Monographs of the Víctor Grífols i Lucas Foundation 47

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Ethics and plasma donation: an overview

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# INTRODUCTION

In general usage, plasma donation is often confused with blood donation, and people are unaware of the uses of plasma – which accounts for the majority of the blood used to manufacture essential medicines to treat a range of diseases. Likewise, there is little awareness of what collecting and processing plasma involves. As a result, discussions of "altruism and solidarity" with regard to donation tend to deal in generalizations, while ethical evaluations fail to distinguish between blood and plasma donation.

For decades, blood donation has been the ultimate paradigm of altruism and solidarity in Spain, with its origins in the social solidarity shown in response to calls for blood to treat the wounded during the Spanish Civil War (1936–39). In popular culture, blood donation is seen as a voluntary altruistic action, for which the only recompense is social recognition.

Plasma donation, by contrast, arose out of the health system's needs for sufficient quantities of raw material to produce medicines that were essential to treat those suffering from specific diseases for which there was no alternative therapy. The plasma recovered from whole blood does not come close to meeting production requirements, and this prompted the development of plasmapheresis, a technique that makes it possible to collect plasma alone, which has the additional benefit of far faster recovery times than whole blood donation. However, plasma collection cannot easily follow the pattern of whole blood donation, because it requires regular donors, the donation process is longer, and it requires costly infrastructure to guarantee the safety and quality of the plasma submitted for fractionation and manufacturing.

This means that it is questionable as to whether plasma self-sufficiency is attainable in an individual country or region, at least in the short to medium term, and particularly if based exclusively on unpaid donation. The reality is that most countries have to purchase plasma products from companies that manufacture them using plasma from individuals who are remunerated for their donation, as the plasma obtained from each country's altruistic donors is not remotely sufficient to meet demand for these products.

In view of this fact – which is confirmed by statistics – the Víctor Grífols i Lucas Foundation considered whether payment for plasma donation can be justified, and if some of the arguments traditionally raised against remuneration ("the commercialization of blood exploits the poor", "human life should never be the object of trade", "financial incentives undermine the intrinsic value of the altruistic act because it changes the objectives", "paid donation endangers the safety of donated product" etc.) are still valid, or whether medical progress and the growing needs of the world population mean we should review some of our beliefs about donation, as has happened in other spheres such as assisted reproduction.

The participants in "Ethics and plasma donation: an overview" provided both information and analysis, enriching this ongoing debate to help readers reach an informed decision on the issue.

*Núria Terribas*
Director of the Víctor Grífols i Lucas Foundation

# Paid plasma donation. Ethical reasons


## Victòria Camps

*Philosopher, President of the Víctor Grífols i Lucas Foundation*

The notion that the human body should never be the object of commercial transactions is the principle that provides the basis for prohibiting compensation – whether monetary or otherwise – for the donation of human organs or body parts, including blood and plasma. A series of declarations from international institutions, such as the World Health Organization and the Council of Europe, and legislation in most European countries, recommends and in some cases dictates that blood donation should be voluntary and unpaid. The ethical principles of altruism and solidarity, along with the idea that unpaid blood donation is a guarantee of safety, reinforce the belief in altruistic donation.

The principal source of arguments in favour of altruistic donation is Richard Titmuss' book, *The Gift Relationship*, published in 1970. In it, Titmuss considers the phenomenon of gift-giving in primitive societies in which there is no economic exchange. Drawing on the theories of anthropologists such as Marcel Mauss, Bronislaw Malinowski and Claude Lévi Strauss, Titmuss describes donation as a reciprocal relationship which has disappeared in so-called advanced societies. The book's great achievement lies not just in its identification of the value of gifts at a time when giving without expecting anything in return is so rare, but also in the fieldwork he conducts to stress the importance and necessity of defending such relationships. He compares the blood donation system in the United States and Japan, where donors are paid, with that in the United Kingdom, where donation occurs as part of a public system in which there is no remuneration. The study uses empirical data to show that altruistic donation is a self-supporting system where it is dominant, but disappears where it co-exists with paid donation. He found that, over the same ten-year period, while unrewarded donation almost disappeared in the United States and Japan, it remained stable and actually increased in the United Kingdom.

Richard Titmuss was an interesting individual, an autodidact and civil servant with limited academic training, who became a professor at the London School of Economics. Convinced of the value of social policies, he dedicated his life to defending them and demonstrating their benefits. His book on donation reflected his unbreakable commitment to building a solid welfare state as the only way of overcoming poverty and meeting people's basic needs.





Titmuss' text is extremely important. However, it is also true that both blood donation and the wider medical needs it has to meet have changed radically in the almost half-century since the book was published. Nor can we ignore the technological innovation or the far-reaching social, economic and cultural changes which might have influenced his analysis.

We need to start by asking three fundamental questions:

1. Can the concept of the "gift" be extrapolated to contemporary societies?
2. Can blood donation and plasma donation be compared?
3. Is financial payment justifiable for plasma donation?

In reality, the widespread commercialization of products and services in today's societies makes it difficult to see how gift-giving can be compatible with a modern economy. It is also important to remember that 'primitive' gift-giving was not entirely altruistic. Rather, it established a reciprocal relationship. This was a "collaborative" economy, to use a current term, within which donation was based on each person's capacity and willingness to contribute to the good of the community. This situation is very different from our own. When we talk about things that "money shouldn't be able to buy", to use Michael Sandel's phrase,[1] we are talking not about reciprocity or collaboration but about withdrawing certain products from the market and from economic transactions, and entrusting them to the good faith of altruistic individuals who are prepared to help those in need. We argue for a principle in which we believe: that organs, tissue or products derived from the human body should neither be bought nor sold. If we have abolished slavery – understood as the purchase of men and women – then the commercialization of parts of the human body strikes us, in some sense, as a prolongation of the very system of slavery we have rejected. From an ethical point of view, this is a basic premise and one that is beyond question. However, like all of the basic premises or principles of ethics, it is an abstract principle. And abstractions alone cannot resolve practical conflicts. Otherwise, we run the risk of imposing a rigid approach whose consequences may be unjust and even unethical.

In light of the development of medicine and of biomedical research, given the growth of research with cells and tissue extracted from the human body, and taking into account the expansion in therapeutic applications, we must con-

sider whether the collection of material extracted from the human body should be limited by the altruism of donors, prohibiting any kind of compensation for this donation, or whether this elevation of the principle of non-commercialization of the human body is, itself, ethically unacceptable. To put it another way: Is donating a kidney the same as donating blood or sperm? Why not, and what is the significance of this? When altruistic donation of blood or plasma is not sufficient to meet the therapeutic needs of patients, should the altruistic principle prevail even if this means that patients do not receive medicines?

We need to take actual situations and real problems as our starting point. And we must consider not just the ethical principles themselves but also the consequences that arise from applying them rigidly and without acknowledging the specific circumstances and characteristics of each situation. Here, we are concerned with the donation not of blood but of plasma, and with the real difficulty we face in meeting a level of demand that is not satisfied by unpaid donation alone. It is a fact that donating blood and donating plasma are not the same. Blood donation is quick, simple and straightforward, and does not pose any risk for healthy donors. Extracting plasma from blood using the technique of plasmapheresis is a lengthier and more complex process. Part of the extracted blood is returned to the donor, but the process is longer than simple blood extraction. This difference between donating blood and donating plasma means that, while blood donation is sufficient to cover existing demand except in special circumstances, it is not so easy to recruit plasma donors, and altruistic donation does not currently cover the therapeutic demand for the plasma products derived from human plasma. Neither Catalonia nor Spain nor Europe are self-sufficient in plasma; if the pharmaceutical industry is able to attend to current demand for plasma products, it is thanks to the plasma collected in the United States, where donation is remunerated.

Global demand for plasma has risen due to development and innovation by the pharmaceutical industry. At the same time, there is a fundamental right to health, which means that it must be guaranteed for all citizens. However, this guarantee is hindered by the insistence that the availability of treatment is dependent on the altruistic attitudes of citizens who are prepared to donate





plasma to supply the pharmaceutical industry. It is hard to describe this situation as anything other than hypocritical. In general, in Spain, with a few exceptions, the principle of unpaid blood and plasma donation has been maintained without distinction. At the same time, nobody objects to the use of plasma from paid donors to attend to the therapeutic needs of our patients. The question is this. Which is ethically more acceptable: maintaining the altruistic principle of unpaid donation along with the attendant hypocrisy, or accepting reasonable reward for plasma donation so that countries are able to supply their own needs?

Any analysis of these conflicting ethical arguments needs to consider the following issues:

1. The cost of altruism.
2. Ethical arguments for altruism.
3. Safety and demand in plasma donation.
4. Ways of rewarding plasma donation.

## The cost of altruism

Altruism is defined as "willingness to do things that bring advantages to others, even if it results in disadvantage for yourself" (Cambridge). From a philosophical perspective, it contrasts with selfishness and is synonymous with a moral attitude, in so far as it entails the duty of recognizing other people's reality and showing solidarity towards them. Achieving a balance between one's own interests and the interests of others is one of the goals of ethics, which does not strive to make people strictly altruistic but rather encourages them, in addition to pursuing their own interests, not to disregard the good of others and to show solidarity with the vulnerable.

Philosophy has considered altruism in general terms, differentiating between altruism as a moral value to which we should aspire and altruism as a reality. As is the case with most moral values, appreciating the value of altruism does not mean that we are altruistic by nature. Thomas Nagel expressed this clearly when he wrote: "To say that altruism and morality are possible in virtue of something basic to human nature is not to say that men are basically good."[2]

But if altruism is a moral aspiration, we cannot take its existence for granted. When legislation establishes altruistic donation as the sole condition for blood or plasma donation, it is assuming something that is not necessarily "real". And this raises at least two questions. Firstly, whether we should continue to base ourselves on the supposed altruism of donors, even at the cost of prejudicing patients. And secondly, given that we are not altruistic by nature, what should the state – which defends free donation of plasma – do to promote altruism and ensure its capacity to meet the needs of patients who require plasma products?

To clarify both questions and determine to what degree paid donation is incompatible with ethics, we need to analyse some of the reasons for viewing altruistic donation as ethically superior to paid donation.

## Ethical arguments for altruism

If we return to the specific issue of blood or plasma donation, the reasons put forward by theorists who prefer altruistic to paid donation are as follows:

a) the commercialization of blood exploits the poor
b) human life should not be the object of commercial exchange
c) the commercialization of blood suppresses the expression of altruism and erodes our sense of community
d) financial incentives undermine the intrinsic value of people's actions because they change their purposes
e) paid donation endangers the safety of the donated product.

Each of these claims needs to be examined in the light of the current situation, and must be checked against verifiable facts:

a) It is true that the system of donation in exchange for material reward attracts those who are most in need. We cannot close our eyes to the fact that we live in a world of economic inequality, where many people do not have access to very basic goods and where the only way they can acquire these is by engaging in practices that we might prefer did not exist. However, the best way to fight such inequality is not by preventing the disadvantaged from





exploiting opportunities to improve their situation but through more ambitious measures to promote social equality.

In the meantime, we need to consider whether permitting practices such as payment for plasma donation is so ethically unacceptable as to justify depriving these people of a resource which helps them to solve some of their problems. At the same time, paid donation – where permitted – is not an obligation. The system does not prevent those who wish to donate blood for free from doing so. What remains to be seen is whether they will be sufficiently motivated.

b) The principle that human life should not be the object of commerce is too general and abstract: selling a kidney is not the same as receiving a small reward in exchange for donating blood or plasma. We need to consider each case in the context of therapeutic needs, and decide which is more important: maintaining a principle that is, to some degree, a convention deriving from what is arguably an excessive sanctification of the human body in general and blood in particular; or deciding that rewarding for the donation of something as commonplace as blood is a lesser evil when compared to the benefits for human life offered by plasma collection.

At the same time, it is important to analyse in detail why a semi-sacred aura attaches to blood donation but not to other types of donation. Both sperm and egg donation are remunerated – extremely well, in the case of eggs – and neither of these practices is subject to the criticism and rejection directed at the possibility of extracting plasma in exchange for a reward or compensation. Why is this? Is it another example of hypocrisy?

c) The third claim is difficult to verify, like many claims regarding human behaviour. It is derived directly from Titmuss' book, which appears to show that paid donation automatically discourages altruistic donation. According to his statistics, in the United Kingdom altruistic donations rose by 31% between 1961 and 1967, while in the United States, over the same period, altruistic donations declined in favour of the paid alternative. In Japan, the reduction was greater, and 98% of donations are currently remunerated.

Titmuss' argument has been criticized by several authors, of whom the best known is Kenneth Arrow,[3] who argues that the thesis that the introduction of

the "laws of the market" inhibits altruistic donation has not been sufficiently proven and, indeed, is impossible to demonstrate convincingly. He adds that, because "the creation of a market increases the individual's scope for choice, it delivers a greater benefit: it allows each individual to choose the manner in which to donate." In summary, according to Arrow, commercializing an activity does not change its meaning: it is better for some but worse for nobody. People are not obliged to receive compensation for donating plasma if they do not wish to.

d) The theory that, by remunerating an action, we change its meaning, is defended very strongly by Michael Sandel in the work cited earlier.[4] He refers to the excessive commercialization of certain activities in the United States, not only in the sphere of health but also of education. For example, rewarding students to encourage reading, or fining parents for being late when collecting their children from nursery. Sandel argues that these measures undermine what should be the intrinsic value of punctuality or reading. Furthermore, he argues that they do not achieve the stated goal: parents didn't stop being late because they were fined; instead, they took the fine to mean they had paid for their lack of punctuality. It is undoubtedly the case that certain activities should be protected from commercialization, but the reasons for doing so cannot be identical both for the acquisition of habits, such as reading, and for process of obtaining a therapeutically essential product.

e) The premise that unremunerated donation helps guarantee the safety of blood or plasma is not empirically verifiable. What is true is that tighter checks maintain safety, irrespective of whether the product in question comes from free or paid donation. It is true that, from the 1980s onwards and in the context of AIDS and HIV, a series of scandals relating to the use of contaminated blood led to the conclusion that paid donation introduced an incentive to ignore the minimum controls designed to ensure that blood was safe. However, the key element here is the controls, not the question of whether the blood or plasma is donated freely.

The idea of the "gift" used by Titmuss is attractive because it come with the glamour associated with certain supposedly archaic behaviours when compared with our own atomized individualistic societies, where everyone looks





after their own interests and solidarity is rare. It is important to remember, though, that such reciprocity operated between members of the tribe, and did not apply to "strangers", as occurs in modern society. To argue that altruistic donation should prevail as the most humane form of action in every case is to ignore the many other factors – such as the need to obtain the donated substances – which should not be ignored in favour of an abstract appreciation of altruism or the general idea that human life is sacred and cannot be the object of commerce. Peter Singer, for example, with regard to the debate between Titmuss and Arrow, argues that the calculation of material benefits should not be the overriding consideration, and that the basic objective should be how to create more caring societies. The question "What type of society do we want?" should come before the question "How can we obtain more blood at a lower cost?" This is true, but the move towards a better society does not depend solely on whether or not we permit payment for blood or plasma, in an attempt to prevent the expansion of a commercial mentality. A society with more therapeutic resources is also better. The balance between therapeutic needs and the protection of certain values is not something to be achieved by eliminating specific practices which are not harmful in themselves, and which help to achieve greater benefits. This is not a case of arguing that the ends justify the means. Here, not only are the ends good; it is also far from clear that the means are so bad.

## Remunerate, compensate, reward

It is never possible to analyse human behaviour in terms of simple binary parameters such as good or bad, fair or unfair, black or white. Human behaviour always involves shades of grey. Often, ethics is not a question of choosing between good and evil but between greater and lesser evils, because human beings are not perfect and values generally become an issue when we need to make complicated choices between options that are not easily reconciled.

The argument so far makes it clear that, when analysing or evaluating the ethics of any problem, we must always consider it from two perspectives:

principles and consequences. These are two complementary, not opposing, considerations. In the case of plasma donation, the basic principle is the one that establishes the illegitimacy of making the human body or any of its parts the object of economic transaction. We can call this the altruism principle, in so far as we understand that altruistic donation is the only legitimate alternative to commercialization. However, as we have seen, the human condition is not totally altruistic and financial remuneration cannot always be seen as the pernicious pursuit of personal profit. This is why we tend to refer to remuneration for plasma as "compensation", a word that some argue is a euphemism that avoids the true nature of the economic transaction but which, in reality, can be understood – without distorting reality or introducing perverse incentives – as the logical reward for the time the donor "loses" while donating plasma or the inconvenience that arises from this donation. Rather than maintaining the distinction between altruism and remuneration, why not accept that the individual who donates plasma is also altruistic, even if they require the encouragement of "compensation" to act upon this altruism?

Blood banks that defend the altruistic public donation system are well aware that they need to activate incentives to promote altruism among the population, not only to donate blood but also to donate plasma, which – as we have seen – is more complex. We should not rule out the possibility of our society becoming more cooperative, of people becoming willing to do for free many things for which they currently expect to be rewarded. It is the role of the public authorities to promote cooperation and solidarity. However, if such efforts are unsuccessful, we cannot close our eyes to the reality of a therapeutic demand that the authorities must also strive to satisfy. If persuasion alone does not work, then we need to encourage solidarity in other ways, using material incentives (in the same way that taxes are used to influence behaviour).

As is the case in the majority of ethical dilemmas, the issue here is one of conflicting values. On the one hand, we are defending the value of altruism. On the other, we are defending the universal right to healthcare. As things currently stand, there is one indisputable fact: neither in Catalonia nor in Spain is sufficient plasma obtained from altruistic donation to cover the therapeutic needs of our patients. Or, to put it in other words, there is insufficient





altruism in society to meet demand. This reality means that we must address and resolve – without ambiguity or evasion – the following question: is renouncing treatment with plasma products to safeguard the principle of altruistic donation the most just option?

## Notes

1 Sandel M. What Money can't Buy. New York: Farrar, Straus and Giroux; 2012.

2 Nagel T. The Possibility of Altruism. New Jersey: Princeton University Press; 1970.

3 Arrow KJ. "Gifts and exchanges", Philosophy and Public Affairs I. 1972; 4.

4 Sandel, op. cit.

# Global Plasma Resources. Ensuring a Sustainable Supply

**David Ian Bell**

*Chairman Global Board of Directors*
*Plasma Protein Therapeutics Association*

The development and availability of plasma protein therapies over many decades has provided patients with unmet medical needs the ability to lead productive, essentially normal lives. These therapies are used to treat a number of chronic diseases including immune deficiencies, hereditary emphysema and angio-edema, coagulation disorders, neuromuscular and cognitive disorders and hepatic disease. Additionally, they have proven essential in managing acute injuries and exposure to infectious agents. In addition to the known benefits of therapies derived from human plasma, exciting research into the development of new proteins and the expansion of indications for existing therapies is opening the door to a new age of medicine.

However, where will the plasma necessary for these "natural" therapies come from? Certainly, some proteins can be engineered with recombinant technology, but the vast majority of patients who benefit from these therapies can only realize their value when they are derived directly from plasma.

The Plasma Protein Therapeutics Association (PPTA) is an association representing the companies supplying plasma protein therapies and their recombinant analogues to patients.

The mission of PPTA is to promote the availability of and access to safe and effective plasma protein therapeutics for all patients in the world.

## A tale of two liquids

- Blood, a living tissue circulating throughout the human body, is comprised of red blood cells, white blood cells, platelets and plasma. Although often collected as whole blood and separated into major components prior to transfusion, automated collections have become common practice whereby the components that are needed for transfusion are the only ones collected.
- Plasma is the aqueous part of blood containing proteins and salt in which red and white blood cells and platelets are suspended. It constitutes approximately 55 per cent of total blood volume. Important elements in plasma include albumin, coagulation factors, fibrinolytic proteins, immunoglobulin and other proteins.





Plasma can be obtained in two primary forms: recovered plasma (obtained from the "by-product" of whole blood collection) and source plasma (obtained through dedicated plasmapheresis). Currently, the primary source of plasma utilized in processing plasma protein therapies is from plasma centers located in the United States. Through the process of plasmapheresis, plasma is removed and the blood cells, platelets and other blood components are returned to the donor. This process can take as long as two hours to complete and the plasma obtained can be used only for the further manufacture of plasma protein therapies. Unlike blood cells from whole blood donations, the proteins in plasma lost through donation can be regenerated by the body in less than 24 hours. Donors of source plasma in the United States are compensated in light of the time and commitment necessary for the donation process. Without the minimal "compensation" provided, there would not be sufficient donors of source plasma with the frequency necessary to provide sufficient plasma for further manufacture into life saving products to meet the growing demand from patients.

The collection process for plasma for further manufacture ("normal source plasma") is highly regulated by the United States Food and Drug Administration and other governmental regulatory authorities. In addition to the stringent regulations and good manufacturing procedures imposed by healthcare regulatory agencies, PPTA sets and monitors certain additional voluntary standards which further document the safety and quality of plasma collection for both the plasma donor and the receiving patient.

## FDA Regulatory Definitions

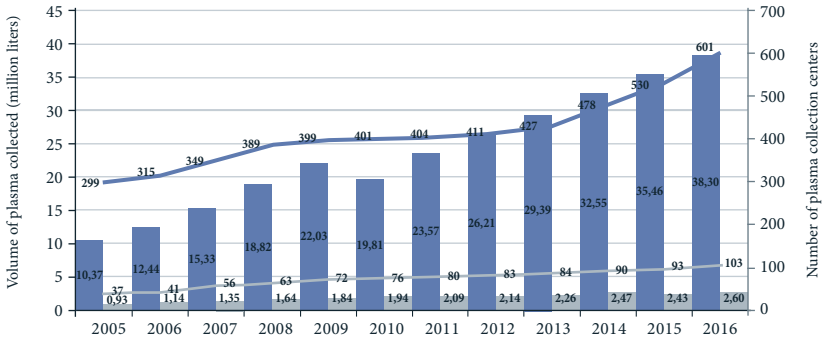
### § 606.3

a) Blood means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

c) Blood component means a product containing a part of human blood separated by physical or mechanical means.

d) Plasma for further manufacturing means that liquid portion of blood separated and used as material to prepare another product.

**USA vs. Europe (Collections & Collection Centers)**




**Source: PPTA data** USA Collections Europe Collections USA Centers Europe Centers

## § 640.60 Source Plasma

The proper name of the product shall be source plasma. The product is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. The definition excludes single donor plasma products intended for intravenous use.

## Question

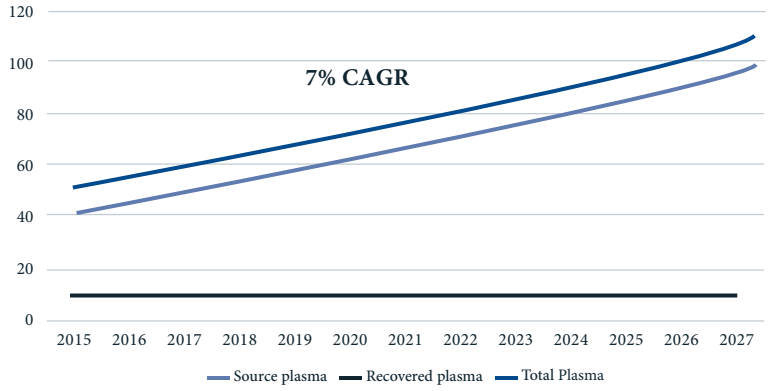
Can the world continue to rely on the United States for the primary supply of source material for plasma protein therapies?

What is Europe's responsibility to provide sufficient raw material for therapies used by its citizens?





**Required Plasma Growth to Meet Projected Growth of Plasma Therapies***




*PPTA does not make forward looking statement; Data based upon public statements by Industry and Analyst

# Plasma is a strategic resource

Changes in clinical practice in developed countries have reduced the need for red cells and significantly reduced volume of recovered plasma. In order to meet the continuing and growing demand for plasma derived protein therapies, alternative/additional sources of plasma need to be identified and developed. The geographic imbalance in plasma collection gives rise to potential disruptions of plasma supplies that could result in regional and global shortages of necessary therapies.

Many countries outside of the United States have resisted increasing the supply of plasma for further manufacture of plasma protein therapies due to perceived mandates of self-sufficiency and reluctance to "compensate" donors. As a result, the imbalance in plasma supply and availability will only increase, putting patients at risk of losing access to necessary therapeutics.

The resistance to "compensated" plasma donation for further manufacture is based upon a number of unsubstantiated claims.

## Common Myths – (Compensation)

**Myth:** "Source plasma is the only industry that compensates donors"

**Fact:** Whole blood donors are often given other rewards which have monetary value that can exceed the typical amount given to compensated plasma donors.

Rewards given to whole blood donors include:

- Tax credits.
- Paid day off work.
- Meals.
- Tickets for events.
- Discount on medical services.
- Telephone cards.
- Points for commercial redemption.

## Common Myths – (Safety)

**Myth:** "Plasma protein therapies are safer when made from non-compensated donations"

**Fact:** Plasma donation is proven to be safe and the products derived from that plasma are safe.

Final product safety is proven:

- Pharmacovigilance data show that there has been no transmission of HCV, HIV and HBV for plasma derived medicinal products since 1994. On the other hand, there have been recent transmissions through whole blood products.
- European regulatory policy documents note that there is no difference in safety between products made from plasma donated by compensated or non-compensated donors.
- This is different from the profile of whole blood and component collections, which cannot undergo equivalent viral inactivation methods as source plasma without becoming unstable, and which cannot be held in inventory as long as source plasma because of their labile nature. Transfusion of whole blood and blood components (not PPTs) even today can result in viral transmissions of HIV and hepatitis.





## Common Myths – ("Crowding Out")

**Myth:** "Plasma centers take away donors from whole blood collection centers, leading to a shortage of whole blood products"

**Fact #1:** There is no empirical evidence to support the "crowding out" myth.

**Fact #2:** There are data which shows the exact opposite of "crowding out."

- Data demonstrates that, when plasma donations increase in the private sector, they also increase in the public ("non-compensated") sector.

## Common Myths – (Self Sufficiency)

**Myth:** "Using plasma from compensated donations prevents countries from having consistent national supplies of safe plasma protein therapies to meet the needs of their health care systems"

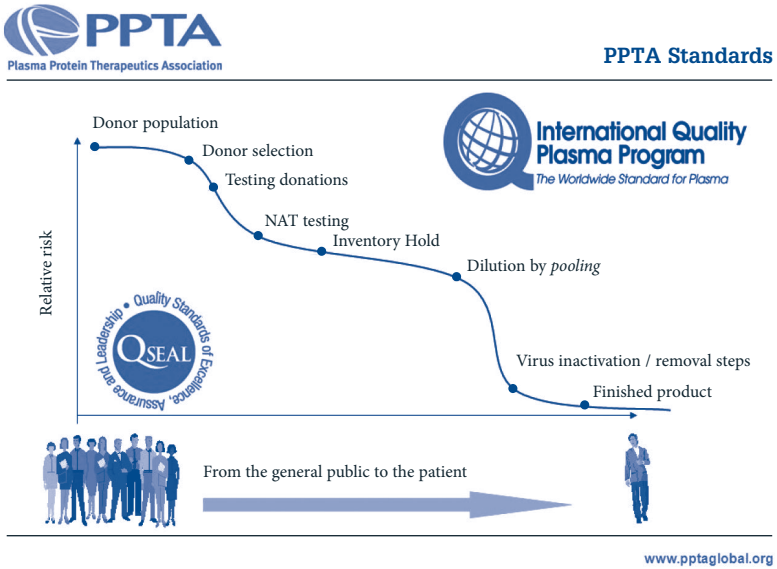
**Fact:** Non-compensated donations do not provide enough plasma to manufacture the needed supply of therapies to treat patients in most countries.

- Whole blood donations provide < 10% of plasma required to manufacture enough plasma protein therapies to satisfy patients' needs globally. The rest (about 90%) comes from compensated plasma donor– almost all of which (73% according to Market Research Bureau) comes from the United States.
- Some countries manufacture plasma protein therapies domestically and claim self-sufficiency through the use of plasma derived from whole blood donations alone. However, many of these countries lack the infrastructure to properly diagnose patients and provide appropriate access to patients. Many patients go untreated and the claim of self-sufficiency relates only to treating those patients who have actu-

ally been diagnosed, while the majority of patients remain undiagnosed and go without treatment.

## Key Points to Remember

- Residual risk for source plasma is not the same as residual risk for whole blood. Whole blood is direct risk of transmission by transfusion. Source plasma is risk of a potentially contaminated unit entering manufacturing pool.
- All manufactured source plasma derived products have virus removal and inactivation.
- Residual risk of transmission through source plasma derived products is essentially reduced to zero –significantly less than the risk of viral transmission through whole blood transfusion.








## Conclusions

- Separate regulations governing whole blood and the compensated collection of source plasma for further manufacture under a vigilant regulatory program are clearly compatible with supporting the continuing requirement and increasing demand for safe plasma derived therapies.
- Countries can continue to separately pursue self-sufficiency for whole blood transfusions while providing patients access to adequate supplies of ethically derived life-saving therapies through a regulated program for source plasma for further manufacture, providing access and enhanced safety and quality to patients.

# Plasma self-sufficiency in Catalonia

**Lluís Puig**

*Care Director, Blood and Tissues Bank of Catalonia*

# 1. Introduction

Industrial plasma fractionation has its origins in the United States. During World War Two, a stable albumin solution derived from human plasma was developed, enabling it to be transported to the battlefield and urgently administered to the wounded. Subsequently, the ability to isolate other proteins and the clinical success of their application in numerous diseases gave rise to the current scenario.

The manufacture of plasma-derived products generates more than 13.9 billion dollars per year. Globally, more than 15 million litres of plasma are fractionated, 10 million of which are processed in the United States. Sixty per cent of the plasma products manufactured in that country are exported. Approximately 73% of the plasma for fractionation comes from the United States and is obtained from donation via plasmapheresis: in other words, global use of plasma products depends on the plasma collected in the USA.[1]

Human plasma has recently been classified as a strategic resource, like drinking water or energy, with individual countries seeking to ensure their own supplies.[2] As a result, several states have launched plasma donation programmes to improve self-sufficiency in plasma products.

The project developed by the Blood and Tissues Bank (BST) focuses on the needs of patients treated in Catalonia and aims to meet these needs from plasma donated here. We are not considering donation focused on the systematic export of plasma or plasma products, as occurs in the United States and some European countries such as Germany, the Czech Republic and Hungary, which have high levels of plasma donation.

Plasma-derived products, which are classified as medicines, are subject to different regulations than other blood components (plasma, concentrated red blood cells and concentrated platelets). Moreover, their manufacture requires more complex technology, which is only available to some companies. Despite this, we believe that obtaining plasma derivatives and blood components are conceptually similar, as both come from donation by a section of the population and are used to treat people suffering from a range of diseases.





# 2. Plasma collection

All whole blood donations (450 ml of donor blood with 65 ml of anticoagulant solution) are fractionated into three blood components: red blood cells, platelets and plasma, in addition to the white blood cells, which have no therapeutic application. Approximately 250 ml of plasma are obtained from each whole blood donation. A male donor who makes the maximum four donations per year therefore contributes one litre of plasma.

In Catalonia over the last eight years, whole blood donations have fallen by 44,000 units per year. This is due to the decline in the need to transfuse concentrated red blood cells. This development, which is found across the developed world, is due to the application of non-invasive surgical techniques, the administration of drugs to reduce bleeding during surgery, the use of treatments to improve anaemia in elderly patients who undergo scheduled surgery and, finally, more restrictive criteria for the application of blood transfusions.

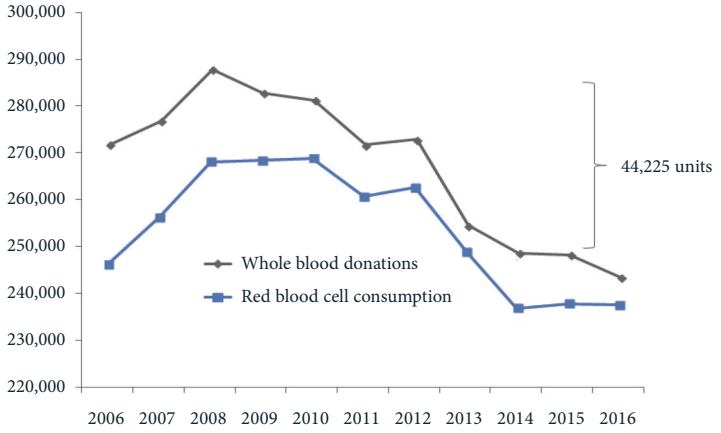
The reduction of whole blood donations has led to the quantity of plasma available falling by approximately 11,000 liters per year. At the same time, it is possible to specifically obtain plasma using plasmapheresis procedures, which only collect plasma, and return all the other blood components (red blood cells, platelets, white blood cells) to the donor. As plasma is rapidly regenerated, plasmapheresis can be performed far more frequently than whole blood donations.

In Spain, regulations permit the donation of 600 ml every two weeks. This means that a donor can donate 15 litres of plasma per year. This compares with permitted annual plasma donation levels of 29 to 38 litres in Germany, 35 in Austria, 25 in the Czech Republic and between 63 and 83 in the United States.

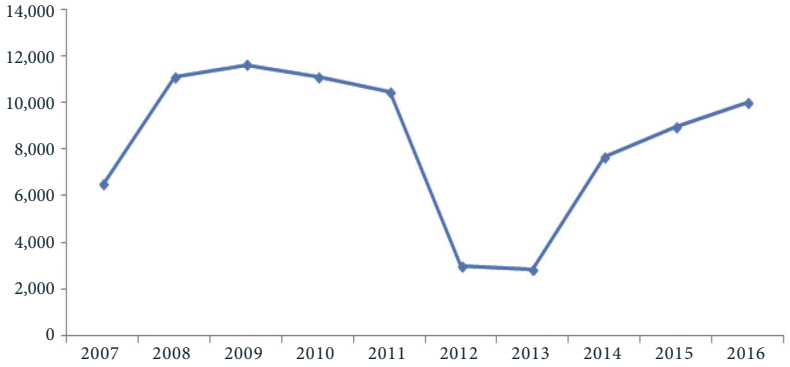
Over the last nine years, with the exception of reductions in 2012 and 2013, between 6,000 and 12,000 plasmapheresis procedures have been performed annually, yielding between 3,600 and 7,200 litres of plasma. At the same time, demand for plasma for hospital transfusion has fallen significantly since 2007, allowing more plasma to be allocated to the manufacture of plasma

products. As a result of trends in both whole blood and plasma donations and their use in hospital transfusion, over the last decade between 51,000 and 62,000 litres of plasma per year have been allocated to the manufacture of plasma products.

**Diagram 1.** **Transfusion of red blood cell concentrates and donation of whole blood (a), plasma donation by plasmapheresis (b) and hospital transfusion of plasma (c).**



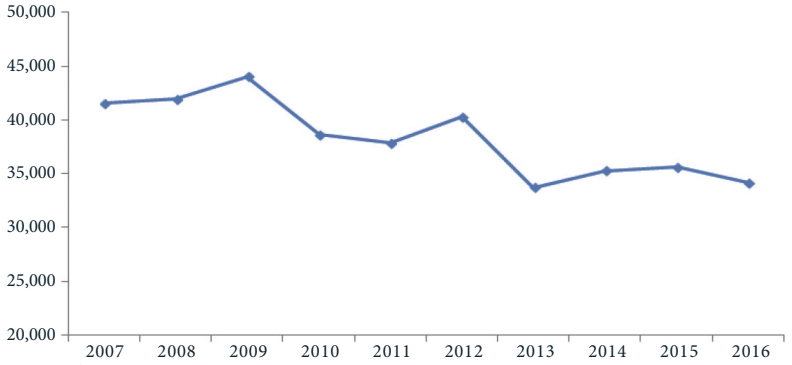

(a)




(b)








(c)

## 3. The management of plasma and plasma products in Catalonia

During 2016, the BST obtained 243,115 whole blood donations and 10,011 plasma donations by plasmapheresis. These donations enabled the transfusion of 32,742 units of plasma (approximately 8,200 litres). With the remaining 52,279 litres, Instituto Grifols, under a manufacturing contract, produced albumin, immunoglobulins, factor VIII, factor IX and alpha-1 antitrypsin. These plasma products were then returned to the BST for distribution to hospital pharmacies.

## 4. Manufacture and consumption of plasma products in Catalonia

Between 2012 and 2016, there was a significant increase in the efficiency of plasma fractionation to obtain purified proteins. Due to changes in industrial technology by Instituto Grifols, yields of immunoglobulin rose from 3.6 g to 4.45 g per litre of plasma processed. Improvements to the process of

obtaining plasma from whole blood by the BST has led to an increase in yields of factor VIII, from 87 IU per litre of plasma to 119 IU. Albumin yields remained stable at 25 g per litre of plasma (table 1).

During 2016, fractionation of 52,279 litres of plasma allocated to plasma products, with the yields noted above, produced 1,314,031 g of albumin, 232,410 g of immunoglobulin and 6,241,126 IU of factor VIII (table 1).

During this period, 1,798,418 g of albumin, 473,632 g of immunoglobulin and 5,426,000 IU of factor VIII were used, meaning that self-sufficiency in these proteins from altruistic donation was 73%, 49% and 115% respectively (table 1).

Between 2012 and 2016, demand for albumin, immunoglobulins and factor VIII rose by 62%, 11% and 30%, respectively. This trend and predictions for the future are in line with those for other European countries.

**Table 1.** Manufacture and use of plasma products in Catalonia in 2016

| | Yield/l | Plasma products obtained | Plasma products administered | Self-sufficiency (%) |
|---|---|---|---|---|
| Albumin | 25.16 g | 1,314,031 g | 1,798,418 g | 73 |
| Immunoglobulins | 4.45 g | 232,410 g | 473,632 g | 49 |
| Factor VIII | 119.5 IU | 6,241,126 IU | 5,426,000 | 115 |

## 5. Towards self-sufficiency

The BST has identified a need to increase the level of self-sufficiency for two reasons, both related to safety. Firstly, for the recipients of plasma-derived products, there is the possibility of importing pathogens from the plasma's country of origin. The risk of known pathogens is small, due to the measures





used to select donors, the plasma fractionation process and, in particular, the pathogen inactivation techniques applied. Despite this, we must recognize the potential risk of the appearance and transmission of pathogens that are currently unknown or not present in our society.

Secondly, there is the possibility of restrictions on the export of plasma and plasma products from the United States to other countries. The current situation is a cause for concern, as most countries depend on imports from the United States, and these could be interrupted for all sorts of reasons. (For example, an increase in demand as a consequence of new indications or the introduction of protocols requiring increased doses of plasma-derived products.)

And we must also note the risk of epidemic events, which could prevent the export of plasma or plasma products. Finally, we also need to take account of economic interests, which could lead to plasma products being exported to some countries, to the detriment of others.

For all of these reasons, plasma has come to be seen as a strategic resource and, as such, every country needs to establish programmes to achieve self-sufficiency. To achieve this, we need to identify the difference between existing levels of demand and supply for plasma products, and how we can close this gap.

## 6. Existing level of demand for plasma products

To identify the existing level of demand for plasma products, we will refer to the definition of self-sufficiency provided by Professor Gunson in 1989: "Self-sufficiency in blood and blood products means that a nation is able to provide from within its own population enough blood and plasma to meet the clinical need for the products derived from them."[3] This definition introduces two concepts: national self-sufficiency, as noted at the start of this essay; and the coverage of "clinical needs".

With respect to clinical needs, it is important to note the analysis of the use of immunoglobulins in different hospitals in Catalonia, published in 2010, which analysed 1,287 prescriptions. This found that 50% of immunoglobulins are administered for unapproved indications, and of these half of the cases represented pathologies for which there is no evidence of efficacy.[4]

A study conducted in 2015, which evaluated indication of immunoglobulins in immuno-mediated inflammatory illnesses, found that 13% were administered to patients with unclear diagnoses and in 4% indication was clearly not justified. This study concluded that 59% of indications should be reviewed in these pathologies.[5]

If we analyse the data for the consumption of immunoglobulins in different countries, huge differences emerge. The United States, Canada and Australia have very high levels of consumption: between 120 and 140 g per 1,000 inhabitants per year. Other European countries, with well-developed health systems, have dramatically lower levels of consumption. Levels in France are 97.4 g per 1,000 inhabitants per year, in the United Kingdom they are 56, and in Germany, 41.5.

This data suggests we could be witnessing two very different phenomena. On the one hand, it is possible that in high-consumption countries the use of plasma products is excessive as a result of inappropriate administration. In this event, self-sufficiency should be based on meeting clinical needs, not necessarily on covering current demand. On the other hand, in low-consumption countries, it is possible that there are latent, unmet therapeutic needs. If so, these countries should increase their consumption of plasma products.

Whatever the reality, we need to explore the correct indication of plasma products, based on scientific evidence and the application of agreed guidelines. In this respect, we should explore whether the principles of "patient blood management" – a multidisciplinary approach developed with the aim of rationalizing the use of blood components – could be applied to plasma products. This approach has brought about a significant decline in the administration of red blood cell concentrates, particularly in those countries with the highest levels of consumption (United States, Germany and





Denmark), and is based on administering the best product possible, at the correct time and dosage, and for the best possible reason.

Rationalizing the use of plasma products is essential for three fundamental reasons. Firstly, their use can be associated with negative effects. Secondly, obtaining plasma always requires an effort for donors. Finally, there is the fact that these medicines are used in the public health system and are very costly.

## 7. Existing level of supply for plasma products

Whole blood donations in Catalonia currently cover 49% of demand for immunoglobulin, 73% of albumin and all of plasma-derived factor VIII (table 2). Achieving self-sufficiency in albumin would require 71,479 litres of plasma and approximately 32,000 plasmapheresis procedures, which would deliver 67% self-sufficiency in immunoglobulins.

**Table 2.** Level of self-sufficiency in immunoglobulins (Ig) and albumin.

| Production Ig (g) | Self-sufficiency (%) | Plasma collection (l) | Albumin production (g) | Self-sufficiency (%) |
|---|---|---|---|---|
| 232,410 | 49 | 52,279 | 1,314,031 | 73 |
| 250,908 | 53 | 56,384 | 1,418,621 | 79 |
| 318,081 | 67 | 71,479 | 1,798,418 | 100 |
| 376,367 | 79 | 84,577 | 2,127,957 | |
| 473,632 | 100 | 106,432 | 2,677,879 | |

To achieve total coverage of current consumption of immunoglobulins, 106,000 litres of plasma would be needed, the result of 90,000 plasmapheresis procedures.

Over the coming years, any increase in plasma allocated to the manufacture of plasma products above the current level of 52,000 litres would generate a surplus of factor VIII. Immunoglobulin self-sufficiency levels of 67% would also generate a surplus of albumin. This excess product should be used in an appropriate manner that justifies plasma donation and enables the sustainability of the model.

## 8. Closing the gap

To increase the plasma available to manufacture plasma-derived products it is possible to increase donations of whole blood, reduce the transfusional use of plasma, and increase donations using plasmapheresis.

Donations of whole blood must reflect the need for red blood cell concentrates. Increasing this, to obtain more plasma, would generate a surplus of red blood cell concentrates, which could not be used in transfusion and would thus expire.

Over the last ten years, there has been a slight decline in the transfusional use of plasma, which has opened up the possibility of allocating more plasma to the preparation of plasma products. However, this measure is not without its limitations and would not resolve the problem of plasma availability.

The only viable alternative is to increase plasma donations through plasmapheresis programmes.

## 9. Altruistic donation

The BST's plasmapheresis programme is based on unpaid voluntary donation. In the first place, Spanish Royal Decree 1088/205 of 16 September stipulates that the donation of blood and blood components are voluntary altruistic acts, defining these as any donation for which no payment is received, whether in cash or in kind where this might be deemed to constitute a cash substitute. The concept of unpaid voluntary donation is compatible with small 'thank you' gifts or reimbursement of travel costs.





In addition, the BST shares and adheres to the ethics code of the International Society of Blood Transfusion (ISBT) and to the standards and recommendations of the World Health Organization. Both of these clearly establish that the donation of blood and other biological products should be voluntary and unpaid.

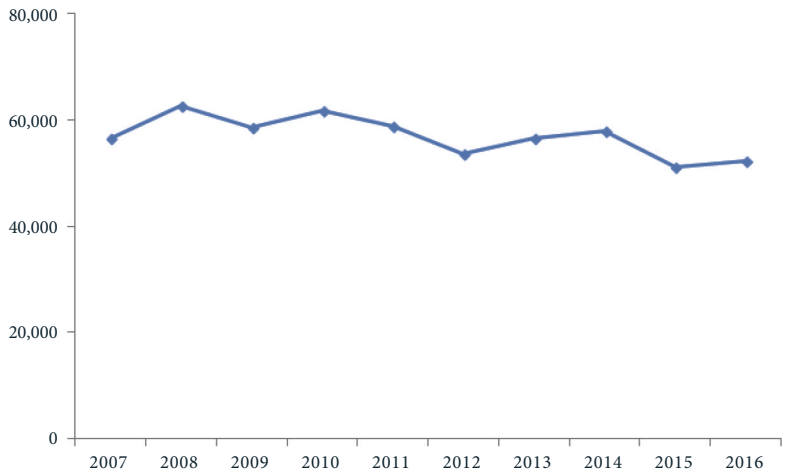
As a consequence of the safety protocols established in paid plasma donation programmes, the high sensitivity of analysis methods used, and pathogen inactivation techniques that plasma products undergo, it is difficult to argue that voluntary plasma donation is safer than the paid alternative. However, it is important to note that payment may incentivize donors to hide information which could disqualify them from donating plasma, potentially endangering both the donor and the recipients.

Payment for plasma donation has sometimes been justified on the basis that plasmapheresis takes longer than the donation of whole blood. However, other processes – such as the donation of platelets and blood-forming progenitor cells – also take longer and may be associated with more side effects. Despite this, payment to these donors has not been proposed.

We also need to consider whether payment for plasma donation could have a negative impact on those who voluntarily donate blood or other cells, if this payment is not justified by the special characteristics of this type of donation.

The voluntary plasma donation programme developed by the BST is based on information, on excellence throughout the process, the limited compensation of donors, and safety guarantees. The promotion of plasma donation, like other types of donation (blood, umbilical cord blood, breast milk) requires information about the needs for and benefits of the therapeutic administration of the biological products obtained from such donations (graph 2).

**Graph 2.** Plasma supply for manufacture of plasma derivatives




Key to promoting repeat donation on a regular basis is excellent treatment of donors during the donation process and the reward that comes from recognizing the value of their contribution and the benefits of their efforts for patients. This can be supplemented by small gifts which reinforce this recognition and gratitude.

It is essential that the plasma donation programme takes account of donor safety during plasmapheresis, along with the potential side effects that may arise from repeat donation. The plasma donation process is not usually associated with acute complications. Several publications[6,7] have shown that the plasma from donors who have participated in intensive plasmapheresis programmes has lower concentrations of total proteins, albumin, immunoglobulins (IgG, IgM) and some clotting factors (factor V and factor VIII) than the plasma from donors who donate less frequently. Despite the fact that no link has been established between these biological findings and the health of plasma donors, it is advisable to establish moderate donation programmes such as those conducted in most European countries.





## Notes

1 Herrero E. Personal communication.

2 Strengers P. Plasma is a strategic resource. Transfusion 2016; 56: 3133–3137.

3 Gunson HH. National self-sufficiency in blood and blood products. Brit Med. J 1989; 299: 1514–1516.

4 Ruiz-Antorán B et al. Use of non-specific intravenous human immunoglobulins in Spanish hospitals; need for a hospital protocol. Eur. J. Clin. Pharmacol 2010; 66: 636–641.

5 González-Guerrero C, Montoro-Ronsano JB. Evaluation of the immunoglobulin use in inflammatory systemic and immuno-mediated illnesses in a Tertiary Hospital. Journal of Pharmacy and Pharmacology 2015; 3: 194–198.

6 Laub R, Baurin, S, Timmerman D, Blanckaert T, Strengers P. Specific protein content of pools of plasma for fractionation from different sources: impact of frequency of donations. Vox Sanguinis 2010; 99: 220–231.

7 Hellstern P, Bach J, Haubelt H, Hitzler WE, Mathis S, Vogt A. The impact of the intensity of serial automated plasmapheresis and the speed of deep-freezing on the quality of plasma. Transfusion 2001; 41: 1601–1605.

# The donor's view

# Towards plasma self-sufficiency. The altruistic donation model in Catalonia

Marc Ibars

*President of the Catalan Federation of Blood Donors*

## 1. Model of blood and plasma donation in Catalonia

The Catalan blood and plasma donation model is recognized internationally and consists of two basic elements:

- The ethical commitment of voluntary blood donors, organized in associations and brought together under the umbrella of a federation. The federation and its associations have the human potential and the capacity to stimulate responsibility, public-spiritedness and community participation, and to promote international initiatives which make the country a leader in blood donation.
- A single blood bank for the whole of Catalonia, with the aim of ensuring its capacity for research and technological innovation, and focusing efforts on maximizing quality and control.

This model is setting an example, both within Spain and beyond, with the Catalan model of blood donation inspiring the four global agencies that promote World Blood Donor Day (WBDD) to nominate Barcelona as WBDD capital in 2010.

The model establishes the following objectives:

- to lead and guide new associations with regard to promotion techniques
- to design and implement measures to improve donor satisfaction
- to inform donors of their rights and duties, and about how donated blood is used





- to ensure the availability of active committed volunteers
- to share our experiences with the rest of Spain and internationally
- to promote blood, plasma and organ donation in order to achieve self-sufficiency
- to raise public awareness that blood donation is the responsibility of all citizens
- to promote a popular movement in favour of altruistic blood donation
- to recruit new donors (especially young people) and to promote regular donation by existing donors.

This model, based on altruistic donation, is supported by all international institutions: the WHO, the EU and the European Parliament, the European Blood Alliance, the International Society of Blood Transfusion, the International Federation of Blood Donor Organizations and the International Red Cross.

The WHO would like to see this model being extended globally. Currently, only 62 countries have a fully altruistic blood and plasma collection model. The DOMAINE project (European Donor Management) reports that the donations of 83% of blood banks in the European Union are altruistic. The WHO's aim is for all countries to move to fully altruistic donation over the next eight years.

In Spain, remuneration has been prohibited since Royal Decree 1088/2005 (PNH, adopting European directives). Blood, plasma and cell components may only be donated on a voluntary, altruistic basis, without payment in cash or in kind where this might be deemed to constitute a cash substitute.

Altruism guarantees the non-commercialization of the human body – whether in the donation of whole blood, organs, tissues etc. – and democratic access to blood, organs, plasma and tissues, and ensures that their availability is not affected by economic cycles.

The Catalan blood donation model is one of the most advanced and efficient in the world, regularly permitting up to a thousand blood donations per day, and meeting the spikes in demand that may arise due to exceptional situa-

tions, so that all patients in Catalonia have sufficient safe blood when they need it. This model also maximizes quality and control.

In 2016 we obtained 8,000 litres of plasma for transfusion and 52,000 litres of plasma for plasma products, from 243,000 whole blood donations and 10,000 plasmapheresis donations.

## 2. What do we mean when we talk about plasma self-sufficiency?

In order to cover patients' clinical needs, we must double the number of litres of plasma allocated to plasma products (from 10,000 to 20,000 plasma donors). We will achieve this by working hand in hand with the Catalan Federation of Blood Donors, the BST, public institutions and the private sector.

We have already developed a plasmapheresis programme designed to deliver self-sufficiency over the coming years.

At the BST, in partnership with the Federation and associations, we have launched a plasma donation plan to achieve self-sufficiency. For this to be successful, we must involve institutions and the industry so that all of the sub-products of plasma donation are utilized, either within or outside Catalonia, and so that hospitals prioritize the use of products from altruistic donation (plasma albumin).

The Catalan plasma management model ensures:

- maximum use of donations
- fractionation of all units of whole blood
- partnership with local fractionation industry to obtain plasma-derived products
- distribution of plasma-derived products by BST
- transparency with blood donors
- desire to achieve self-sufficiency.





## 3. Blood and plasma donation in Catalonia (2012–2016): towards self-sufficiency

The table clearly shows that, while blood donations have fallen (although they remain sufficient to supply our hospitals), plasma donations have more than tripled. This trend is set to continue over the coming years.

| | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|
| Blood donations | 271,901 | 253,783 | 248,005 | 247,757 | 243,023 |
| Plasma donations | 2,336 | 2,002 | 6,580 | 7,651 | 8,475 |
| Other donations | 1,650 | 1,487 | 1,509 | 1,538 | 1,665 |
| Total | **275,887** | **257,272** | **256,094** | **256,946** | **253,163** |

Source: Data from Blood and Tissues Bank of Catalonia (2012–2016)

Further information is available at the following:

- *Campaña para los 10,000 donantes de plasma*: bancsang.net/blog/necessit-en-10-000-donants-plasma/ [10,000 plasma donors needed]
- *1ª Maratón de donación de plasma de Cataluña*: elgarrotxi.cat/video-ex-it-de-la-primera-marato-de-donacio-de-plasma-de-catalunya/ [Video: Plasma donation maratón]
- *La donación de sangre voluntaria, un asunto pendiente*: bancsang.net/blog/donacio-sang-voluntaria-assignatura-pendent-paisos/ [Voluntary blood donation: an ongoing concern]
- *10 facts on blood transfusion*: http://www.who.int/features/factfiles/blood_transfusion/en/

# A donor's journey


## Christian Rovira

*Donor and Director of Communications at ESCI-UPF*


Social media have transformed the way we communicate with each other. Companies have no choice but to adapt to this digital revolution, and blood donations have, inevitably, been affected by this change.

In my opinion, blood donation is a completely altruistic act, as is the act of sharing on social media when one gives blood. Communicating this experience satisfies two drives: to share a positive act (and thus satisfy one's ego!) but also to influence other people to support a good cause.

This new social and communications context has created an opportunity that the Blood and Tissues Bank (BST) has exploited, providing access to regular blood donors who shared their experience via social media. All that was required was to create a shared message to amplify the communication, and word of mouth did the rest.

The "First Big Marathon for Blood Donors 2.0: Catalonia" was a spectacular communication campaign, organized by the BST at the end of 2012. Timed to coincide with Christmas, when blood reserves are at their lowest point, and with the altruistic collaboration of blood donors who were also keen Twitter users, the aim was to achieve 5,000 donations in just three days. That was my "baptism of fire" in the world of blood donation.

I worked with the BST sharing messages with the hashtag #MaratóDonants (donors' marathon) on social media, took part in a radio discussion and a TV programme, and participated in the debate on blood donation at the Academy of Medical Science, organized in response to some controversial statements by Mr Grifols.

Following the debate, and although there was a large gap between our views, Grifols invited me to visit the company's facilities so I could see what they do. This gave me a broader view of the manufacture of plasma-derived medicines, an industry of which I previously had almost no knowledge. The visit enabled me to understand the difference between blood and plasma donation, and caused me to revise my opinions.

My work at ESCI-UPF provided another opportunity to learn about the world of blood donation. Clàudia Pardo, who in 2014 was a 4th year student on the International Business and Marketing degree, contacted me because she was interested in doing her undergraduate thesis on plasma donation.

For her "Study of potential plasma donors and their motivations", she received amazing support from the Blood and Tissues Bank and from Grifols, she did extensive research and reading, analyzed databases, conducted personal interviews, held focus groups with donors and non-donors, and created a questionnaire designed to identify the reasons for donating plasma.

She offered two key main conclusions:

1. Blood donors are more likely to donate plasma, an action they view as altruistic and voluntary.
2. There is a lack of knowledge about plasma donation and the plasma products industry.

I will share the results of Clàudia's research, although I believe that, in the case of plasma donations, altruism should receive some kind of social recognition. It could be a tax incentive or another option, but I believe we should find a formula that "rewards" donors, as they need to be prepared to make regular donations, something which requires both willingness and time.

What follows is a summary of Clàudia Pardo's detailed undergraduate thesis, which won the prize for best thesis, 2013–2014.

# Study of potential plasma donors and their motivations

## Report

This report summarizes the methodology and conclusions of "Study of potential plasma donors and their motivations" by Clàudia Pardo. The study aimed to identify who potential plasma donors are and what motivates them.

In order to understand this behaviour and the main motivations for it, the first stage was to conduct a literature review on the subject. Due to the lack of up-to-date studies of plasma donors and their motivations, the author decided to supplement the bibliography with studies of the behaviour of blood donors and their motivations.

Firstly, she looked for information about the definition of altruism and the different types of altruism that have been identified. She then used various studies of altruism in blood donation, identifying the motivations deriving from each type of altruism. On the basis of this, she identified altruism profiles that were also applicable to plasma donations, with the ultimate aim of identifying the most common type of altruism in the plasma donation system in Catalonia and, as a consequence, the motivations behind it. She also looked for information about incentives, classifying them on the basis of the categories used by AABB-Advancing Transfusion and Cellular Therapies WorldWide.

In parallel, she studied the plasmapheresis process and how it differs from blood donation. She also identified the different international models in operation – and the corresponding donor types – from the perspective both of international organizations (for example, the WHO) and of existing models in Germany, the United States, Italy and Spain.

Next, using all of the information about motivations and types of blood donor (from reference studies), the factors that influence blood donations were identified and extrapolated to the case of plasma donation. These factors were classified as: environmental factors (culture, religion, existing donation model, beliefs about blood donation, etc.); factors relating to potential donor (gender, parental status, public recognition, conscience, social pressure, etc.); factors relating to the donation event (time, level of knowledge about use of donation, medical centre team, etc.); and factors that lead people not to donate (such as fear and ignorance).

The factors were then screened, with the most significant, observable, analysable and quantifiable being included in the subsequent stages of the study, while factors that could not be observed or quantified were excluded.

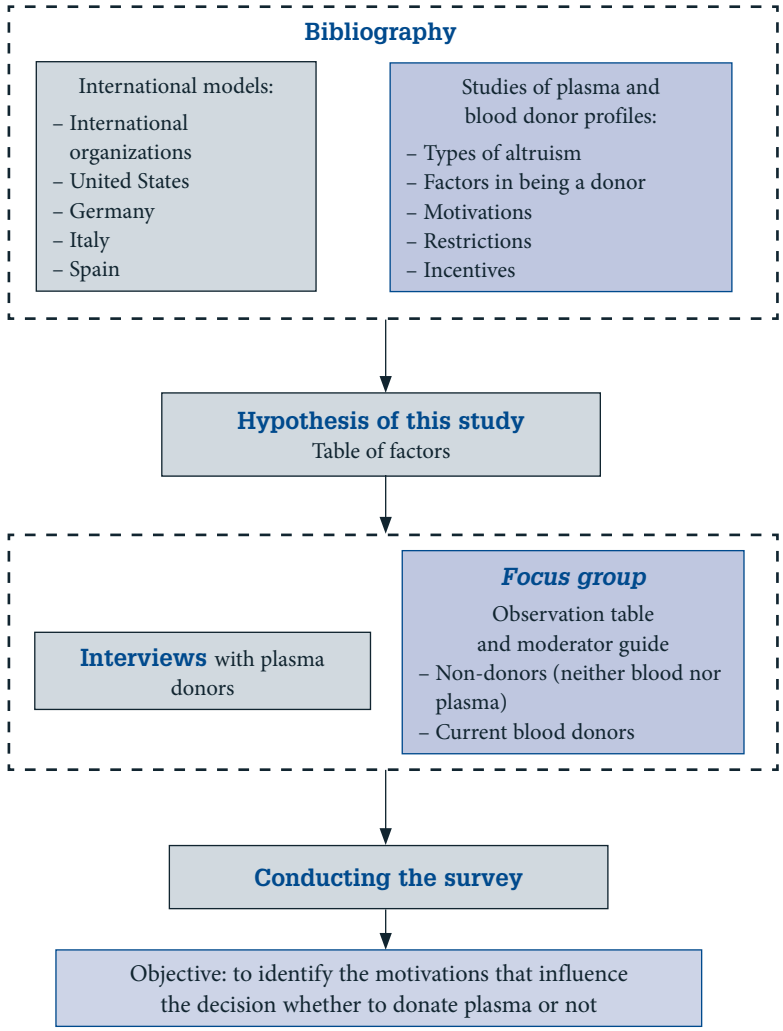
The selected factors were: gender, age, knowledge and awareness of plasma donation, motivations (including thoughts and feelings, incentives, the





impact of donation on society, having received communion as a child, or experience of volunteering) and the perception of the importance of time.

The process is shown in the following diagram:



## Focus group

To identify which motivations influence the decision about whether to donate plasma, it was important to distinguish between two populations of potential plasma donors: non-donors (of blood or plasma) and current blood donors. As a result, two focus groups were created, with the aim of observing and comparing the principal motivations, incentives and factors influencing the decision whether or not to donate blood and plasma, and to determine if there were differences between the motives and factors affecting the decision to donate plasma among current blood donors and non-donors.

With the aim of ensuring that the sample was as representative and diverse as possible, individuals were selected according to variables of gender and age as a function both of the total population of Catalonia in 2013 (in the case of non-donors) and of the total population of blood donors (in the case of blood donors). Two focus groups were established: one of non-donors, with eight members; and one of blood donors, with six members.

For the focus group, a table of factors was drawn up, identifying which factors were measurable and which were not. For the factors to be measured using participant responses – non-quantifiable factors – an evaluation table to rate participant responses was created, using the considerations and classifications drawn from reference studies.

A script was provided for the focus group discussion, containing questions and visual techniques to promote discussion.

A guide was produced for the moderator, and observation tables for observers to evaluate each of the factors identified above. The observers then familiarized themselves with the evaluation table in two sessions, to ensure they had sufficient knowledge of the topics to be discussed in the focus group, and to discuss the structure, evaluation table and each of the parameters.

The focus group was then held on 27 February 2015.

### *In-depth interviews with plasma donors*

Due to the small size of the plasma donor population, it was decided to use the focus group questions and interview plasma donors during a mobile campaign at Esparraguera. Six plasma donors were interviewed on 4 March 2015. The aim was to identify whether the factors that influence the decision to donate blood (or not) are the same as those for plasma donors.





### *Survey of blood donors*

The results of the focus group and interviews were used to design a survey of blood donors with the aim of validating if the following factors are relevant to the decision to become a plasma donor:

- gender
- age
- level of education
- being a regular blood donor or not
- type of altruism
- knowledge of plasmapheresis
- whether the motivations for donating plasma would be the same as those for donating blood.

The survey was drawn up using reference studies and the conclusions obtained from the focus groups and interviews.

As one of the variables was the level of knowledge and, after acquiring it (if they didn't already have it) participants were asked to talk about the motivations that they thought would change, and those that wouldn't, it was decided to create a video explaining what a plasma donation is and what it is used for. A pilot test was conducted with ten individuals to check whether the scales used were appropriate and if the time for the questionnaire was sufficient.

With an approximate population of 191,000 blood donors in 2013, the survey would need to be distributed widely to obtain a response ratio of 0.20% of the population. The questionnaire was designed and formulated based on the methodology used, with the idea that, following the study, any organization wishing to quantitatively evaluate the results should be able to do so publicly.

### *Conclusions*

The plasma donation system, independently of existing legislation and policies, is seen by donors as altruistic and voluntary. This is reflected in the conclusions.

According to the interviews, the motivations leading a section of the population to donate plasma are the same as those leading another part of the population to donate blood; this would need to be verified at the whole population level using the survey.

Blood donors are more likely to donate plasma because they have better access to information about plasma donation as a result of their links to the Blood and Tissues Bank. Due to lack of knowledge, the non-donor population does not consider donating plasma. It would therefore be worth informing this large segment of the population of the growing need for plasma. In other words, the lack of awareness of the possibility of donating plasma and why it is needed results in people not considering making a donation.

According to the conclusions observed in the focus group and the interviews, time is not a limiting factor and – according to participants – once you're at the donor centre, another 20 minutes makes no difference. This would need to be verified by survey.

Although a single plasma donation does not allow donors to observe the direct impact of donation, during interview both the members of the blood donor focus group and the current plasma donors considered that the motive for donation was the same.

Knowledge about the existence of plasma donation is therefore the key point for donating plasma. It is important to make the Catalan population aware of this possibility, what it is for and how the plasma is processed.

Finally, it should be noted that regular blood donors will find it easier to become plasma donors because, as regular donors, they are the group most likely to donate plasma regularly if they are informed.

# The prescriber's view

## Javier de Gracia

*Head of Pulmonology Service, Vall d'Hebron University Hospital*

Progress in transfusion medicine over recent decades has meant that the transfusion of blood and plasma products is safer than ever before, particularly with respect to the risk of infection or adverse reactions. The principal purpose of administering plasma products is the treatment of specific processes in patients who require this therapy and for whom there are no alternative treatments. Plasma products are used to maintain or restore sufficient blood volume to prevent or counteract hypovolemic shock; to maintain and restore the capacity to transport oxygen in the blood; and to replace specific components, such as plasma proteins or other elements (red blood cells, platelets or white blood cells) a deficit of which would seriously compromise the patient's life.

Plasma is the liquid component of blood and represents 55% of total volume. It consists of 90% water, 7% plasma proteins such as albumin globulins, alpha-1 antitrypsin and clotting factors, and 3% other organic components such as vitamins, hormones, glucose, ions etc. The ions, proteins and other molecules in plasma are essential to maintain blood pH and osmotic balance, in which albumin (the main protein in human plasma) plays a particularly important role. Other proteins have more specialized functions: antibodies for example, recognize and neutralize pathogens, while clotting factors promote the formation of blood clots in wounds.

A significant portion of blood consists of immunoglobulins, which the WHO defines as an essential medicine.[1] Immunoglobulin, for example, is increasingly recognized as an effective treatment for a wide variety of medical conditions, not only due to its capacity to fight infections as replacement therapy but also for its anti-inflammatory and immunomodulatory effects. The clinical indications for intravenous immunoglobulin (IVIG) which have been authorized by the FDA[2] include: the treatment of primary immunodeficiencies; the prevention of bacterial infections in patients with hypogammaglobulinaemia and recurring bacterial infection due to chronic B cell lymphocyte leukaemia; the prevention of coronary artery aneurisms in Kawasaki disease; the prevention of infections, pneumonitis and acute illness following host rejection and bone marrow transplant; reduction of serious bacterial infection in children with HIV; increased platelet count in idiopathic thrombocytopenic purpura to prevent or control bleeding; treatment of chronic inflammatory demyelinating polyneuropathy and, recently, multi-focal motor neuropathy. And, while treatment with immunoglobulins is essential for a wide range of diseases, it may also be clinically useful in many others included in the National Guideline Clearinghouse.[3,4] Because current IVIG preparations are produced from human plasma and require a number of steps, the supply of such products is limited and their use must be considered carefully. This means that immunoglobulin therapy must be applied where the evidence is strongest and where it provides the greatest clinical benefit.

As we have noted, the availability of plasma products, including immunoglobulins, is finite. The raw material is limited, the technology required to collect it is also limited (and costly), the products have a limited shelf-life and stability, and only a few of them can be manufactured using genetic recombination techniques. To this we must add the fact that they are essential treatments for which demand is continuing to grow, and there are no alternatives available. It is hardly a surprise that governments classify their manufacture as a strategic activity.

The big challenge we face is how to resolve the imbalance between supply and demand without harming patients. As doctors, we need to be responsible in our prescribing practices; the manufacturers of plasma products must apply the tightest possible safety measures to their manufacturing and handling activities; and governments must strive to stimulate R&D and promote donation. The WHO recommends that countries should have efficiently organized, well-integrated supply networks to coordinate all activities related to the extraction, verification, treatment, storage and distribution of blood, at a national level. The national transfusion system should be governed by national policies and legislation on blood transfusion to ensure uniform standards, and to promote the quality and safety of blood and blood products. In Spain and Catalonia, we have associations of unpaid voluntary blood donors who

do amazing work so that these treatments can be made available to everyone who needs them. And we also have an efficient organization of blood banks and one of the largest plasma product manufacturing sectors. Despite all of this, however, we are still unable to cover our own needs for plasma products and, like most countries, have to import them. Spain currently covers all of its blood transfusion needs, 80% of albumin and 48% of immunoglobulins, according to the president of the Spanish Blood Transfusion Society (SETS) and Fundación CAT.[5]

World Health Assembly Resolution WHA63.12 recommends that all member states should develop national transfusion systems based on low-risk unpaid voluntary donors, and should work to achieve self-sufficiency. The WHO also states that it is the responsibility of every government to guarantee adequate and fair supplies of plasma-derived products such as immunoglobulins and clotting factors, needed to prevent and treat serious conditions that are found in every region of the world. The European Parliament also endorses a strategy of self-sufficiency and safety in blood supplies, using unpaid voluntary donations in the European Union. In Spain, Royal Decree 1945/1985 establishes donation as a voluntary altruistic act and prohibits paid donation.

As doctors treating patients who suffer from illnesses requiring treatment with plasma products, we agree that all necessary measures should be taken to ensure the availability of blood and plasma products that meet the highest quality and safety standards. We are also in favour of unpaid altruistic donation, but we believe that self-sufficiency is equally important. And the reality is that – with the exception of a small handful of countries (which does not include Spain) – there is no self-sufficiency and we have to import these products, primarily from the United States.

What prevents us from being self-sufficient? Although Spain follows WHO and Council of Europe recommendations, our legislation actually goes further, prohibiting all donation which is paid or rewarded in any way, something that is not excluded by the aforementioned institutions. The result is that we import from other countries – whose donations may indeed be paid or otherwise remunerated – somewhat more than 50% of the plasma products in which we are not self-sufficient. The question that arises is clear. Why





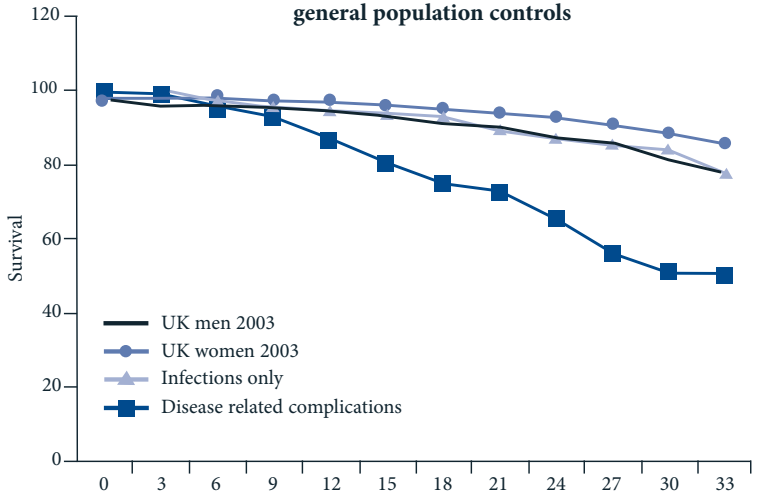
don't we authorize the collection of plasma products from paid or remunerated donors to achieve self-sufficiency, as occurs in other countries? Plasmapheresis technology makes it possible to extract plasma from blood and return the other cells to the donor and this, in turn, enables more frequent donation.

Many people have expressed their opposition to such an approach. Of these, the view for which I have most respect is that of blood donors and their associations, who have enabled many patients to continue with their lives. Some argue that, if we authorize paid or remunerated donation, those of us who already donate (or have done so in the past) might feel cheated because others would be paid for something that we do altruistically, or we might lose our motivation for donating. It is possible that some donors would stop donating, although I certainly wouldn't; I would just need to remind myself that the purpose of my donation is to help improve or save the lives of those who need something that only we can offer, and that at present we are a long way from achieving self-sufficiency.

Another argument, which many find convincing, is that donations should not be paid because altruistic donations are safer than paid ones because the latter provide an incentive for risk by encouraging people to conceal information that might lead to their exclusion. This is indeed a danger, but it is precisely for this reason that so many safety measures are applied to the manufacture of plasma products, measures whose effectiveness has been demonstrated for many years. Plasma products can never be one hundred per cent safe, particularly if they come from unknown donors, but it is also true that there is no absolute guarantee of the safety of raw material that has been donated altruistically. The reality is that Spain acquires the additional plasma products it needs from countries where they are primarily manufactured from raw material obtained by plasmapheresis from paid or compensated donors; in other words, we already accept the possible risk associated with paid donors. This means that Spain imports plasma products obtained from groups considered to be high-risk, a practice prevented by the law in our country, but the products themselves can be administered because they have been approved by the FDA (US Food and Drug Administration), the European Medicines Agency (EMEA) and the Spanish Medicines Agency (AEM). I can only conclude that

these three bodies – all of which are committed to safeguarding the efficacy and safety of medicines – take the view that these products comply with the highest quality and safety standards required of biological products, irrespective of whether they come from paid or unpaid donors, as the safety standards applied to their production are the same. As a prescriber of one of these products, immunoglobulins, I know that if I do not prescribe it to those patients for whom it is indicated, in the correct dose and frequency (figures 1 and 2), their lives will be significantly shorter, and they may suffer serious infections or develop chronic conditions that will have a major impact on their quality of life.[6,7,8] For all these reasons, Spain must be self-sufficient and not be vulnerable to the shortages of these products that regularly occur due to production shortfalls or spikes in demand. We can be self-sufficient: we have plasmapheresis technology, networks of blood banks, a strategic plasma products industry and a community of dedicated altruistic donors. All that

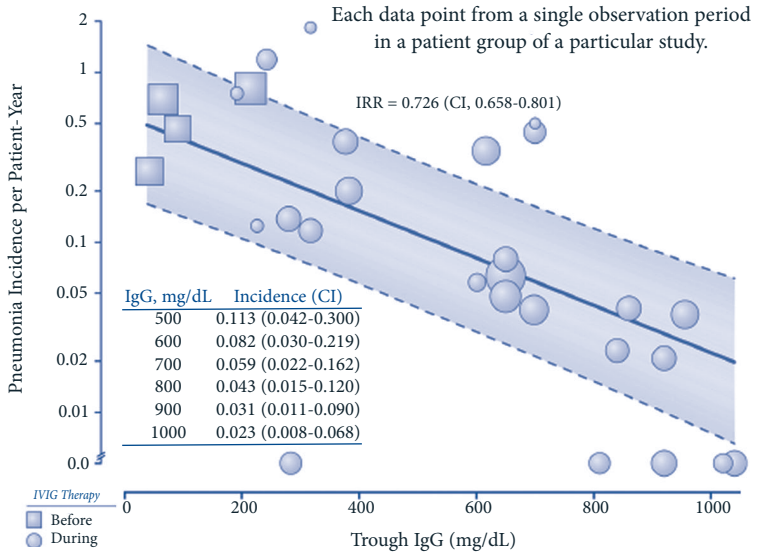
**Survival (as %) of patients with CVIDs, with or without disease related complications, compared with UK general population controls**




[UK controls corrected for median age at diagnosis of cohort (33 years)]








remains to be done is for parliament to consider reforming the law, taking into account the views of all groups with a stake in this issue, and to recognize paid donation as occurs in some other countries.

Finally, it is worth considering the definition of health formulated by the WHO in 2017: health is the state of complete physical and social well-being. The WHO believes that enjoying the maximum level of health possible is one of the fundamental rights of every human being. This includes access to high-quality health services, the freedom of each person to control their health and their body without interference, and the right to have the same opportunity as everyone else to achieve the highest level of health.[9]

## Notes


1 WHO. The expert committee on the selection and use of essential medicines. 20th WHO. Essential Medicines List (EML) and the 6th WHO. Essential Medicines List for Children (EMLc) 2017. Available at: http://www.who.int/entity/selection_medicines/committees/en/index.html

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9 WHO, World Health Day, 7 April 2017







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## 1. Current prescription scenario

Some plasma products are classified by the WHO as essential medicines, and some countries even classify them as strategic resources. This is because plasma and its derivatives are essential to prevent and treat a significant number of diseases.[1] Despite this, both in Catalonia and in most other countries across the globe, we are not self-sufficient in plasma products.

Over recent decades, evidence has accumulated demonstrating the efficacy of these products not only for "classical" indications but also for other diseases. This is illustrated by the fact that, over the last ten years, the list of conditions for which there is evidence for the use of immunoglobulins has expanded, particularly in the field of immune-mediated conditions.[2,3] In addition, medical and socioeconomic progress is making it possible to diagnose a growing number of patients who could benefit from these products. And, while there are risks associated with the use of biological products, the fact that they must satisfy strict safety and quality standards means that health professionals perceive them to be safe. These factors, among others, explain why demand for plasma products is growing at an estimated annual rate of 6 to 8%.[4]

## 2. Actions to improve self-sufficiency

We need health policies designed to promote responsible use of plasma products, as uncontrolled prescription could have a negative impact both on the availability of these medicines for patients and on the economic cost for the health system. However, control measures alone (proactive controls by hospital pharmacy services, dose optimization, training of prescribers, etc.) are not enough to ensure self-sufficiency given that, as noted above, demand for plasma products continues to rise.

Collecting plasma from whole blood is subject to limited yields (a maximum of one litre of plasma per year, per donor). In addition, technical progress means that the need for red blood cell transfusions and thus for blood donations is declining.[5] As a consequence, whole blood donation does not generate sufficient plasma for fractionation to guarantee self-sufficiency in plasma products.

The majority of global plasma comes from plasmapheresis, the only technique that makes it possible to obtain a significant quantity of plasma per patient. Most of this plasma comes from paid plasmapheresis (80% from the United States) and is fractionated primarily by private companies. World Health Assembly resolutions and European directives promote self-sufficiency by voluntary donations wherever possible. In light of the existing legal context, one measure that could have a significant impact would be to invest resources in information campaigns to promote voluntary plasma donation by plasmapheresis. This measure has great potential, as is demonstrated by the fact that Catalonia has always been self-sufficient in red blood cells, even in situations of rapid spikes in demand, and we should also remember the enthusiasm for volunteering demonstrated at events such as the Barcelona Olympics of 1992 or the *Marató* drive on TV3.

Other measures to consider are improved fractionation efficiency, the optimization of pharmacokinetics or obtaining medicines with lower rates of inhibitors. In this respect, recombinant technology already offers the possibility of manufacturing medicines to treat hemophilia,[6] while gene therapy is a real option for some types of immunodeficiency. It is therefore reasonable to hope that in the future other pathologies could also benefit from these technologies, thereby further reducing the demand for plasma.

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# The patient's perspective

**Otília Ragull**

*Vice-president of the Catalan Haemophilia Association*

# Patient perception of need for treatment with plasma products, and evaluation of current policies in our health system

## 1. Haemophilia in Catalonia

Haemophilia is a genetic disorder which causes clotting factor deficit. The best-known of the congenital clotting disorders are haemophilia A, which consists in a deficit or absence of clotting factor VIII; haemophilia B, which entails a deficit or absence of clotting factor IX; and von Willebrand disease, which alters one of the coagulation components with this name.

The Catalan Haemophilia Association has 318 members with haemophilia A, 60 with haemophilia B, 126 with Von Willebrand disease and 42 with other, rarer clotting disorders. Of these, 80% are adults, while 103 members are minors.

During the 1980s, approximately 80% of patients with congenital clotting disorders treated with plasma derivatives were infected with HIV or hepatitis C. To date, more than 130 of these people have died, and the association currently has 80 members living with both HIV and hepatitis C, and 118 living with hepatitis C.

With respect to the severity of their condition, 221 of the association's members are classified as severe (defined as having less than 1% of the affected clotting factor). This means they are at risk of spontaneous haemorrhage. A further 111 members have a clotting disorder classified as moderate (producing between 1% and 5% of the affected factor) while 96 individuals are classified as mild (between 5% and 40%). We do not have records of the severity of the other members' condition.

## 2. Treating haemophilia

The treatment of congenital clotting disorder is complex and can involve a number of different approaches, which we will not discuss in detail here





(treatment on demand, prophylactic treatment, analgaesia, anti-inflammatories, rehabilitation, etc.).

However, the priority and most appropriate treatment to stop major haemorrhage is intravenous administration of the deficit clotting factor. Clotting factors can now be derived from a number of sources: plasma-derived products, recombinant products (which may use animal cells), long-lasting recombinant products, bypass products for inhibitors, etc. And haemophilia treatment has developed radically over time.

In broad terms, we can summarize this as follows:

- Mid-1960s: cryoprecipitates
- 1970s: pfVIII concentrates, treatment at home, prevention, screening donors for HBV
- Early 1980s: appearance of AIDS, heat-based viral inactivation
- Mid-1980s: screening donors for HIV, intermediate purity plasma fVIII concentrates
- Late 1980s: high-purity plasma fVIII concentrates, chromatography technique
- Early 1990s: recombinant fVIII, HCV screening
- Late 1990s: HAART, recombinant FIX, nanofiltration
- Early 2000s: gene therapy, IFN-RBV, changes in manufacture of rfVIII
- Late 2000s: changes to formulation of rFIX.

## 3. Need for treatment with plasma derivatives

Despite advances in treatment and the multiple therapeutic options now available, the reality is that plasma-derived and recombinant factor currently co-exist.

As an association which advocates the best treatment for people with congenital clotting disorders, we need to ensure that:

- no person with haemophilia is ever left without treatment
- it is possible to choose between different therapeutic alternatives

- the safety and efficacy of treatments is always guaranteed
- exhaustive safety procedures are applied.

And above all, we advocate a healthcare system that is public, universal, fair and not subject to the laws of the market, one that is based on justice and the social right to access health services.

## 4. Evaluating current policy

We need to consider how global health issues are managed and regulated, and we need to analyse the responsibility of authorities, institutions and associations with respect to models for obtaining material of human origin, particularly given its scarcity.

According to the World Health Organization (WHO), the best way to guarantee a safe adequate supply is through altruistic donation, both of blood and of plasma.

This is defined as a voluntary selfless act to help others, and for which no benefit or payment is expected. Such donations occur without any pressure to do so and where the potential recipient is unknown to the donor. Donation is motivated by a commitment to the common good, and depends on social awareness.

Spain is one of 62 countries where all blood donations are altruistic. Other countries have a dual system in which there is compensation for travel or for the time spent donating.

The WHO has set a goal for all countries to establish altruistic donation processes by 2020. However, the situation is complex because some countries are self-sufficient in whole blood donations but not in plasma, and they thus remain reliant on plasma from countries where extractions are remunerated.

At present, both in Spain and elsewhere, there is a lively debate as to whether remuneration is ethically justifiable as a means of achieving self-sufficiency.

In Europe in 2013, the WHO and other international organizations in the world of health and human rights issued the Rome Declaration advocating





the need for self-sufficiency in safe blood and blood products, based on unpaid voluntary donations.[1]

## 5. Arguments for and against the altruistic and paid models

Some of the arguments in favour of altruism are:

- clinical: it has been shown that altruistic donors are more truthful as potential donors do not hide information to avoid exclusion;
- social solidarity: a belief in the common good;
- ethical, relating to human dignity: if the act of donating blood is remunerated, we are no longer talking of donation but of sale.

The main problem is that we cannot guarantee self-sufficiency if there is no clear wish to do so. By contrast, while the paid model ensures that demand is covered and can be defended on the grounds that the ends justify the means, the question is whether this makes it ethical.

Does the inclusion of a financial aspect undermine solidarity? How much should donors be paid? Who sets the price? Will all patients receive the resulting medicines? Under what conditions? Where is the limit? (One could even use the same line of argument to advocate paying for transplants.)

*Not everything that is effective is ethical.*

## 6. Conclusions

To summarize, the altruistic model of blood and plasma donation is inherently ethical, and if altruism delivered self-sufficiency, then there would be no question of remuneration. We believe in a public, universal healthcare model, in which resources such as blood and plasma are not subject to the laws of the market.

Society should seek to promote regular altruistic donation and to design policies and plans to guarantee self-sufficiency. And this does not involve paying

donors or importing plasma derivatives, but implementing health policies designed to increase donations, to educate people and to promote social responsibility and solidarity, to invest in promoting donation and encouraging donors to attend regularly.

For the sake of patients, there should never be a lack of plasma, and this should always be of the highest quality, something that can be achieved through an altruistic model. If the authorities, industry and civil society (both patients' and donors' associations) have the will, then the ethical debate around remuneration will become obsolete.

Finally, if you wish more information you may want to consult the following articles:

WHO Blood safety and availability. Available at: http://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability

Serrahima Mackay G. Aspectos éticos de la obtención de sangre y plasma: una cuestión de salud global. Available at: http://diposit.ub.edu/dspace/bitstream/2445/99342/2/spa_TFM_Gemma_Serrahima_2016.pdf

## Note

1 High-level policy makers forum on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated donation. The Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation. Rome; 8–9 October 2013 p. 1.

# List of participants

## Speakers

- David Bell, Chair of Global Board of Directors of the Plasma Protein Therapeutics Association (PPTA)
- Victoria Camps, President of the Víctor Grífols i Lucas Foundation
- Javier de Gràcia, Head of Pulmonology Service, Vall d'Hebron University Hospital
- Marc Ibars, President of the Catalan Federation of Blood Donors
- Lluís Puig, Care Director, Blood and Tissues Bank of Catalonia
- Otília Ragull, Vice-president of the Catalan Haemophilia Association
- Christian Rovira, donor 2.0 and Director of Communications, ESCI-UPF
- Xavier Solanich, Internal Medicine Service, University Hospital of Bellvitge

## Invited specialists

- Enric Argelagués, Managing Director of the Blood and Tissues Bank of Catalonia
- Javier Arias, Professor of Surgery, Complutense University of Madrid
- Josep M. Busquets, Secretary of the Bioethics Committee of Catalonia
- Teresa Español, Scientific Advisor to the Spanish Association for Primary Immune Deficiencies (AEDIP)
- Jesús Fernández, Blood and Tissues Bank Unit, Vall d'Hebron Hospital
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- Eduardo Herrero, Assistant President, Grifols Bioscience Ind. Group
- Raquel Lumbreras, Grifols press office
- Elvira Mallafré, Blood and Tissues Bank of Catalonia
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- Aurora Masip, Communications Director, Blood and Tissues Bank of Catalonia
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- Josep Monterde, President of Asserta Foundation
- Francisco Montero, Supervisor of Clinical Laboratories, Vall d'Hebron University Hospital
- Pilar Ortiz, Blood and Tissues Bank of Catalonia
- Joan Ovejo, Director of Operations and Engineering, Blood and Tissues Bank of Catalonia
- Elisenda Papiol, Director of Corporate Communications at Grifols
- Clàudia Pardo, Open Innovation Consultant at Induct
- Rafael Parra, Coordinator of the Haemophilia Unit, Blood and Tissues Bank of Catalonia
- Mariano Pastor, President of the Alpha-1 Association Spain
- Joan Profitós, Blood and Tissues Bank of Catalonia
- Gaspar Puig, President of the Catalan Association for Primary Immune Deficiencies (ACADIP)
- Àngel Puyol, Professor of Moral Philosophy and Politics, Autonomous University of Barcelona

- Bernabé Robles, Neurologist and Chair of the Clinical Ethics Committee, Parc Sanitari Sant Joan de Déu
- María Rodríguez, Blood and Tissues Bank Unit, Vall d'Hebron Hospital
- Gemma Serrahima, philosopher specializing in social rights in health and care ethics
- Fuensanta Soria, Vice-president of Alpha-1 Association Spain
- Núria Terribas, Director of the Víctor Grífols i Lucas Foundation

# Publications

## Bioethics monographs

47. *Ethics and plasma donation: an overview*
46. *Comités de Ética y consultores clínicos: ¿complemento o alternativa en la ética asistencial?* (Ethics committees and clinical advisors: complementary or alternative approaches to clinical ethics?)
45. *CRISPR... ¿debemos poner límites a la edición genética?* (CRISPR: Should there be limits on genome editing?)
44. *Crisis y salud mental en niños y jóvenes: ¿causa o consecuencia?* (The crisis and mental health in children and young people: cause or effect?)
43. *¿Debemos revisar el concepto de muerte?* (Do we need to reconsider the concept of death?)
42. *Iatrogenia y medicina defensiva* (Iatrogenesis and defensive medicine)
41. *Eutanasia y suicidio asistido* (Euthanasia and assisted suicide)
40. *Ethical aspects of research with children*
39. *Discapacidad, nuevos enfoques y retos éticos a la luz de la Convención de la ONU* (Disability: some reflections on the position of the United Nations)
38. *Ética, salud y dispendio del conocimiento* (Ethics, health and waste of knowledge)
37. *Determinantes personales y colectivos de los problemas de la salud* (Individual and collective determinants of health problems)
36. *Ética y altruismo* (Ethics and Altruism)
35. *Treinta años de técnicas de reproducción asistida* (Thirty years of assisted reproductive technology)
34. *Ética de la comunicación corporativa e institucional en el sector de la salud*
33. *Alcance y límites de la solidaridad en tiempos de crisis* (The scope and limits of solidarity in times of crisis)
32. *Ethics and public health in times of crisis*
31. *Transparencia en el sistema sanitario público* (Transparency in the public health system)
30. *The ethic of care*
29. *Case studies in ethics and public health*
28. *Ethics in health institutions: the logic of care and the logic of management*
27. *Ethics and public health*
26. *The three ages of medicine and the doctor–patient relationship*
25. *Ethics: an essential element of scientific and medical communication*
24. *Maleficence in prevention programmes*
23. *Ethics and clinical research*
22. *Consent by representation*
21. *Ethics in care services for people with severe mental disability*
20. *Ethical challenges of e-health*
19. *The person as the subject of medicine*
18. *Waiting lists: can we improve them?*
17. *Individual good and common good in bioethics*
16. *Autonomy and dependency in old age*
15. *Informed consent and cultural diversity*
14. *Addressing the problem of patient competency*
13. *Health information and the active participation of users*
12. *The management of nursing care*
11. *Los fines de la medicina* (Spanish translation of *The goals of medicine*)
10. *Corresponsabilidad empresarial en el desarrollo sostenible* (Corporate responsibility in sustainable development)
9. *Ethics and sedation at the close of life*
8. *The rational use of medication: ethical aspects*
7. *The management of medical errors*
6. *The ethics of medical communication*
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## Reports

6. *La interacció públic-privat en sanitat* (Public–private interaction in health care)
5. *Ethics and synthetic biology: four streams, three reports*
4. *Las prestaciones privadas en las organizaciones sanitarias públicas* (Private provision in public health organizations)
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