ETHICAL ASPECTS IN OBTAINING BLOOD AND PLASMA:

A GLOBAL HEALTH ISSUE.

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Abstract

This article aims to specify the arguments supporting the world's two most

widespread models for obtaining blood and plasma: the so called paid-donation model,

by which blood and plasma are obtained in exchange for payment, and the altruistic

model, by which blood and plasma¹ are obtained through unpaid donations. The

intention is to make an ethical evaluation.

Blood management is a little known subject that needs to be divulged in the face of

the legal and policy changes that are occurring worldwide with access to universal

healthcare. Therefore, it is imperative to understand what use is made of this raw

material, how countries organize themselves to obtain it, and to evaluate whether it is

necessary to consider new lines of action, given that it is a limited resource. Blood can

only be obtained from living persons, so how it is obtained opens a crucial ethical

debate, bringing to the fore what conception we humans have of ourselves, what value

we give health and what model of society we want.

Keywords: ethics, efficiency, remuneration, altruism and social justice

Introduction

Before directly addressing models for obtention, we will briefly define related terms

-donation, solidarity and altruism- as they are often used erroneously. Rather than

making a philosophical inquiry, the aim is to clarify the common use of these words.

¹ From now when refers to blood, though no explicitly, is also valid for plasma.

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According to the Spanish Royal Academy's dictionary, **donation** is "1. Action and effect of donating. 2. Liberality in gratuitously giving something that belongs to them to another who accepts it" However, the term donation is often used improperly when, depending on the country or institution, it is remunerated. Someone from whom blood is drawn in exchange for payment, however small, is not making a donation but a sale. It is important to note this, as the use of the term 'donation' is reiterated in the context of obtention against payment. Furthermore, the term 'altruistic donation' is also used, which is redundant. In this article, care has been taken with the terminology, but sometimes the word 'donor' is also used when talking about a sale for lack of other terms and to avoid naming them 'sellers', although it is better suited.

Solidarity is "1. Circumstantial commitment to the cause or the endeavor of others. 2. Duty or liability "in solidum." The philosopher Victoria Camps points out that solidarity is the condition of justice, the measure that compensates for the shortcomings of this fundamental virtue. Camps reveal the will to broaden the sense of self and to do so it should include the will of approximation among human beings: benevolence.⁴ Altruism is "diligence in seeking the welfare of others even at the expense of oneself." Both concepts seek the well-being of others. The difference is that in the first case they do not have to sacrifice themselves to be supportive, while the altruists go one step further and make sacrifices for the good of others. Donation, altruism and solidarity are human predispositions in which the figure of otherness is very present. They are essential in all spheres of community life and make these more equitable and just. They are all taught and instilled.

A bioethical issue

This article falls within the scope of bioethics and takes *principlism* as its paradigm, being the most widely used in the field of health. It offers four principles to guide moral decisions in medical practice and biomedicine. They are the *principles of beneficence*,

² Real Academia Española (RAE)

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⁴ Camps, V., Virtudes públicas, Madrid: Espasa Calpe, 1990, pp. 35

⁵ Op. cit., RAE

non maleficence, autonomy and justice. They are prima facie principles: in case of conflict, the principle which is to prevail is to be assessed according to each case.⁶

Our starting point here is the specific case of the ethical aspects of blood collection; but we will gradually escalate and pose ethical problems concerning the configuration of the patent system, the institutions —both local and global— that legislate on global health issues, and the role of policies that support them. We are faced with a question of biopolitics: of how the powers that be —the political ones— manage our lives. In this regard, the importance of bioethics as a branch of applied ethics that reflects on life sciences and their moral implications is vindicated.

Medicine and health are social products that require a profound sense of ethics and humanism. Curing diseases falls within the ethics of civic minimums, of justice, but also within the organization of a community: how to get limited resources (such as blood) and the responsibility of institutions, associations and public health policy. Biomedicine needs people —or their parts— for research, for clinical trials, and to manufacture drugs. Therefore, it is important to generate a debate about the various models for obtaining raw materials of human origin.

What is the current issue?

Blood and plasma

First of all, it is important to understand what kind of resource we are talking about, why it is so necessary at a vital level, and what it means to become a donor.

Blood is a fluid tissue essential to life and can cure very serious illnesses, but may also cause them. The blood tissue is used for transfusions, and its strictly liquid

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⁶ According to Beauchamp and Childress, the principle of beneficence indicates "a moral obligation to act for the benefit of others", while the principle of non-maleficence refers to provoking no harm. The principle of autonomy is opposed to the long tradition of paternalism in the medical and clinical spheres, where the doctor takes all decisions without taking into account the specific preferences of each patient. It vindicates the patient's freedom to make their own decisions and the doctor becomes the professional who informs and advises. Finally, the principle of justice, which does not refer to the personal sphere but to that of the community, defends equal access to healthcare and also equitable distribution of medical resources.

phase –plasma– is used for research and the production of biological medicines. Therapeuticals obtained from plasma are often the only effective treatment for curing certain diseases.⁷

What is involved in obtaining blood and plasma?

Giving blood takes between 20 and 30 minutes with a minimum interval of around two months.⁸ It involves minor discomfort and has no adverse physical effects. Extraction does not require extensive infrastructure: it can be carried out in mobile units and in hospitals without too much specific equipment.

When donating plasma, some things change. Initially, there are two different types of collection depending on what and how it is obtained. One is termed *Recovered Plasma*. This takes about forty minutes and is for internal hospital use. It may only be extracted every three months, and no component is returned to the donor organism. The other type is *Source Plasma*, which takes 90 to 120 minutes to extract and is strictly intended for the industry. It is recommended extractions be made no more frequently than every 15 days, with a maximum of 12 times a year.⁹

The need for blood and plasma in the world

The West is self-sufficient in blood components (products obtained from whole blood) but not in blood products (pharmaceutical products, the active ingredient of which comes from plasma). The constant need for these involves finding a stable source of supply that can only come from living human beings. It is important to create a blood collection and management model, without forgetting that the aim should not be lucrative, but curative.

Spain is self-sufficient in red blood cells for internal use in hospitals, but not in plasma, which is used in the industry. The data shows that many European countries that have implemented the altruistic model are not self-sufficient. In fact, 76% of the

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⁷ Grifols Department of Public Affairs. (2014). *Bioethics of Compensated Plasma Donation*, p. 1

⁸ Cruz Roja Española, ¿Puedo donar si...? http://www.donarsangre.org/puedo-donar-si/

⁹ Grifols pioneering spirit, *La ética en la donación de plasma*. pp. 4-8

plasma used in the manufacture of blood products worldwide is the so-called *Source Plasma*, of which 85% comes from the United States¹⁰, where remunerated extractions are possible:

"With the adoption of World Health Assembly resolution WHA63.12 Availability, safety and quality of blood products (3) in 2010, working towards self-sufficiency in safe blood and blood products based on voluntary non-remunerated donation¹¹ is a policy direction already agreed upon by World Health Organization (WHO) Member States. However, self-sufficiency is not yet a reality in many countries with inadequate supplies of blood and blood products from voluntary non-remunerated donors (VNRD), and dependence on family/replacement donation systems and payment to blood and plasma donors to fill the gaps between supply and demand. The increasing global demands for blood and blood products, the complex nature of systems to supply these products, the inability of many national health systems to meet these urgent needs and the impact of globalization have also resulted in a rapid expansion of international commercial activities in relation to the provision of blood and blood products, as shown by increasing global markets in commercial plasma collection." ¹²

This situation opens the debate on whether countries that use the altruistic model should approach paying for donations in order to achieve self-sufficiency or if, on the contrary, paying for the obtention of human tissue is unethical and that morally creative solutions should be sought in order to achieve self-sufficiency.

An altruistic or a remunerative model?

The most widespread model in Europe is altruistic. This does allow for reimbursing the direct costs involved in the donation (transport and snack). It makes no difference between giving blood or plasma, nor if it requires more or less time for extraction, nor whether any of its components are returned. It considers that what is being given is a liquid tissue from a living human being.

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¹⁰ *Ibid.*, pp. 9-18

Here is an example of the misuse of the word 'donor'. The concept used in this article, 'voluntary non-remunerated donation' is redundant given that the meaning of the word 'donation' implies non-remuneration, that it is a free and voluntary act. If instead there is compensation, one should speak of 'sale'. Throughout the article one can see how the same mistake is made in several quotations. Donation is very commonly qualified by the adjective "voluntary" and those who are paid are also –incorrectly–called 'donors', which makes it difficult to distinguish the two types (of 'donor').

¹² World Health Organization (WHO). Towards Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated Donation: Global Status 2013, p. 3

Extraction and use do generate some costs: the "costs of processing blood." The National Health Services usually assumes the cost, except in private hospitals where health insurers or the patients themselves do so.

In 2013, a meeting of WHO and other international health and human rights organizations was held in Europe to draft *The Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non Remunerated Donation*, which defends the altruistic model and requires countries to be self-sufficient and to manage their blood.¹³

The paid model is used especially in the United States. It coexists with the altruistic model as they are not considered incompatible. The paid model differentiates between extraction types, and labels extractions according to whether the acquisition is voluntary or paid. ¹⁴ If it is in exchange for remuneration, no distinction is made on the basis of who has paid for it. ¹⁵

Arguments for the altruistic model

The reasons for the altruistic model are fundamentally *clinical* and of *efficiency*. Donations are considered *safer* because by not having any financial compensation, it prevents people who are interested in compensation, even though they know they are carriers of an infectious disease, from trying to pass the medical interview to obtain money. Therefore, the altruistic model guarantees safety for both the donor and the recipient. WHO stresses this when it says that "*voluntary non-remunerated blood donation is the cornerstone of a safe and sufficient blood supply and is the first line of*

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¹³ 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, Italy 8-9 October 2013, p. 1

¹⁴ In general, all those extractions obtained voluntarily are those used for several types of transfusions, while the extractions that have been paid for are usually for the manufacture of medicines, research or clinical trials.

¹⁵ U.S Food and Drug Administration. Protecting and Promoting *Your* Health. CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor. p. 1

defense against the transmission of infectious diseases through transfusion." Similarly, this model favors the cost-effective use of this resource: fewer units are discarded upon passing quality controls. Furthermore, paying for the extraction of blood might also result in charging the patients who need it most.

But there are also *ethical* arguments, such as social solidarity. The donors' motivation is to help, to collaborate and, at least, to obtain psychological benefit in knowing that they form part of a community that will "return" the effort when they need it. It is an exchange and not a sale exploiting the human body, as the European Council stated in 1997 at the Oviedo Convention on Human Rights and Biomedicine:¹⁷

"Recognizing that payment for the donation of blood, plasma and other blood components not only threatens safety but also contravenes the Council of Europe's Oviedo Convention on Human Rights and Biomedicine of 1997, which explicitly prohibits any financial gain from the human body and its parts, which erodes community solidarity and social cohesion that can be enhanced by the act of voluntary non-remunerated donation." ¹⁸

Advocates of altruism argue that providing a financial reward could be coercive toward those in need of money, thus increasing vulnerability and attacking social cohesion. As the Rome Declaration highlights:

"(...) may exploit the poor and vulnerable by providing them with financial incentives to donate and that voluntary non-remunerated blood donor programmes may be compromised or undermined by the presence of parallel systems of paid donation." ¹⁹

Other ethical arguments refer to the concept of human dignity: liberalizing sales implies trading with the human body, which we view as inalienable (without going as far as sacralizing the body; we are for the right to the possession of our bodies, but it is not considered ethical to trade in them); that is, it is argued that it is unethical to put a price on the human body or any of its parts, whether regenerable or not.

¹⁶ WHO Expert Group on Self-sufficiency in Safe Blood and Blood Products based on VNRBD, *Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation (VNRBD)*, 2012, p. 3

¹⁷ Instituto Borja de Bioética. *Convenio sobre los Derechos Humanos y la Biomedicina*. Bioética&Debat (año II, n°5). Barcelona. p. 5

¹⁸ *Op. cit.*, High-level Policy Makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation, p. 2 ¹⁹ *Ibid*.

Advocates of altruism believe that this should be the only model because the paid providers endanger their lives, and it may cause an imbalance in the National Health System. Promoting values such as solidarity, the feeling of belonging to a community or of mutual assistance, helps them propagate and spread. Breaking with this would be ethically and socially disastrous.

The altruistic model advocates for a public health model where a resource such as blood is in the hands of public institutions and owned by all citizens. WHO believes that if there is to be social justice, an equitable health model is necessary, without being subjected to market forces:

"Prevention of the commercialization of blood donation and exploitation of blood donors are important ethical principles on which a national blood system should be based. The right to equal opportunity in access to blood and blood products of uniform and high quality based on patients needs is rooted in social justice and the social right to health care." ²⁰

Criticism of the altruistic model

Criticism of the altruistic model revolves around the argument for *efficiency*: it is a model that cannot guarantee national self-sufficiency. Those who oppose altruism believe that forbidding compensation may lead to a global catastrophe with undesirable consequences:

"The introduction of legislation to prevent payment in cash for the donation of plasma will result in catastrophic undesired outcomes. The total number of donations that our members collect annually to manufacture the life-saving therapies approaches 30 million per year. There is no alternative for these donations."²¹

Therefore, they do not accept or support the reasons that lead to the defense of altruism as it is precisely compensation that meets the demand. This is demonstrated by data from European countries that are siding with this option:

p. 5
²¹ Bult, J.M., President and CEO from Plasma Protein Therapeutics Association to Dr. Kieny, MP Assistant Director General Health Systems and Innovation, World Health Organization, 2014

²⁰ Op. cit., WHO Expert Group on Self-sufficiency in Safe Blood and Blood Products based on VNRBD, p. 5

"Of the 29 European countries that supplied sufficient data for the European Committee on Blood Transfusion (ECBT) to perform a tern analysis, the two countries with highest statistically significant increases in litres of plasma for fractionation *per capita* between 2001 and 2008 were the Czech Republic and Germany, which allow compensated donation." ²²

Moreover, the clinical argument according to which all those who are aware that they are at risk of harboring an infectious disease and may offer donation, endangering the health of recipients in the absence of the filter of self-exclusion is denied. This argument has become obsolete: currently protocols to be followed in both models ensure the quality of extractions. It is also argued that the economic incentive is not to the detriment of social and community values as remuneration precisely recognizes the efforts of the donor:

"In the United States there is no policy restricting remunerated voluntary donations of plasma. (...) There is no evidence that remunerated plasma donations have increased safety risks for patients in the United States. Rather, there is a robust and safe supply of plasma products for the ever-increasing demand for such products to treat various rare and chronic disorders." ²³

Finally, in preparing conventions and declarations on this subject, the parties involved have never all been heard. In meetings between public institutions and organizations, the private agencies that regulate these therapies and other countries that buy the plasma have not been invited; not even the industry's private sector. Giving these parties a hearing would be desirable as they can provide argumentation. The outcome of the discussion would doubtlessly be more valid and *fair*.

In this sense, the *American Plasma Users Coalition* considers the Rome Declaration lacks a sense of reality:

"This Rome Declaration lacks a sense of reality. It is incomprehensible that some WHO and government officials do not seem to realize the enormous negative impact that the implementation of some of the suggestions will have on the patients whose lives are dependent on the therapies that are being manufactured from plasma obtained from compensated donors by the private sector industry."²⁴

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²² Op. cit., Grifols pioneering spirit, p. 13

²³ American Plasma Users Coalition to Dr. Chan, M. Director General, World Health Organization, Geneva, Switzerland, 2014

The reasons given for a paid model are similar to those of the altruistic model. Firstly, the dual US model (where plasma collection is rewarded but blood donation is not) is strictly regulated and controlled by the Health Authorities –*US Food and Drug Administration*– and coexists with the altruistic model. This covers the needs of the country and allows export of both plasma and blood products.²⁵ According to this *clinical* and *efficiency-oriented* argument, the fact that it reaches the necessary objectives legitimizes the model.

Grifols, a multinational, is a leader in the production of biological medicines derived from plasma, and in plasma collection, and is a world leader in transfusion medicine. This company pays for plasma extractions for reasons of *efficiency*. They consider from a point of view of public health and justice that there must be a right of access to treatment that will cure as many patients as possible and ensure a reasonable cost for the system, providing the best quality of life and allowing the patient access to a continuous supply of blood as needed for healing. The time and effort that the person engages in the extraction justifies payment.

The *ethical foundation* is *utilitarian*: an action is ethically better than another if it benefits a greater number of people. The aim is to reach all patients, to continue curing diseases, to save lives and to have sufficient surplus to allow research and to manufacture drugs. That is considered reasonable, especially because today there is no alternative to current treatments.

One of the most compelling reasons for compensation is that if altruism is required for extraction, it should also be required of the doctor, the head of the center, the bag supplier and all those who collaborate in obtaining this tissue. On the contrary, this entire chain of people who are professionally involved in the extraction are paid for their time and commitment. The payment quantifies the time spent on one or another type of collection. It is thus considered *ethical* as it also remunerates the donor by showing gratitude and values their effort. Furthermore, if a private company generates

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²⁵ *Ibid.*, p. 27

profit from a raw material, it is *ethical* that the primary "provider" also receives payment.

Another argument refers to the concept of freedom: consider that those who sell are as free to do so as those who give away; the fact that there is a financial benefit through this medium does not annul the capacity of decision-making, and so there is no apparent possibility of coercion. Moreover, freedom is also the faculty to dispose of one's body as one sees fit (*principle of self-determination*).

Remuneration is not considered harmful to the dignity of people: this concept is quite extended and varies according to each culture and individual. However, what is harmful is that there is not enough blood to cure those who depend on it. The end justifies the means to achieve it; in this case, the purchase of blood from people who freely decide to sell it.

Henry Grabowski and Richard Manding in their article *Economics and ethics of plasma donation* set out a list of benefits that are attained by remunerating for extractions. They are: consistency and frequency of donations, thanks to the financial incentive, that allows the control of donors; the increased volume of extractions, which increases performance in research and manufacturing tasks; or the diversity that is achieved, as more people are attracted, and that makes it easier to get, for example, particular types of antibodies that are not always present in all blood types.²⁶

The paid model is clearly viable as it supports global demand and, therefore solves a significant ethical problem: that thousands of patients can have access to adequate medical treatment. But questions arise on the criteria of social utility and facts: if it is ethical to pay, what should the price be? Who decides? And, on the other hand, is medication resulting from the extraction accessible to all on equal terms? This does not seem to be the case in the United States. Remember that it is advisable that what is ethical should be efficient, but not everything that is efficient is ethical *per se*.

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²⁶ Op. cit., Grabowski, H., Manding, R., p. 16

Criticisms of the paid model

The main argument is upheld by the evidence that the paid model is efficient: "Debates on ethical issues around giving rewards for donations should be encouraged. But there should be little debate that the most relevant empirical evidence shows positive effects of offering economic rewards on donations."²⁷

In this case, the end justifies the means. But advocates of altruism believe that there are limits that should not be crossed: what are the benefits that are defended by those supporting a paid model? Are both models equally ethical?

One of the *economic* arguments for compensation is that "financial incentives leave the donor in a better financial position." This argument fits perfectly with the concern that there is among advocates of altruism that some of the "donors" are there because they need the money, with all the ethical consequences that this entails. Can it be said that these people decide freely or does their vulnerability push them into it? In the paid model the possibility of coercion increases:

"Donors sit upright on uncomfortable, hard chairs. Some have just come off night shift; others have no money for food. Staffs are concerned about how many units will test positive from blood-borne viruses. Potential donors worry about being accepted. A woman without an up-to-date residency certificate is turned away. A man insists he should be allowed to donate; he is broke and desperate for the 850 roubles (£8.85) payment. It is clear that most donors come for the money: for some, it is a lifeline."

Compensation may infringe upon human dignity, instrumentalizing the body, against the principle of social justice, coercing the most disadvantaged who do not possess private insurance. Moreover, it could also reduce the will for altruism of society and ruin the model in other areas such as in organ transplantation. The dogmatism of the facts can make us forget ethical limits.

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²⁷ Lacereta, N., Macis, M., Slonim, R., *Economic Rewards to Motivate Blood Donations*. Policy Forum, Public Health, 2013, p. 928

²⁸ *Op. cit.*, VV.AA., p. 7

²⁹ Harvey J., "Blood money: is it wrong to pay donors?", *The Guardian* (January 25th, 2015)

One must be conscious of the main problem and what each model achieves. The thesis is not exclusion, but the complementarity of both models.

Ethical evaluation of the two models

Regarding the *principle of beneficence*, the altruistic model qualifies by promoting social and community values and thus educating in the moral obligation to act for the benefit of others. The model also respects this principle since it is self-sufficient and guarantees that dependent patients always have and will not lack treatment.

Regarding the *principle of maleficence*, by which no intervention should cause harm and should be proportionate, the altruistic model respects it. It is necessary to consider which the greater evil is: that patients should not have access, or that they should have it by "extorting" healthy persons? It is a model that respects dignity as it avoids exploiting and abusing the disadvantaged. On the contrary, the paid model does not care for the economically insecure, and that breaches this principle. Depending on which view one has of human dignity, this is also affected since remuneration exploits the individuals who, by being in need, trade in their own bodies.³⁰

The *principle of self-determination* is guaranteed in the altruistic model as there is no form of gratification; donation becomes an end in itself, which ensures that the will of those who give is free and disinterested. This is also fulfilled in the paid model based on individual will and freedom to dispose of one's own body. The will to have an extraction drawn is free since it is known that material or financial interest is the driving force that may condition, but does not delegitimize or nullify it. It may be questioned however, by alleging that the donor has not been provided with all the information regarding the route the person's blood takes once it has been sold. There is very little information on whether intermediary companies cover costs or make profits with the sale of medicines they manufacture. If one is not afforded this knowledge, the users are

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³⁰ Imagine the case of a donor who has a rare blood type; could it be sold at a higher price? The donor could set the price and negotiate. A very clear line should separate compensation for the inconvenience, from making money on it.

not equitably informed, and therefore, they are not provided with fair transparency, accessibility and proximity.

Finally, regarding the *principle of justice*, the altruistic model does take it very much into account. By not paying for this resource, it causes blood to pass into the public domain and access to medication or transfusions to be more equitable within a public health system; it thus respects equitable distribution of scarce resources. It is a fact that in the United States the paid model coexists with the altruistic one, but it should be investigated whether the remuneration of extractions causes a decline in voluntary donations, although it is somewhat complex to ascertain categorically. Remuneration takes into account the physiological effort and time the donor devotes to it and that it is quantifiable; under this principle, providing financial compensation is therefore coherent. That this means an increase (moderate) in the final cost of blood products is reasonable for the system, given that it provides a better quality of life to those who most need it, ensuring domestic self-sufficiency.

It can be concluded that the altruistic model turns out to be ethical in itself. This model is linked to the conception of a public and universal healthcare model. Unfortunately, at present, it is inefficient. The paid model justifies itself as it can cope with the current demand for blood. It is a model based on the casuistry of the facts. Efficiency, in consequence, converts it into an ethical model. However, by allowing certain coexistence with the altruistic model it reveals the widespread conception that the latter is considered desirable despite its inefficiency.

Besides the four principles, there are other elements to consider when assessing the two blood collection models. It is important to think about what kind of healthcare model is desirable and whether it should be universal. It would be good if blood were kept as a public good accessible to all. Paying for what is needed is justifiable, but it cannot be the principle upon which to base the action, but rather just another argument. On the other hand, ethics seeks universal principles to legitimize actions. If altruism were to achieve self-sufficiency, the argument for compensation would collapse, and thus it cannot be the fundamental principle of this model.

It is necessary to ascertain what we are looking for when we say *the best obtention model*, and to assess what limits should not be crossed and if both models are equally ethical. What does better mean? What ethical and anthropological theory and what model of society lie behind it? Within the capitalist system, monetary remuneration is efficient, and perhaps also ethical: compensation is utilitarian. But that the model is efficient does not mean it is ethical. If payment is prohibited, it is for ethical reasons and not for simply gaining medical or healthcare efficiency.

The altruistic model does not generate as many ethical doubts, even though since it does not achieve self-sufficiency (a fact that could be described as *maleficent* regarding the sick), it purchases what it is short of from the model it repudiates.

The ethical evaluation of each model depends on where it frames the criteria from which the ethical and anthropological theory is observed. Therein lies the difficulty of considering certain arguments as decisive. The arguments for the paid model are based on the *lesser evil* which monetary reward implies in the face of the need for blood and they have a very different ethical basis from the altruistic model: it seems that remuneration is legitimate *as long as* the altruistic model is not self-sufficient. These arguments are of a *consequentialist* nature: it is the end of the action which legitimizes it. But can an efficient action be placed at the same level as one that is legitimate and ethical? Would advocates for compensation accept altruism as the only model if it were shown that it can achieve self-sufficiency? No argument is brandished against altruism per se, but its inability to achieve self-sufficiency discredits it.

The paid model is efficient but generates unease by including blood within the law of markets and commercialization and turns it into a tradable product. The altruistic model does not generate ethical doubts but of efficiency: this is an instrumental resource, sometimes necessary for the common good, but that by itself may not always be the ultimate goal if it goes against the ends it pursues. Efficiency should serve moral purposes, as are freedom, justice, solidarity and welfare - not supplant them.

The arguments for the altruistic model are mainly of an *deontological* nature and focus on what it *should* be, and what should be done to take into account the common interest and not only whatever is the most immediate problem. It should be addressed

according to ethics and not just what is simply efficient, since what is correct and efficient do not always go hand in hand. Paying for something that comes from human beings, but is expected to yield positive consequences, is in itself ethically reviewable in our anthropological tradition and consistent with the model of society we seem to want (just, solidarity, fostering human dignity and integrity...). Weighing up the greater or lesser evils implies clarity regarding what the evil is.

All things considered, from an ethical point of view the altruistic model is more easily defensible than the paid model. But the worldwide lack of blood makes it difficult to maintain the value of altruism. All this forces us to foster a culture of donation.

A public health and civic ethics issue

Blood is a product for transferring between people and is used for healing various diseases. One wonders whether we consider blood a public or private good and consequently, whether it should be managed by the state. The debate takes on a biopolitical dimension.

Converting blood into a product governed by the law of markets creates ethical problems of various kinds:

Who sets the price? This may vary from country to country; it is not the same to pay twenty Euros for blood in Nigeria than in Spain. It is quite different to do so in a poor country than in a rich one, or in a country with an extensive public health network or elsewhere that lacks one. The social context may mean having to legislate very differently for the same thing. Pricing often depends on collective agreements and insurers, among others; but a drug is a global commodity, manufactured and sold at differentiated specific places and prices, in the same manner as other types of goods. The difference is that a drug cannot be equated to any *commodity*; these blood-derivatives are vitally necessary products that respond to the right to health.

One important issue is whether advocates for remuneration would accept the altruistic model if it were shown that it could be self-sufficient, or whether they would

continue defending compatibility; in the latter case, the argument for freedom would prevail for both the donor and the company. But if blood became a public good and the state determined prices, that would imply limitations for the pharmaceutical industry.

There should be proportionality between what is paid for extraction and what is obtained from the sale of the drug. The objective is the end-user (cures and improves the quality of life for people in need) and should as far as possible shun profit, although bearing in mind that intermediaries should be compensated for the work they do. There must be a market, but sufficiently controlled and regulated.

The issue directly affects WHO –scientific research and patents– and broad and comprehensive consideration is required to find a fair and equitable solution for all. It is extremely important to create spaces for global bioethical and biopolitical deliberation, beyond national institutions and traditional markets. We must reflect on a new theory of justice that covers the acquisition and management of limited resources. We are confronted with civic ethics and justice for public health, a global issue.

Conclusions

Principlism has its theoretical and practical difficulties. The principles that are used to make moral judgments are indeterminate, abstract and ambiguous; this fact gives rise to multiple interpretations and conceptions of the idea of benefit, prejudice, autonomy and justice. Therefore, the principles applied to determine the ethics of the two models have a close relationship with the ideological position from which they are valued: liberal individualism leads to a utilitarian position while social cooperativism takes an ethical stance. American bioethics generally arises from an individualistic anthropology and an individualized conception of humankind, and so its model for blood collection is more liberal as opposed to European bioethical interpretations. These work from a more cooperative anthropology and see the human being as cooperative, interdependent and prioritizes social ties. In Europe, there is usually a shared conception of good and a commitment to the public sphere where collective benefits are considered. In the American conception, the defense of individual liberties to attain fair distribution

prevails. Depending on what kind of society we want to build, one or the other will be better suited.

Bioethical consideration should provide a solid basis for moral judgments. In this article, we are interested in the concept of justice as equitability and as a defense of human rights, with a philosophical basis in mutual recognition among peers. A model of a just society is one that assigns certain rights and duties to both citizens and their institutions. One should not forget that the model of society is related to the educational model, which should build solidarity citizenship for a cooperative society based on transparency where society can trust their institutions. Private enterprise must also prove transparent and work in coordination with the public sector. It is about finding the *right balance* between public authority and private power, creating a harmonious and supportive relationship between them and, ultimately, understanding health as a matter of minimum civic ethics.

For this reason, the debate about decision making has to be part of the entire society and has to be democratic. Precisely because health is a global issue, comprehensive solutions must be sought through a universal criterion of justice which, by involving the public, private and global powers, will naturally lead to overcoming the inconsistencies of the two existing models of blood and plasma donation. From a deep and thorough study of the subject, a consensus would have to be reached among all the parties involved.

This article has sought, to the extent of our possibilities; help shine some light on the various arguments in defense of either one or the other blood collection models. Since the technology and science are advancing very rapidly, another way to obtain blood and plasma might be found that will make extraction as we know it today obsolete, but so far this is not the case.

References and webography

Alcoberro, R., *Bioètica: concepte i problemàtica*. Disponible a: <www.alcoberro.info/bioetica1.htm>

American Plasma Users Coalition to Dr. Chan, M. Director General, World Health Organization (Geneva, Switzerland) (2014)

Beauchamp, T.L., *Principles of Biomedical Ethics*. New York: Oxford University Press, 1979

Blanchar, C. "Grifols plantea pagar a los donantes de sangre para ayudar a los parados." *El País* (17 de abril de 2012). Disponible a:

http://ccaa.elpais.com/ccaa/2012/04/17/catalunya/1334651946_436308.html

Busquets, E., Mir, T., *Principios de Ética Biomédica, de Tom L. Beauchamps y Jmes F. Childress*; Bioética&Debat. 17 (2011) 64. . Disponible a: <file:///E:/Downloads/257098-346256-1-PB%20(4).pdf>

Bult, J.M., President and CEO from Plasma Protein Therapeutics Association to Dr. Kieny, MP Assistant Director General Health System and Innovation, World Health Organization (2014)

Camps, V., Virtudes públicas, Madrid: Espasa Calpe, 1990

Camps, V., Argumentos éticos para la donación de plasma, 2015

Cortina, A., García-Marzá, D., Razón pública y éticas aplicadas. Los caminos de la razón práctica en una sociedad pluralista, Barcelona: Tecnos, 2003

Cruz Roja Española, *Puedo donar si...?* . Disponible a: < http://www.donarsangre.org/puedo-donar-si/>

EFE. "Grífols pide que se permita vender plasma como un ingreso extra para parados." *El Mundo* (17 de abril de 2012). . Disponible a:

http://www.elmundo.es/elmundo/2012/04/17/barcelona/1334654652.html

Entrevista al Profesor Thomas Pogge para Dilemata, *Dilemata* año 5 (2013), N° 13, 265-282 ISSN 1989-7022. . Disponible a: <<u>file:///E:/Downloads/Dialnet-EntrevistaAlProfesorThomasPoggeParaDilemata-4495004.pdf></u>

FDA Regulation of Blood and Blood Components in the United States. Disponible a: http://www.fda.gov/downloads/BiologicsBloodVaccines/InternationalActivities/UCM 273188.pdf>

Focault, M. Fragmentos sobre biopolítica. A: Ramon Alcoberro i Pericay. *Filosofia i Pensament*. . Disponible a:

http://www.alcoberro.info/docs/examples/foucault/foucault0.html

Fundació Víctor Grifols i Lucas. . Disponible a: www.fundaciogrifols.org/ca/web/fundació>

Grabowski, H., Manding, R., etc, Economics and ethics of plasma donation

Grifols Department of Public Affairs. (2014). *Bioethics of Compensated Plasma Donation*

Grifols pioneering spirit, La ética en la donación de plasma

Goberna, J., *Los métodos de la ética clínica*. Màster Ciutadania i Drets Humans: Ètica I Política, Assignatura "La Presa de Decisions", Universitat de Barcelona, 2015

Habermas, J. Aclaraciones a la ética del discurso. Madrid: Trotta, 2000.

Harvey, J., "Blood money: is it wrong to pay donors?", *The Guardian*, (January 25th, 2015). Disponible a: http://www.theguardian.com/lifeandstyle/2015/jan/25/wrong-to-pay-blood-donors-safety-compromised

High-level Policy Makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation, 8-9 October 2013, Rome, Italy. *The Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation*. Disponible a: http://www.avis.it/userfiles/file/RomeDeclarationSelf-SufficiencySafeBloodBloodProductsVNRD.pdf

El Informe Belmont, Observatori de Bioètica i Dret, Parc Científic de Barcelona. U.S.A. 18 d'abril de 1979.

Instituto Borja de Bioética. Convenio *sobre los Derechos Humanos y la Biomedicina*, Bioética&Debat (año II, n°5), Barcelona

Lacereta, N., Macis, M. Slonim, R. (2013) *Economic Rewards to Motivate Blood Donations*. Policy Forum (Public Health)

Pogge, T., ¿Estamos violando los derechos humanos de los pobres del mundo?, Barcelona: Editorial Proteus, 2013.

Pooge, T., ¿Qué es la justícia global? Revista de Economia Institucional, 10, nº 19 Segundo Semestre, 2008, pp. 99-114.

Prats, J. "La sangre se dona pero no se vende." *El País* (1 de mayo del 2011). Disponible a:

http://sociedad.elpais.com/sociedad/2012/04/30/actualidad/1335812150 848890.html>

Real Academia Española. . Disponible a: < http://www.rae.es/>

Sandel, M. J., *Lo que el dinero no puede comprar. Los límites del mercado*, Barcelona: Debate, 2013

Terribas, N. Valoració ètica dels diferents models / Recomanació per a Catalunya, Banc de Sang i Teixits. Disponible a: <www.bancsang.net>

U.S Food and Drug Administration. Protecting and Promoting *Your* Health. CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor. Disponible a: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm122798.htm

VV.AA., The Ethics Donor Compensation for Plasma-Derived Medicinal Products

Wikipedia, La Enciclopedia Libre., *Sangre*. Disponible a: http://es.wikipedia.org/wiki/Sangre

World Health Organization (WHO) Expert Group on Self-sufficiency in Safe Blood and Blood Products based on VNRBD, *Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation (VNRBD)*, 2012 © 2012 World Health Organization. Vox Sanguinis © 2012 International Society of Blood Transfusion.

World Health Organization (WHO). Towards Self-Sufficiency in Safe Blood and Blood Products based on Voluntary Non-Remunerated Donation: Global Status, 2013. Disponible a: http://www.who.int/bloodsafety/Expert_Consensus_Statement_Self-Sufficiency.pdf

Zamudio, T., *Historia de los Bio Derechos y del Pensamiento bioético*, G. A. T. Z. Ediciones Digitales, 2009-2012. Disponible a: http://www.bioetica.org/cuadernos/bibliografia/singer3.htm