Conference Abstract

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Plasma for Fractionation in Europe: Challenges and Benefits

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Blood donation organizations in the European Union face numerous challenges - donor shortages during the pandemic, difficulties implementing quality systems, a lack of qualified personnel, and salary issues, but primary challenges arise not from ensuring the quality but at the political level.

The prevailing model of blood services in Europe is that of non-profit organizations, where blood donation is voluntary and non-remunerated. Some countries (such as France, the Netherlands, Italy, Spain) have a unified government policy in which the state is responsible for supplying the population with blood components and blood plasma products. At the state level, the production of plasma products is managed within the country or outsourced for contract manufacturing abroad. Blood donations in these countries are strictly remunerated, and while donors are motivated, countries still encounter difficulties attracting blood plasma donors since plasmapheresis takes more time than whole blood donation.

In other countries, often with smaller populations, the state ensures that healthcare institutions are supplied with blood components and compensates for the use of blood plasma products in healthcare institutions. However, their legislation does not impose a requirement for suppliers to provide blood plasma products made from locally collected plasma or even prioritize such products. Countries like Lithuania, Estonia, and Poland do not have an obligation for blood donation organizations to order the medicinal blood plasma products from their collected plasma, thus not receiving any funding for this purpose. Moreover, as non-profit organizations, they are compelled to engage in commercial activities that are not typical for them, seeking buyers for residual plasma—manufacturers of medicinal products or plasma fractionators. This means that such blood donation organizations are not incentivized to engage in plasma collection for fractionation, as they must exert effort to sell residual blood plasma (about 80% of the collected blood volume) according to the country's legislative requirements. They also need to invest additional financial resources in equipment and personnel, which are not available since they are only calculated for the quantity of blood components needed to meet state requirements.

In some countries, in addition to non-profit blood donation organizations, the legal framework allows for the operation of private plasma centers, which prepare only plasma through plasmapheresis for fractionation (Germany, Austria, Czech Republic, Hungary). In some countries, plasma donors are allowed to receive monetary compensation for their donations, which creates conflict with non-profit blood donation organizations that operate on a voluntary basis. This situation creates conflict among the much-needed donors for patients, as blood donation for transfusion is perceived as more honorable in the public eye. State institutions of these countries understand it is only through the private plasma centers they collect sufficient plasma, yet they do not take the lead to amend legislation and equalize the conditions for private and non-profit blood donation organizations and their donors. Meanwhile, in other European countries, the balance of plasma collection is negative, and a significant portion of the plasma needed for manufacturing blood plasma products for European patients (more than 60%) is supplied not even from European blood centers but from paid donors in the USA.

European Union institutions are taking initiatives to change the situation; however, to effect change, it is necessary to start not with advertising campaigns aimed at strengthening donor motivation for plasma donation for fractionation, but by changing the legal frameworks of member states. EU projects aimed at ensuring plasma supply at the regional level, before the legal regulation of plasma collection for fractionation is established in each member country, will not yield significant benefits.

Evidence shows that even the recommendation from the World Health Organization for each country to ensure, among other things, plasma for fractionation from their resources was often disregarded by responsible ministry officials—considered as "only" a recommendation.

Blood donation organizations must focus on their primary activities, producing safe and high-quality products according to the needs of healthcare facilities in their countries for both blood transfusion and pharmaceutical industries; all of these are necessary for patients and honorable. Appropriate funding and legal regulation of this sector should be addressed not by the heads of blood donation organizations but at the state or even international level.The demand for plasma products is increasing, especially for immunoglobulins. No country can expect to supply its patients with medicines made from donor plasma from another country, unless it is necessary due to an epidemiological or other special situation. It is essential to start taking real action, rather than just talking, at both the national and regional levels, as the pandemic and the closing of national borders have clearly shown that such expectations are very fragile.

Disclosure

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