'Guide to the preparation, use and quality assurance of blood components' (20th Edition),

International Symposium on 'Plasma Supply Management'

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TRANSFUSION | SYMPOSIUM | 29 JANUARY 2019 TO 30 JANUARY 2019 | STRASBOURG, FRANCE

This symposium will:

- Discuss the obstacles to strategic independence of plasma for fractionation in Europe;
- Discuss donor safety, donor selection and donor management;
- Provide an update on national and international regulations and current developments.

The symposium will be a unique opportunity to meet and interact with experts who have practical experience and knowledge in the field of plasma supply management and in the elaboration of strategies to increase the availability of plasma for fractionation.

The presentations will be followed by several Q&A sessions.

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thank you

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