SUPPLY

FINAL REPORT FOR LAYPERSONS

SUPPLY: STRENGTHENING VOLUNTARY NON-REMUNERATED PLASMA COLLECTION CAPACITY IN EUROPE

EU4Health

Welcome

"Greetings from the SUPPLY Consortium, and welcome to our final report – together we represented the first united effort across the EU to develop good practices and recommendations to both:

Increase the volume and resilience of unpaid plasma collection in Europe

and

Ensure safe and adequate access for EU patients to essential Plasma medicines."

- **Daphne Thijssen-Timmer**, Director Sanquin Blood bank, Leader of SUPPLY
- **Peter O'Leary**, EBA Executive Director, Coordinator of SUPPLY

When & Who?

SUPPLY was a project co-funded by the European Union's EU4Health Programme. SUPPLY started on September 1 2022, running up to February 29 2024.

The SUPPLY Project is an excellent example of solidarity, with many stakeholders from different EU Member States working together to improve the lives of EU citizens.

The SUPPLY Consortium included the European Blood Alliance (EBA), Blood Establishments, Blood Donor Organisations, Patient advocates, Ministries of Health, Universities, Competent Authorities, the International Plasma and Fractionation Association (IPFA), and the European Hematology Association (EHA).

Co-funded by the European Union

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Glossary

PDMPs

Plasma-derived medicinal products. Also known as Plasma medicines, these are medicines extracted from human plasma, and are crucial for the prophylaxis and treatment of patients with immune deficiencies, autoimmune and inflammatory diseases, bleeding disorders, and a variety of congenital deficiency disorders.

Plasma for fractionation

Recovered plasma or source plasma used for the production of plasma products (Definition from WHO).

SoHO

Substance of human origin. This is any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of that substance.

WP

Work Package. The SUPPLY project was subdivided into work packages, each concentrating on a different aspect of the plasma value chain from plasma donors to patients receiving Plasma medicines.

Plasma

Plasma is the yellow liquid suspending the cell components (red and white cells, platelets) in blood and contains a wide range of proteins essential to life.

Ig(G)

Immunoglobulin(G). A protein found in plasma and which is used to treat various autoimmune, infectious, and idiopathic diseases. IgG is the main driver for the collection of plasma for manufacturing of PDMPs.

SUPPLY

What is SUPPLY?

SUPPLY is a project to increase and strengthen the resilience of voluntary unpaid plasma collection by the public sector in the EU to enable a stable and adequate supply of Plasma-Derived Medicinal Products (PDMPs) for patients.

How did we achieve our aims?

The entire plasma-to-PDMP-to-patient chain is assessed – from plasma donor recruitment, retention, and health, through plasma collection and processing, to procurement, demand, and use of PDMPs.

The SUPPLY project provides a set of recommendations and guidance for the EU, National Governments, blood establishments (BEs), competent authorities, medical societies, and other professional stakeholders to support them in being able to both increase plasma collection in the EU by the public health sector and to achieve optimal availability of plasma medicines for patients, both in a general situation as well as in times of crises.

Why is SUPPLY needed?

The medicines produced from plasma are referred to as PDMPs and are used to treat over 50 different conditions including rare diseases, immune disorders, and genetic conditions. For many of the conditions that PDMPs treat, patients have no alternative treatment and many of these plasma medicines are therefore included in the WHO Model List of Essential Medicines and the EU list of critical medicines.

A substantial part of plasma collection in the EU is conducted by the non-profit BEs from voluntary non-remunerated donors. Currently, however, there is a global dependence on plasma coming from the US to manufacture these essential medicines. The Covid-19 crisis dramatically revealed the world's vulnerability in supply of PDMPs, particularly immunoglobulins, that also face shortages in Europe today. SUPPLY helps address this global imbalance in the collection of plasma. By recommending measures to help ensure safe and adequate access for EU patients to essential PDMPs, SUPPLY contributes to the EU becoming more strategically independent in its need for plasma medicines,

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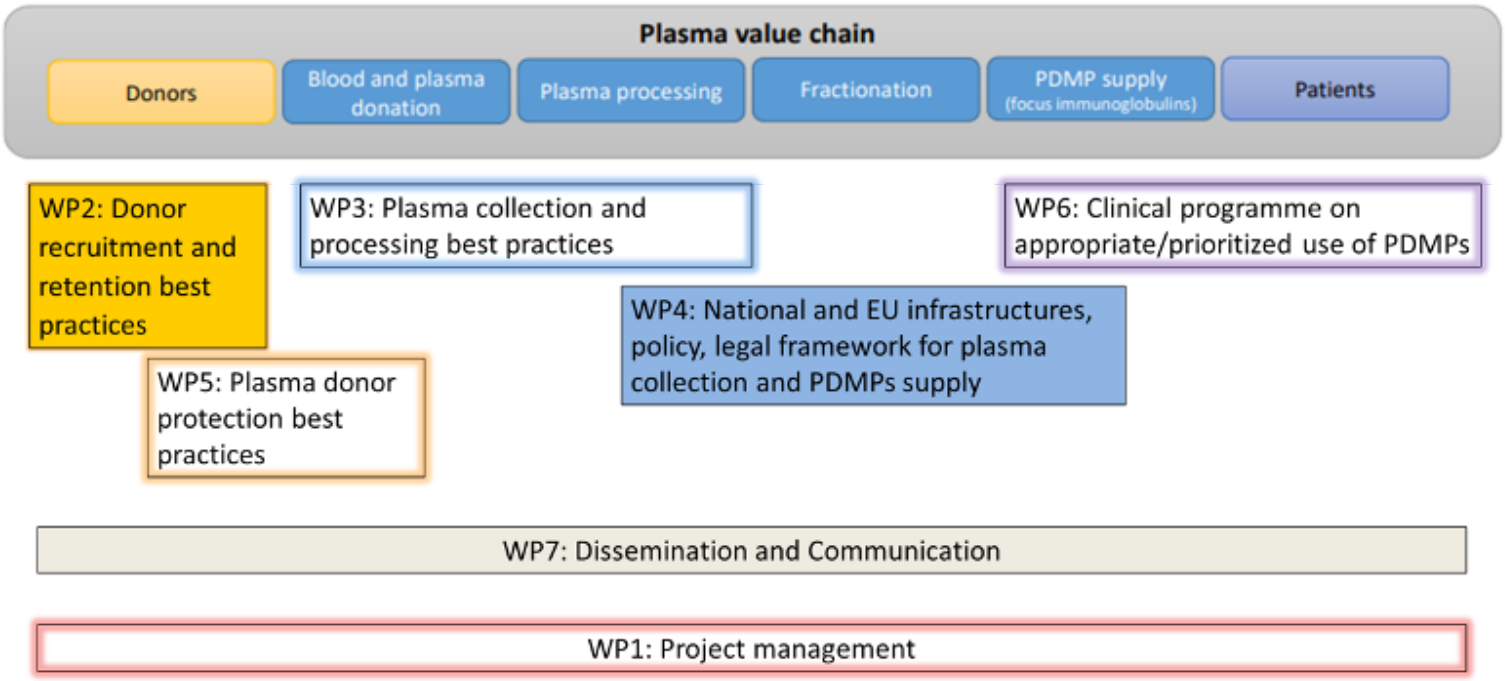
SUPPLY

SUPPLY Structure by Work Packages

Description of the plasma value chain and the steps involved from donors to patients, and the allocation of Work Packages in SUPPLY



In this brochure we will outline the main outputs of the SUPPLY Project. More information (reports, tools, etc.) are available on the SUPPLY website.

'It is of critical importance that national commitments to collect sufficient volumes of plasma to meet the optimum plasma-related requirements of populations are accompanied by sufficient control and monitoring over the plasma-PDMP-patient chain, ideally through legislative guarantees, to ensure that the patient population needs are met.'

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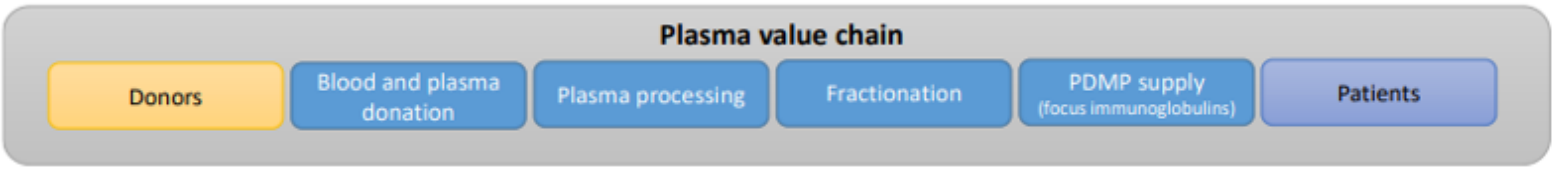

WP1 – Project Management

WP Leader: European Blood Alliance

By characterising 4 types of crisis situation scenarios that could significantly impact the availability of resources (specifically pandemic, war, climate change, and trade-war), we inform, complement, and assist with EU and national plasma strategies, national SoHO emergency plans, and coordinate with other response actions at national and EU level.

Most important recommendations:

1. Plasma is a critical medical raw material and a public resource that requires strategic management.
2. Policymakers, healthcare providers, and stakeholders must work collaboratively to proactively address the risks identified and adopt a systemic approach that combines different solutions and leverages the synergies between them.
3. National commitments to collect sufficient volumes must be accompanied by sufficient control over the plasma-PDMP-patient chain to ensure that the patient population needs are met, including in times of crises.
4. Requisite measures should be implemented during periods of relative calm in most EU Member States to ensure the plasma and PDMP system is robust and resilient in times of crises.
5. During crises, public non-remunerated plasma (and other SoHO) collection programmes have proven more resilient than paid-plasma collection programmes. Therefore, the strategic management of plasma should focus on the collection of sufficient volumes by the public sector.

Find the WP1 Deliverables here

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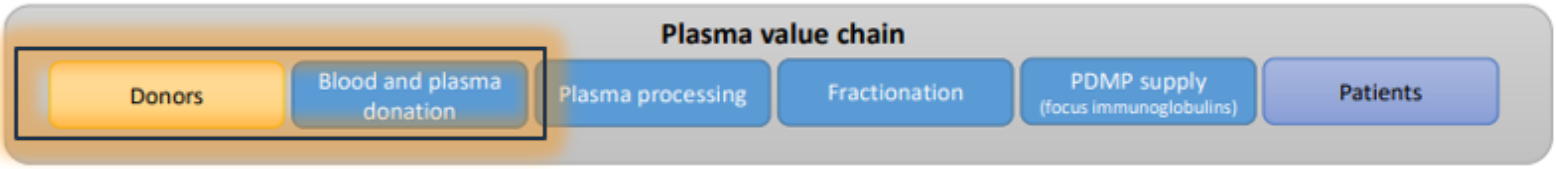

WP2 – Donor recruitment and retention best practices

WP Leader: University of Hamburg

A wide array of tools (including surveys, desk research, and expert interviews) was used to firstly provide an overview of plasma donor recruitment and retention strategies, secondly to assess identified practices regarding efficiency and identifying novel practices, and thirdly to develop a recommendations and transfer plan.

Most important recommendations:

1. Health checks are ranked well among all donor groups and across all countries.
2. In non-remunerated countries, plasma donors are used to, and have a highest preference for, receiving no incentives. Recognition and health checks are also preferred.
3. In remunerated countries (for plasma), plasma donors are used to receive money and they prefer incentives with monetary value e.g. paid day-off from work.
4. Snacks are provided in all countries and should remain in BE's incentive portfolio.

Find the WP2 Deliverables here

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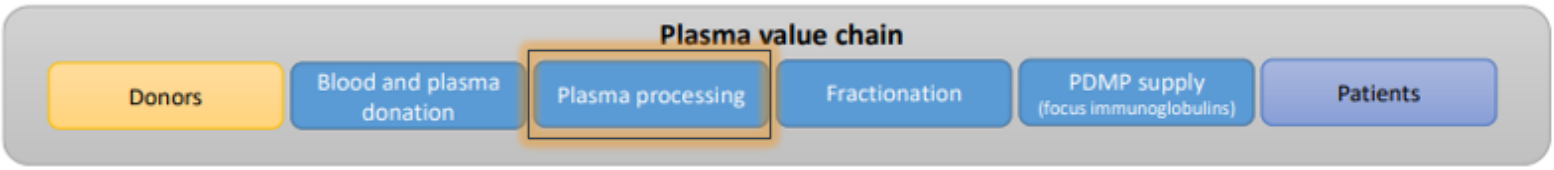

WP3 – Plasma Collection and Processing Best Practices

WP Leader: Sanquin

Our comprehensive analysis included identification of both the most suitable approach for Blood Establishments to start or increase their collection programmes and opportunities for improvements in the plasma collection & processing chain. We characterized the waste of recovered plasma and lost opportunities for plasmapheresis in Europe. We also examined plasma price and cost modelling and evaluated both IgG monitoring in plasma manufacturing processes and data on IgG levels. Through this detailed analysis, we developed a set of recommendations that will support increased, improved, and more resilient plasma collection programmes throughout Europe.

Most important recommendations:

1. To meet the demand for plasma a formula (RADIUS) can be used to determine the optimal number of donor centres and their strategic location.
2. Regulatory requirements and Blood establishments' practices should be simplified and modified to increase plasmapheresis programmes and avoid waste.
3. Build a solid donor base while focusing on retaining donors and increasing donation frequency within scientifically proven safe limits.
4. Invest in cost reduction programmes to make the processes more efficient, for example by automation or digitalisation.
5. Use the IgG concentration to determine the value of plasma as “low-frequency” donors have a higher concentration of IgG.

Find the WP3 Deliverables here

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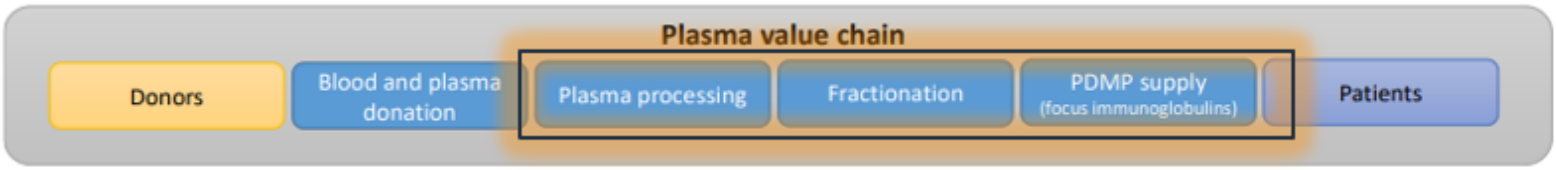

WP4 – National and EU infrastructures/policy/legal framework for plasma collection and PDMPs supply

WP Leader: Centro Nazionale Sangue (CNS)

By gaining insight into the current situation on public plasma collection and its linkage to PDMP access models, both within the EU member states and globally, we formulated recommendations for the development of common EU policies or legal frameworks aimed to support national and EU efforts to achieve a higher degree of strategic independence from non-EU sources in the collection of plasma and its fractionation into PDMPs, also in times of crises.

Most important recommendations:

1. Ensure national commitments to collect adequate plasma volumes are backed by legislative control over the plasma value chain, guaranteeing patient needs are met.
2. Adopt a unified EU legislative framework recognising plasma as a vital resource, prioritising its security in PDMP supply chains. National recommendations should prioritise EU patient access.
3. Encourage legal cooperation between public and private sectors to meet EU PDMP demands sustainably, facilitating cross-jurisdictional plasma utilisation.
4. Implement EU plans to enhance public plasma collection by funding programmes that increase the quantity and quality of plasma collected, and strengthen the resilience of public plasma collection, especially during emergencies.

Find the WP4 Deliverables here

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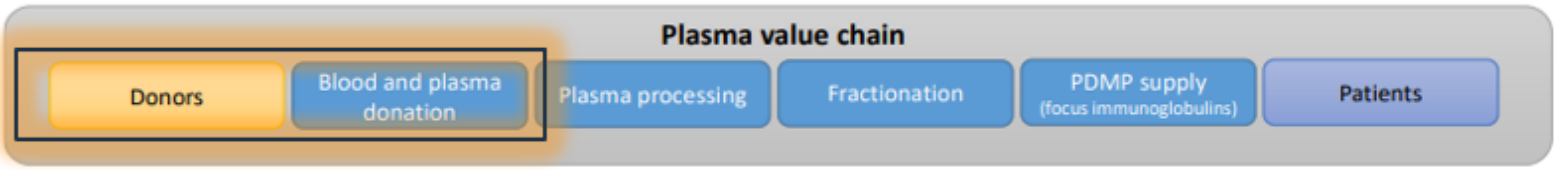

WP5 – Plasma Donor Protection best practices

WP Leader: Aarhus University Hospital

Beginning with the collection and analysis of information on current plasma donor protection practices, our team subsequently evaluated the available scientific evidence on plasma donor protection practices through a scoping review and a systematic review. We also described the requirements for a support tool on standardised donor vigilance data to be collected.

Most important recommendations:

1. Adhere to the EDQM Blood Guide (21st ed., 2023) until more evidence emerges.
2. Limit plasma donations to maximum two per month until safety of higher frequencies is confirmed. This recommendation is based on expert opinion and reflects the view of a majority of WP5 members.*
3. Studies are required to inform monitoring of IgG levels due to a lack of optimal algorithms.
4. Urgently study health effects of different donation frequencies.
5. Mandate a register for standardised haemovigilance data.
6. Prioritise donor safety with precautionary principle pending further evidence.

**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*

Find the WP5 Deliverables here

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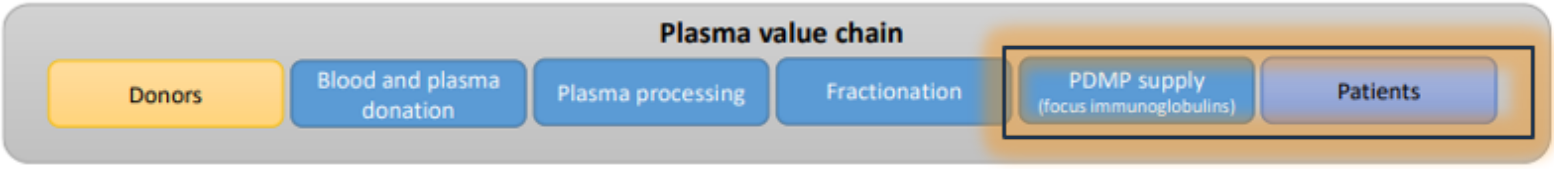

WP6 – Clinical Programme on appropriate/prioritised use of PDMPs

WP Leader: European Hematology Association (EHA)

We deliver a set of recommendations on the appropriate use of PDMPs at baseline and on its prioritisation in times of crisis.

Most important recommendations:

Improving Ig use and healthcare outcomes for patients in need of Ig in the EU.

1. Improved Understanding of Ig Usage:
    a. Create a comprehensive national database in each Member State.
    b. Include, at a minimum, information on Ig use at a granular patient level.
    c. Share information in a structured manner to establish consistent indications across all EU Member States (prerequisite to harmonise Ig usage).
2. Structured Management Plan for Shortages:
    a. Develop a harmonised European prioritisation plan methodology.
    b. Utilise a common backbone adaptable to each country's organisation, epidemiology, and resources.
    c. Implement a harmonised approach for managing Ig use across Europe.
    d. Establish Europe-wide communication and shortage awareness systems.
3. Enhanced Collaboration and Linkages:
    a. Assess opportunities to build on existing initiatives.
    b. Collaborate with relevant stakeholders and expert networks.
    c. Ensure linkages between similar initiatives for optimal synergy.

Find the WP6 Deliverables here

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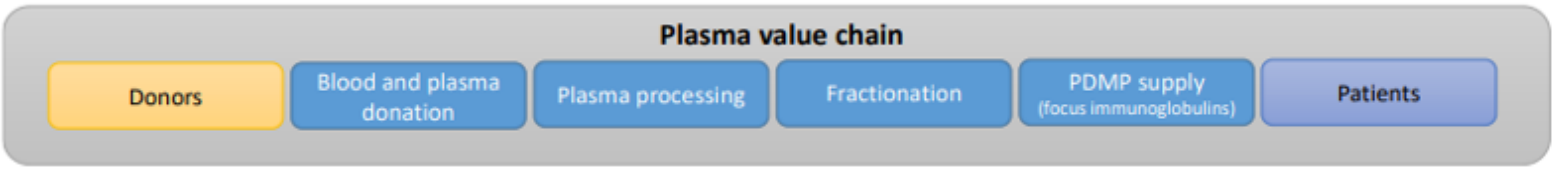

A final message from the SUPPLY Consortium

Many patients depend on plasma medicines and need a stable and adequate supply.

The SUPPLY project provides a set of recommendations and guidance here for the EU, National Governments, blood establishments, competent authorities, medical societies, and other professional stakeholders to meet this need.

Now is the time for policymakers, healthcare providers, and stakeholders to consider the guidance provided and work collaboratively to achieve optimal availability of plasma medicines for patients.

Now is the time to examine the recommendations provided to increase plasma collection in the EU by the public health sector to ensure a sufficient, adequate, and resilient supply of plasma and to contribute to European self-sufficiency.

Now is the time to review the recommendations and guidance provided and implement the measures required to ensure the plasma and PDMP system is robust and resilient now and in the next times of crisis.

Now is the time to act in the interests of patients, donors, and all EU citizens.

Thank you

The SUPPLY consortium thanks all involved for their contributions

OUR PARTNERS

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