The SUPPLY Project, the puzzle is complete?

IPFA/EBA symposium on plasma collection and supply

Leiden February 8th 2024

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Member Executive Committee Sanquin

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Introduction to the SUPPLY Project - 1



Background:

- The need for plasma to produce PDMPs is still increasing, and we have faced shortages in PDMPs.
- Europe is increasingly dependent on plasma collected in the USA.
- Availability of PDMPs is driven by a world-wide competitive market.
- COVID-19 pandemic and global political and economic developments have highlighted urgency in building resilience for crisis situations.
- Sufficient collection of plasma by a country does not automatically mean sufficient supply of PDMPs for its inhabitants.
    - In some European jurisdictions, commercialising public plasma is not leading to an enhanced and evidence-based usage of the products involved in the countries where plasma is collected
- SUPPLY is an 18-month project co-funded by the European Union's EU4Health Programme.
- €1.9Million Project - EC grant of €1.1Million and €756.000 coming from the project consortium members.

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Introduction to the SUPPLY Project - 2



Project goals:

- Increase and strengthen the **volume and resilience** of plasma collection in the EU
- Focus on how BEs can improve and build up **voluntary unpaid** plasma collection programs
- Maintain **donor safety** in a way that benefits donor health and plasma quality
- Evaluate current **legal frameworks and policies in the EU** on plasma collection and tender models to ensure safe and adequate **access** for EU patients to essential PDMPs

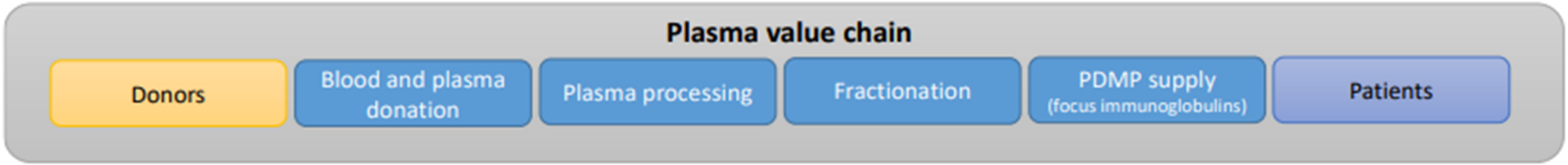
Main project outcomes:

- Set of **recommendations and guidance** for all stakeholders
- Contribute to the EU becoming more **strategically independent** in its need for plasma medicines

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SUPPLY Project – Set-up



WP2: Donor recruitment and retention best practices

WP3: Plasma collection and processing best practices

WP6: Clinical programme on appropriate/prioritized use of PDMPs

WP4: National and EU infrastructures, policy, legal framework for plasma collection and PDMPs supply

WP5: Plasma donor protection best practices

WP7: Dissemination and Communication

WP1: Project management

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SUPPLY Consortium

Participant organisation name	Short name	Country	Role
European Blood Alliance	EBA	The Netherlands	COO
Etablissement Français du Sang	EFS	France	BEN
Stichting Sanquin Bloedvoorziening	SQ	The Netherlands	BEN
Belgische Rode Kruis	RKV	Belgium	BEN
Universitaet Hamburg	UH	Germany	BEN
DRK-Blutspendedienst Baden-Wurttemberg-Hessen GGMBH	DRK-BSD	Germany	BEN
European Hematology Association	EHA	The Netherlands	BEN
International Plasma and Fractionation Association	IPFA	The Netherlands	BEN
Bloddonorerne I Danmark	DBDO	Denmark	AP
Istituto superiore di sanita	CNS	Italy	BEN
The Scottish National Blood Transfusion Service	SBTS	UK	AP
International Federation of Blood Donor Organisations	FIODS	Italy/ Monaco	AP
Servicio Vasco de Salud Osakidetza	CVT	Spain	BEN
Irish Blood Transfusion Service	IBTS	Ireland	BEN
Aarhus Universitet Hospital	AUH	Denmark	BEN
Osterreichisches Rotes Kreuz	RKA	Austria	BEN
Zavod Republike Slovenije Za Transfuzijsko Medicino	BTCS	Slovenia	AP
Ministerio De Sanidad	SCTS	Spain	AP
PHI Institute for Transfusion Medicine of RNM	ITM	North Macedonia	AP
Instituto Portugues do Sangue e da Transplantacao IP	IPST	Portugal	BEN

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Work Package 4

National and EU infrastructures / policy/legal framework for plasma collection and PDMPs supply



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WP 4 objectives:

- gaining insight into the current situation on public plasma collection and its linkage to PDMP access models
- formulate recommendations for the development of common EU policies or legal frameworks aimed to support efforts to achieve a higher degree of strategic independence, also in times of crisis.

Main tasks:

- Survey
- Position paper
- Development of a tool
- Assessment report on Plasma and PDMPs economics and tenders

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Results of the "Survey on plasma collection and PDMPs production from national plasma in EU"

- In 1/3 of Member States plasma is sold to different companies
- In 1/3 of Member States plasma is sold to one company on exclusive basis
- In 1/3 of Member States plasma is fractionated through toll manufacturing agreements

➢ There is a governance gap given that we do not have a full description of the European situation.

➢ In many cases CAs do not have a clear overview of the situation in their Country.

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Main recommendations where common EU legal provisions can favour plasma collection and fractionation in a common EU framework

Legal provisions:

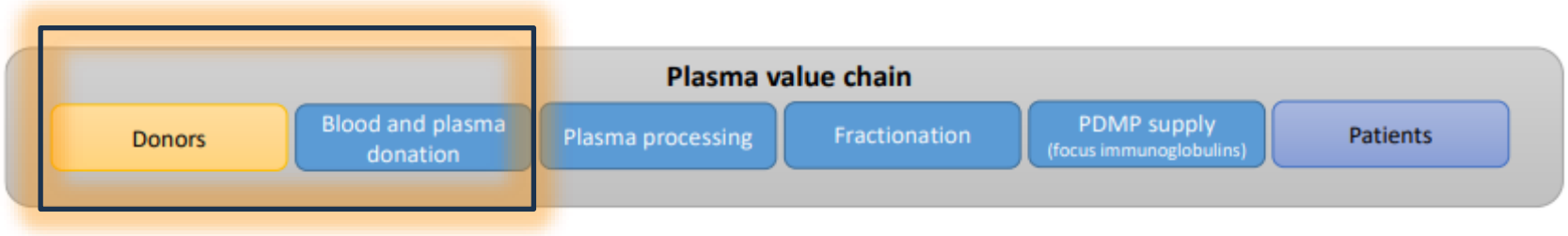
- To consider / define plasma as a strategic resource
- To favour cooperation among different systems and models
- To favour cooperation among MS
- For the priority use of products coming from fractionation of domestic plasma.
- For EU plans supporting the increase and improvement of plasma collection.

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Work Package 2
Donor Recruitment and Retention Best Practices



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Objectives & Recommendations

Objectives

Deliverable 2.1

Overview of plasma donor recruitment and retention strategies

Deliverable 2.2

Assessing identified practices regarding efficiency and identifying novel practices

Transfer plan

Developing a recommendation and transfer plan

Recommendations

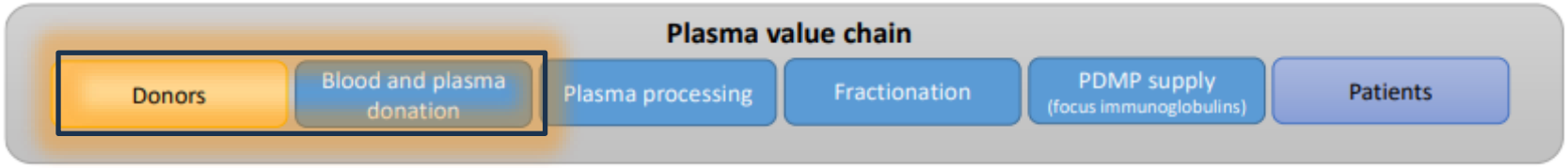
- Snacks are provided in all countries and should remain in BE's incentive portfolio.
- Additional health checks are ranked well among all donor groups and across all countries.
- In non-remunerated countries, plasma donors are used to receiving no incentives and therefore prefer to receive no incentives, recognition, or health checks.
- In remunerated countries, plasma donors are used to receive money and they prefer incentives with monetary value e.g. paid days off
- *N.B. Awaiting final SoHO Regulation text on Financial neutrality etc

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Work Package 5
Plasma Donor Protection best practices



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WP 5 Plasma Donor Protection best practices set up

Collect information on current plasma donor protection practices (survey and analysis report)

Evaluate the available scientific evidence on plasma donor protection practices (scoping review and systematic review)

Describe requirements for a support tool on standardized donor vigilance data to be collected (report)

Formulate (evidence-based) recommendations (report)

Analysis report on the inventory of existing plasma donor protection practices

- All organizations use similar selection criteria e.g., vein suitability, minimum body weight, and Hb, although sometimes with different acceptance criteria
- Donor protection practices vary considerably between plasma collection centers (e.g., difference in special procedures for first-time donors, or mitigation of blood loss)
- Considerable variation in equipment/settings between centers

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Gap analysis and data support tool

Evidence gaps:

- preventive measures including the impact of the technologies used on the safety of donors
- selection criteria including total plasma protein levels, IgG, and Hb
- different donation frequencies and the effect on donor safety
- long-term health effects of plasma donation

Procedural gap:

- registration of adverse events

Data support tool created on standardized donor vigilance data to be collected

Adverse Reaction	
Donation ID	XXXXXXX
internal code	SR 04
Typ of advers reaction	Vasovagale reaction with LOC > 60 sec
Time of occurence	during pd
medicine used?	yes
OMR/EMR	yes
Degree of severity	2
donor information	
age	45
sex	f
Donation type	Plasma (SP/FFP?)
First time donor?	no
No plasma donation in the op	24
total number of plasma donations	112
body weight	82
body height	178
donation/equipment information	
target volume plasma in ml	850
collected volume in ml	340
anticoagulant used in ml	83

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Recommendations on protection of plasma donors

Adhere to the Blood Guide (21st edition 2023) until further evidence is acquired and:

- A maximum of two plasma donations per month, pending sufficient evidence confirming the safety of higher donation frequencies. This recommendation is based on expert opinion and reflects the view of a majority of WP5 members.*

  * Alternative recommendation, supported by two WP5 members: a maximum of two plasma donations per month, unless a donor health and IgG management system is established by the respective blood establishment.

- Monitoring IgG levels. Evidence of optimal IgG algorithms and test intervals are lacking.

- Urgent initiation of prospective studies to examine the health consequences of plasma donation at varying frequencies.

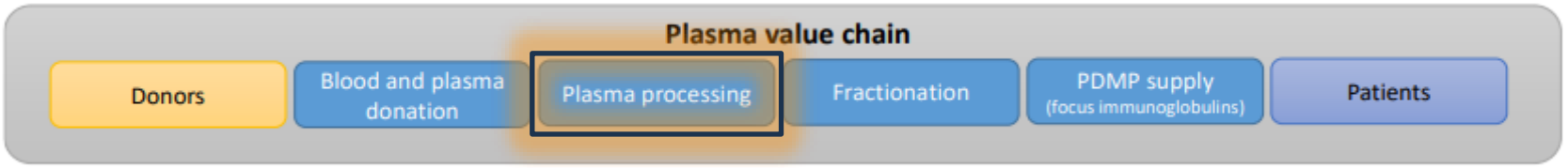
- Implementation of a register for standardized haemovigilance data on a mandatory basis

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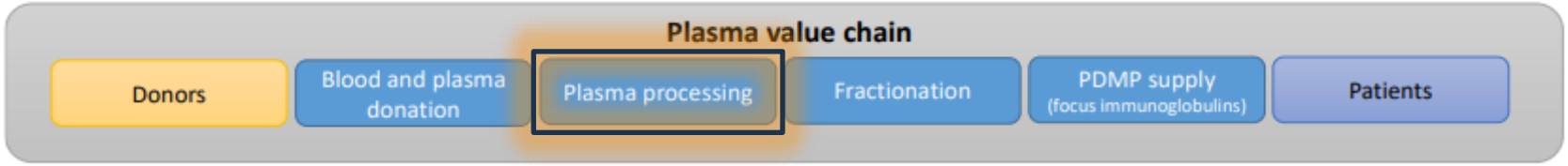
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Work Package 3
Plasma Collection and Processing Best Practices



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WP3: Plasma Collection and Processing Best Practices

WP objective:

To develop a set of recommendations that will support increased and improved plasma collection programmes by BEs throughout Europe and will ultimately strengthen the resilience of plasma collection during crisis.

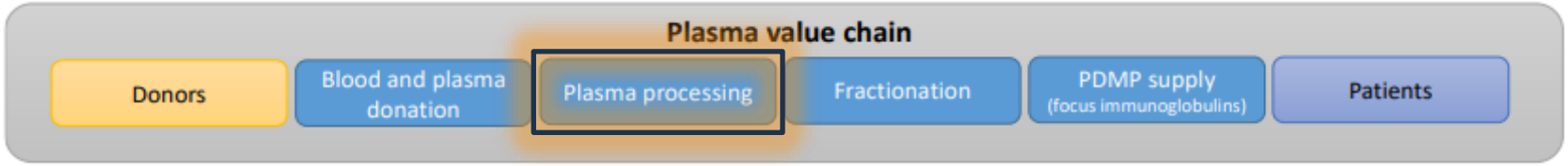
"We strive for the most efficient plasma chain with the highest IgG yield and the lowest waste"

Tasks

- Collection center set up and efficiency
- Improving the plasma collection and processing chain, design of the product journey from collection to transportation and fractionator
- Characterize and explain the waste of recovered plasma in Europe
- Plasma price and cost modelling
- Quality of collected plasma

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WP3: Plasma Collection and Processing Best Practices

Most important recommendations:

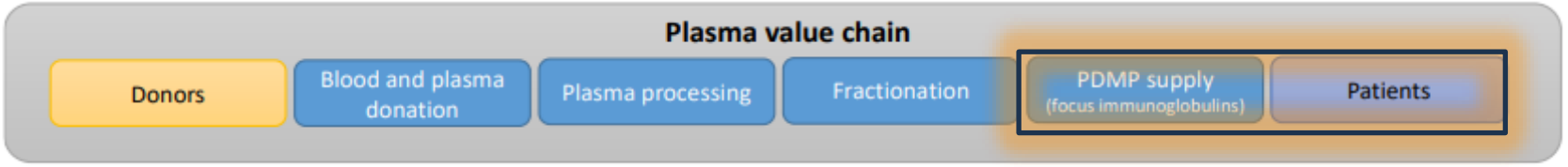
- To meet the demand for plasma a formula (RADIUS) can be used to determine the optimal number of donor centres and their strategic location.
- Regulatory requirements should be simplified and modified to increase plasma pheresis programs and avoid waste.
- Focus on retaining donors and increasing donation frequency while building a sustainable donorbase
- Invest in cost reduction programs to make the processes more efficient, for example by automation or digitalization.
- Use the IgG concentration to determine the value of plasma as “low-frequency” donors have a higher concentration of IgG.

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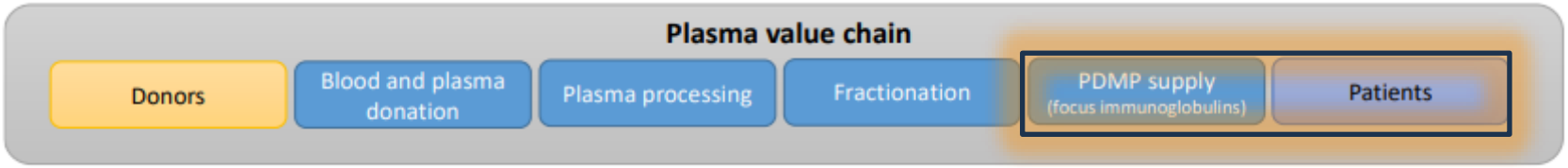
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Work Package 6
Clinical Programme on appropriate/prioritised use of PDMPs



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Results: Data Collection on Ig use

Key Points:

- Member States exhibit uneven data collection capacities for Ig usage.
- Diverse steps needed for systematic data collection.

Prerequisite:

Establish robust policies and regulations on data jurisdiction, control, and management.

- Determine governance structures and identifying key stakeholders at the national level.

Step 1: Identify and map existing data sources on Ig use within each Member State.

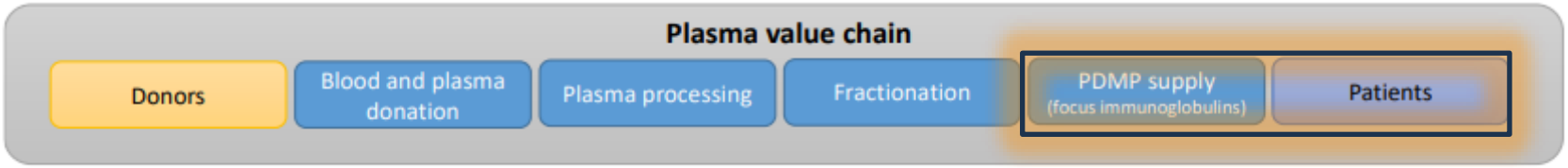
- Utilize registries and databases from existing reference networks and scientific societies.

Step 2: Establish a comprehensive centralized Ig-database and analytics hub.

- At the national or regional level.
- Interconnect aggregated data with the European Health Data Space for optimal analysis.

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Results: Harmonisation

Objective: Establish crisis management plans, integrate harmonised approaches into existing medical guidelines for improved healthcare delivery.

Recommendations:

1) A harmonised methodology for a prioritisation plan in case of shortages that should include:

- High medical need and unmet medical need.
- Added benefit of Ig, considering alternative treatments.
- Quality of evidence.
- Quality of life for patients, with patient involvement.
- Utilizing the EMA list of authorised indications.

2) A harmonised management plan that should:

- Include a system of checkpoints (such as: UK's "Commissioning Criteria Policy for the use of therapeutic immunoglobulin England.“)
- Align with treatment recommendations and guidelines from scientific societies.

Finally, a coordinated communication and shortage awareness system should be set in place at the EU level

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SUPPLY Project Take aways

- Focus on retaining donors while building a sustainable donor base
- Carry out a large prospective study in plasma donors to examine the health consequences of plasma donation at varying frequencies
- Take consideration of the IgG level to determine the value of plasma
- Invest in the increase and improvement of the plasma collection, MS create action plans!
- Introduce legal provisions at national level which link collected plasma to the usage of products manufactured from this plasma by the public health sector
- Create national databases on Ig usage at patient level
- Need for an EU wide harmonized management plan on shortages
- Continue to collaborate!

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EGALITE

European Group For Accreditation And Liaison Of Blood-Tissues And Cells Establishments







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