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Perspectives on Compensated Plasma Donation

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Abstract: The subject of compensating donors has been and sometimes still is a topic for lively discussion. It is my view that compensating plasma donors for their time and effort is appropriate when done in a well regulated environment. I will attempt in this presentation to outline the reasons why this is the case.

INTRODUCTION

Over a million of people in the world often depend on lifesaving therapies made from human blood or plasma, whether these are transfusions with (red) blood components or therapies made from human plasma. However, there are distinct differences between blood and plasma therapies due to contrasting collection, preparation/manufacturing, safety and distribution practices.

Whole blood can be collected several times per year from a donor (from males more frequently than from females). The frequency of donation varies depending on national regulations, but several reports put the average donation per donor at once or twice per year. The average collected volume of whole blood is about 250 ml in a procedure that takes up to 30 minutes. Most whole blood donations are used for transfusion purposes in a hospital setting. In cases when the collected whole blood is not used for direct transfusion, it can be made available for the manufacture of finished products. Plasma collected in this manner is called recovered plasma.

Plasma can be donated more frequently. The plasma donation is done through an automated procedure called plasmapheresis. The procedure normally takes one and a half to two hours. During this procedure, the red cells are separated from the plasma and returned to the donor immediately. The frequency of donation can be higher because plasma regeneration takes place within 24 hours. The average frequency for a plasma donor in the U.S.A. is 17 times per year [1]. The frequency is restricted by national regulations. In the United States a donor can donate up to twice a week, whereas in Europe donation is restricted to once per week or every other week with maximum volumes between 15 and 25 litres per year. The volumes per donation vary between 450 ml and 830 ml.

COMPENSATION

The average compensation for the time and efforts related to a regular plasma donation in the United States is \$15 to \$20. In Germany a compensation up to 25 Euro is given and acceptable by law for both plasma and blood donations. However, many blood donors receive other forms of compensation, such as reimbursement of travel costs, time off work and other tokens of appreciation. Time off work can take two full days. In addition, there are many examples in different countries where blood donors receive T-shirts, tickets for events, discounts on medical services, free Internet use, telephone cards and so on.

In my view these are acceptable practices because it is justified to recognize donors for their willingness to help someone else. It seems strange to me that some people believe that a financial compensation is unacceptable, whereas the forms of compensation described above can easily exceed the averages that are acceptable in our industry. For me, both forms are appropriate and should be encouraged. We are transparent in what we do and believe and are proud that we have so many volunteer compensated donors. In 2002, the approximately 450 collection centres associated with PPTA collected over 13 million litres of plasma.

In the United States, Germany, Austria and Sweden, plasma donors can be compensated for their time and efforts related to the donation. It is no wonder that these countries have the most successful plasma collection programmes in the world and contribute considerably when it comes to the availability of plasma that is so needed for the manufacture of life-saving plasma-derived therapies.

VOLUNTARY OR NOT ?

Each donation is done out of free will and is in my perception therefore a voluntary donation. No individual is forced to donate. Sometimes the suggestion is made that a blood donation is voluntary and a plasma donation is not. This shows disrespect for the plasma donors, many of whom may have the same altruistic reasons to donate that blood donors have. The term "voluntary compensated donor" is a factual description of the reality of the donors we work with. Some have expressed criticism for using that term because it was felt that the use of the word voluntary should only be used for blood donors. It is obvious that I do not share this approach.

DIFFERENCES IN DONOR SCREENING

Before donating, each blood donor receives a physical examination that includes blood pressure and haemoglobin tests. Each blood donation is then checked for different pathogen markers, including HIV, HBV and HCV. This procedure is repeated at every donation. Individuals who donate more than once are called repeat donors by the whole blood community, independent from the inter-donation interval. Even when this interval is five years or more, the blood donor is still considered to be a repeat donor.

The procedure to become a plasma donor is quite different. When an individual attempts to donate plasma in the United States their name is first checked against

the National Donor Deferral Registry (NDDR) to ascertain whether that individual has been deferred from donating in the past for a positive viral screening for HIV, HBV or HCV. If that is the case, then the person cannot be accepted as a donor.

Once a potential plasma donor has been cleared through the NDDR they are given a full medical examination and tested for viral markers. If the results from that test are negative, meaning that no signs of viral infection can be detected, then the individual (then called applicant donor) has to come back to undergo the whole procedure again at a different time. Only a person who successfully passes the screening twice at different times becomes a Qualified Donor. When a donor does not return within six months for another donation, the procedure starts all over again.

The Qualified Donor standard effectively eliminates these so-called "test-seekers". These individuals are only interested in test-results and use the donation process as an easy way to obtain these results. As one can imagine, we are not interested in these individuals becoming donors.

TRUTHFUL INFORMATION ?

Sometimes it is suggested that the promise of monetary compensation can increase the risk that donors will lie or withhold information during the initial screen process. Dr. Simon wrote about this subject recently in an article. I quote: "The concept that paid donors are a less safe source of blood for transfusion than volunteer donors is based on very old data. Often the assumption that people would be untruthful in answering the blood donor questionnaire to receive payment is cited. There is no evidence that this occurs with any greater frequency than untruthfulness due to social pressure among volunteers." [2].

ETHICS

Is it ethical to compensate plasma donors monetarily? This is often determined by cultural and educational differences. The French ethical philosophy may differ from the Anglo-Saxon philosophy, which in turn can be different from the Japanese philosophy. Our members believe that it is absolutely ethically acceptable that an individual be compensated for their time and effort for a plasma donation procedure, as long as it is done in a strict regulated environment set by competent regulatory authorities. Compensation for a donation without the existence of a strict regulatory environment to cover blood- and/or plasma donations should not be encouraged.

The underlying ethical principle that everybody agrees with is to do no harm. Doing no harm also means that therapies should be made available for patients all over the world who are in need of these sometimes live-saving therapies. From that perspective there is no difference whether therapies are made from compensated donations or not. Compensation of a donor does not harm the donor or the patient. The European Medicines Evaluation Agency (EMA) made it very clear in their position statement that therapies made from both compensated and non-compensated donors are safe [3].

During my visits to plasma collection centres, I speak to donors to learn about their motives, but also to say thank you and express my appreciation. It is a good human action that deserves our utmost respect. I have seen donors who changed from being a blood donor to a plasma donor. Has this donor now become a bad donor because a reasonable compensation is given for their time and efforts? Of course not; I believe one should have the greatest respect for a person who is willing to donate plasma in a greater frequency and volume compared with a blood donor! Ethical specialists have stated that it is important that there is no undue inducement, which could happen when a compensation might be outrageous. With the average compensation that plasma donors receive this is not the case.

It is unethical not to do everything we can as a society to collect blood and plasma for the so badly needed therapies. It is my view that it is also unethical not to have measures in place to collect sufficient plasma, including compensation for time and efforts.

SAFETY

The manufacture of safe and effective plasma-derived medicinal products starts with the plasma collected. As mentioned above, an individual who wants to become a plasma donor has to undergo two sets of screening before being accepted as a Qualified Donor. And then, only plasma units collected from Qualified Donors that test negative for HIV, HBV and HCV are accepted.

Once collected, the plasma is kept in inventory for a minimum of 60 days before release for manufacture. This inventory holding period allows for tracing the unit in case post-donation information becomes available that would disqualify the donor (e.g. an unreported illness). The plasma that enters the manufacturing pool is extremely safe. There have been no reports of viral transmission through plasma-derived medicinal products in the last decade, proof of the robustness of the entire manufacturing process.

In contrast to plasma-derived medicinal therapies that undergo many manufacturing steps, whole blood for transfusion purposes carries a higher risk of transmitting pathogens, especially when the donations are given in the window period. Every year reports appear of viral transmission through transfusion products [4]. Safety can only come when all parts of the system work. Safety is the sum of all measures and not the result of one step.

A recent publication of Van der Poel [5] lists a whole series of old data that are analysed over-and-over again about the question whether donor compensation is still a risk. In a published response we stated that there is no evidence from clinical studies and pharmaco-vigilance data that donor compensation increases the risk of viral transmission via plasma-derived medicinal products, which have been subject to proper screening at donation and a validated viral inactivation/removal step [6]. It is more important to focus on what can be done to improve a system instead of reanalysing old data. I am proud to be working for an Industry that takes its role so seriously by developing and implementing voluntary standards and certification programmes that have contributed to the situation that one can say that products have never been safer than they are today. The already-mentioned EMEA position statement confirms the safety and quality of the therapies manufactured today [3].

What is left is the calculation of the residual risk that an infectious unit which escaped detection (window period) enters the manufacturing pool. The findings of Dr. Schreiber comparing pools made from compensated donations and from recovered plasma show that the (theoretical) residual risk calculation show that all products are equally safe [1]. That is a comforting message for all users.

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