How to make plasmapheresis more efficient: a study model

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The workshop entitled "How to make plasmapheresis more efficient: a study model" took place on 29 May 2015, during the SIMTI's IV National Conference of Transfusion Services. Its aim was to bring together representatives of the various parts of the Italian blood donation system in order to identify rigorous and shared methods capable of guiding the national plasma/plasma derivative system towards a model of growth that respects the current legislation and is concretely practicable, and ethically, culturally, economically, organisationally and socially sustainable.

It was first necessary to consider the current situation and legislative context in an analytical manner, as summarised in the next few paragraphs.

Legislative context

According to Italian law "self-sufficiency in the supply of blood and blood derivatives is a national objective aimed at guaranteeing that the quality and safety of transfusion therapy is the same for all citizens" (Art. 14, comma 1, Law No. 219/2005) and must be founded "on voluntary, periodic, responsible, anonymous and gratuitous donations of human blood and its component" (Art. 14, comma 1, Law No. 219/2005)

Furthermore, it is laid down that the plasma-based drugs produced using the plasma collected by the public transfusion system are to be supplied by authorised third-party companies (Art. 15, comma 1, Law No. 219/2005)

Collection data

In the years 2011-2012, the amount of whole blood collected in Italy remained stable at about 2,680,000 units, but decreased by 1.9% in 2013 and by a further 1.7% in 2014.

The collection of plasma by means of apheresis also remained substantially stable in the years 2011 and 2012, slightly increased in 2013 (+1.42%), and then significantly decreased by 3.5% in 2014.

Production data

The amount of plasma outsourced for fractionation during the last three years has remained substantially stable at about 770,000 kg, after having steadily increased annually from just over 450,000 kg in 2000. This amount represents about 13 kg/1,000 inhabitants although the considerable differences from Region to Region ranged from 4 to 22 kg/1,000 inhabitants in 2012.

Separation accounts for about 75% of the plasma produced in Italy, and apheresis for about 25%.

Just under 500,000 plasmapheresis or plasma/plateletheresis procedures are carried out, and average productivity is 319 procedures/machine.

Consumption data

The consumption of red blood cells was about 2,530,000 units in 2011 and 2012, and decreased by 2% in 2013 and by a further 1% in 2014.

Italy's albumin consumption rate of 600 g/1,000 inhabitants makes it the largest consumer of albumin in the world, although there are some regional differences that are difficult to explain. National collection centres meet just under 60% of the demand.

The Italian consumption of intravenous immunoglobulins is 60 g/1,000 inhabitants, about half that of the USA and Canada, and tending to increase. The amount coming from Italian plasma covers about 70% of the demand.

On the contrary, the amounts of antithrombin III, factor VIII and factor IX produced using Italian plasma exceed the demand.

Production costs

A number of articles analysing the Italian costs of plasma destined for fractionation have recently been published. Although considering different organisational contexts and using different methodological approaches, they substantially agree the cost of a litre of plasma obtained by means of apheresis is about € 280-300. This is clearly higher than the international market value since the plasma is obtained from private centres who only supply the raw material and who collect from paid donors.

Even a summary analysis of the above figures makes it clear that the self-sufficiency in the supply of plasma and plasma derivatives referred to in the Italian legislation is still far from being achieved. It is equally clear that reaching this still challenging objective will require the full commitment of all of the players in the system to finding shared solutions that take into account the following consideration.
1- Self-sufficiency should only be defined on the basis of appropriate demand, and there should be no ambiguity between consumption and therapeutic need.

2- Even if this is done, it is likely that the currently collected amounts of plasma are not enough given the increasing number of indications for immunoglobulin treatment and the very recently presented and significant results of the SIPPET study\textsuperscript{14}, which suggest renewed interest in plasma coagulation factors.

3- The fall in demand for red blood cells for transfusional purposes shows no signs of recovery and is a trend shared by all countries offering quality health care. This means that, in the future, recovered plasma will not help solve the problem.

4- The plasma derivative industry will have to invest in order to ensure a generalised improvement in technology that will allow greater yields of some products per litre of plasma than those obtained today.

5- National institutions need to adopt a cultural approach in which national self-sufficiency is seen as part of the broader scenario of international cooperation and at ensuring balanced production and the full ethical and solidarity-based use of plasma derivatives.

6- As collecting plasma by means of apheresis is essential in order to reach the objective, the costs of doing so must be reduced by making the system more efficient. The current cost structure of plasmapheresis in Italy is unsustainable, even though it is important to acknowledge that such plasma has intrinsically greater value (including economic value) as a result of the plus arising from the fact that it is provided by voluntary and unremunerated donors.

The thread running through all of the contributions to this supplement is the identification of possible structural, organisational and operational means of containing costs by improving process efficiency without affecting quality, guaranteed healthcare, or clinical appropriateness.

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References


