

Plasma donation: new thinking to serve Europe's patients

Practices & approaches for countries



Executive Summary

Toward new approaches to plasma donation

In the coming decade European countries will see an increased need for plasma-derived medicines to treat their patients for a range of rare diseases and critical medical conditions. While demand for blood components for transfusion remains relatively stable, a European Commission survey (2014) shows that demand for plasma derivatives is increasing by some 6% per year.

PER PATIENT PER YEAR:

MORE THAN 1200:  Plasma donations to treat **ONE PATIENT** for HEMOPHILIA.

MORE THAN 900:  Plasma donations to treat **ONE ALPHA-1 PATIENT.**

MORE THAN 130:  Plasma donations to treat **ONE PATIENT** with a **PRIMARY IMMUNE DEFICIENCY.**

The patient population that these plasma-derived medicines can treat has been growing steadily in recent years for four reasons: more people are being diagnosed with conditions thanks to the increased precision of medical diagnostics; more are being diagnosed early; people benefiting from these treatments are living longer; and there is more clinical evidence of these therapies' benefits for patients.

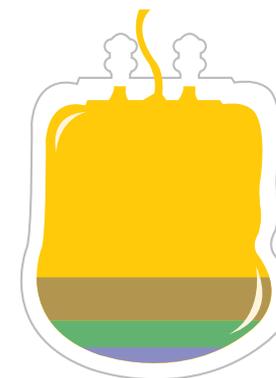
To meet this anticipated increase in need for plasma-derived medicines, and the donated plasma needed to produce them, health sector policy makers will need to put strategies in place to ensure a safe and stable supply of this blood component.

Additionally, new developments on the public health landscape, and unpredictable events such as COVID-19, highlight a need for countries to put in place private plasma donation approaches, that will help provide stable access to plasma-derived medicines to their citizens over the long term.

Plasma in Europe today is provided by a combination of nationally collected and imported donations. Some 30% of plasma used is given by volunteer donors in the US who are compensated for their efforts*.

*This figure excludes UK volumes.

PLASMA PROTEINS AND THE DISEASES THEY TREAT



- **Albumin (25 grams*)**
Shock, Burns, Major Surgeries, certain chronic liver diseases.
- **IVIG (Intravenous Immunoglobulin) (4 grams*)**
Primary Immunodeficiency Diseases, Autoimmune Diseases, Chronic Inflammatory Demyelinating Polyneuropathy, immune thrombocytopenia
- **Alpha-1 Antitrypsin (.15 to .30 grams*)**
Alpha-1 Antitrypsin Deficiency (Genetic COPD)
- **Coagulation Factors (Factor VIII: 300 to 450 IUs, Factor IX: 180 to 200 IUs*)**
Hemophilia A & B, von Willebrand Disease, other rare bleeding disorders

** Plasma Protein Yields per Liter of Plasma*

Looking to the decades ahead, imported plasma will continue to be an important contribution to plasma-derived medicines produced for European patients. But as patients' needs and populations grow, countries can consider new thinking on how more locally donated plasma can be collected in their public systems to contribute to sustainable plasma supply in Europe.

Today's European plasma donation landscape

Some 30% of the plasma used in Europe today to treat patients is imported from the US.*

*This figure does not include UK volumes.

Today Europe has some 150 plasma private plasma donation centers (2020); around US has 900.

Some 55% of all directly donated plasma in Europe is given by donors in only four countries: Austria, Czech Republic, Germany and Hungary.

Plasma is fundamentally different from blood

Plasma is a blood component. But it is unique and fundamentally different from blood in several ways. Some key facts:

- For many conditions that plasma-derived medicines treat, patients have no alternative treatments.
- Donating plasma takes longer than giving blood, but plasma donors can give larger volumes more frequently.
- The process for making medicines derived from human plasma is more complex and expensive than producing chemically synthesized medicines. It takes up to 7-12 months from donation to when a plasma-derived medicine is available. Some 57% of the cost of a plasma-derived medicine is in the manufacturing process; for small molecule medicines it is 14%.

Authorized frequency of plasma donation

When they donate blood, donors lose blood cells and plasma. Plasma donors lose only blood proteins. The differences in recovery periods for people in these two donation processes is the basis for national regulators

to allow donation of higher plasma volumes at a higher frequency than for whole blood. In Europe donors can give 650-850ml of plasma per donation. National rules on frequency of donation vary widely – between 20 and 60 times yearly.

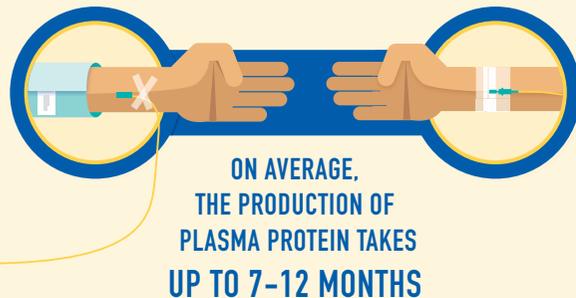
Combined public-private plasma donation

New approaches to plasma donation focus on moving from a public plasma donation system to a combined public-private donation network. In this model, donations to established national blood bank services are complemented by plasma given directly in a network of private donation centers. In some countries, such as Germany, all centers are private.

There are different variations on this model. The public-private plasma donation networks operating in Austria, Czech Republic, Germany and Hungary for the past decade provide excellent examples of how the public sector blood system can coexist with private sector plasmapheresis donation services to collect more plasma per capita.

How long does plasma protein production take?

The process to manufacture plasma protein therapies is lengthy because several complex steps must be taken to ensure products are safe and effective.



Will opening more plasma donation centers reduce whole blood donations in a country?

There is no empirical evidence to support the idea that plasma donations have a negative influence on traditional blood supplies in a country. Data from European countries that have opened private plasma donation centers show an opposite trend – when plasma donations increase, blood donations also increase.

A recent study of the evolution of the Czech Republic’s combined public-private donation system shows that blood collection volumes

and frequency have remained stable as private plasma donation has grown. There have been no decreases in the blood donation figures, despite the opening of ten plasma donation centers between 2007 and 2010. During this period, volumes of whole blood collection remained stable, as private plasma donation increased significantly.

Donations evolved nearly tenfold – from 6.8 liters per 1000 people in 2006 to 50 liters per 1000 people in 2010.

Austria, Germany and Hungary report that their combined plasma donation systems show similar results to their Czech counterparts over a ten-year period. Health professionals in these countries found that compensating donors for their effort and inconvenience is a determining factor in their ability to increase and sustain stable volumes of locally donated plasma.

Building long-term relationships with plasma donors

Potential donors across Europe generally do not know about the vital contribution that plasma makes to society and to transforming patients’ lives. This situation is complicated by the low public awareness of the possibility to donate

plasma and of the difference between blood and plasma. These are reasons why the level of plasma donations in Europe is below its potential. More effective donation can be achieved by including countries who are not currently pursuing private donation programs.

Compensation

In their policies and regulations all European countries align with the principles of voluntary unpaid donation of blood and blood components, as set out in the European Commission’s report on the topic.⁵ At the same time they allow donors to be compensated for the costs they incur, recognizing the

 Austria	Up to 50 times yearly
 Belgium	Every 2 weeks, no more than 23 times yearly
 Czech Republic	One donation every 2 weeks
 Germany	Up to 60 times yearly
 Hungary	Maximum 33 donations yearly, and one whole blood donation per year before giving plasma

considerable effort and inconvenience of donating plasma. While countries have different approaches, all are aligned with the principles of voluntary unpaid donation. For example, the system in **Czech Republic and Germany, is based on a fixed allowance**. Others reimburse specific expenses. Depending on what is authorized in national legislation, donors can give between 20-60 times yearly

Incentives for plasma donors in Europe

The report shows that 24 countries provide some form of incentive to donors of plasma and blood platelets: Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Malta, Poland, Romania, Spain, Slovenia, Sweden, and the United Kingdom.

Incentives include:

- Reimbursement of medical costs
- Compensation linked to loss of earnings
- Small tax deduction for costs incurred
- Free physical check-up
- Food vouchers
- Time off work
- Reimbursement of travel costs
- Small tokens
- Refreshments

Rethinking countries' plasma self-sufficiency

The goal of attaining national plasma self-sufficiency is specified in global health forums and policies (EU, WHO) and in a number of European countries national health strategies.

If national health authorities' ultimate goal is to secure stable access to plasma-derived medicines for their patients, it may be useful to reframe the concept of self-sufficiency around an access approach.

This would include practices such as increasing networks in countries for private plasma donation (plasmapheresis). This can be linked to Plasma-for-Product agreements with medicines producers for efficient medicines supply; and to contract fractionation – where plasma production resources can be shared among countries who do not have this infrastructure, or the scale to invest in it.

COVID 19 & pandemics: a changing situation for plasma donation

The efficacy of plasma and its derived medicines as a treatment for COVID-19 have not been conclusive, except for treatment at the very early stages. But the pandemic has raised interest in the potential of convalescent plasma to treat other viruses.

The experience of the pandemic, coupled with the effectiveness of plasma in treating diseases such as Ebola, has heightened the perception that plasma can be considered to help manage future outbreaks – creating more interest in securing a national plasma supply.

This shift in thinking may affect the global landscape for plasma donation in the medium term, suggesting that countries will need strategies to secure more donations in their pandemic preparedness plans.

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