Hyperimmunes Plasma Procurement and Products

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1) General Considerations about Hyperimmune Globulin Products

Hyperimmune globulin preparations have been manufactured from the beginning of plasma fractionation. Offering passive immunization to individuals affected by acute and severe conditions, such as rabies or tetanus, they have saved many lives in the past fifty years. Today, their use has significantly diminished as a result of large-scale immunization campaigns in a number of countries, and of improved sanitary conditions in many countries, and the general increase in living standard. Some hyperimmune preparations are no longer manufactured because there is no more clinical need for them: for instance, most populations are now protected against mumps, pertussis and varicella. Small quantities of botulism immune globulin are still made. In addition, most immune globulin preparations are also made by using equine plasma instead of human plasma, at a considerably reduced cost. However, these preparations are not tolerated by all patients, who require human-based hyperimmune products. Today, most hyperimmune preparations are administered along with a vaccine for full protection. Some manufacturers produce small quantities of large vials of some hyperimmune (tetanus) for treatment rather than prophylactic use. The number of cases requiring such large therapeutic doses is quite limited. Most hyperimmune preparations are manufactured by commercial companies instead of governmental fractionators, mainly because of the need to use specific plasma, which the former can access more easily than the latter organizations. Even though the needs for hyperimmune globulin products have eroded in recent years, sales have remained steady, and usage is relatively confined to stable markets, in particular in the industrialized countries, where the human plasma-based products are used, while the equine plasma-based products are mostly used in the developing world. Most hyperimmune preparations are still administered

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through the intramuscular route, and most are administered once, as they target acute, and not chronic conditions (except hepatitis).

2) Global Hyperimmune Globulin Products Market

In 2009, global sales of hyperimmune preparations were estimated at $768 million, representing about 7% of the worldwide plasma proteins market (1). The breakdown among the main preparations was:

Rho(D) immune globulin	33%
Hepatitis B immune globulin (intramuscular)	17%
Hepatitis B immune globulin (intravenous)	15%
Tetanus immune globulin	10%
Cytomegalovirus immune globulin	8%
Rabies immune globulin	4%
All other immune globulins	12%

Table 1- The breakdown among the main preparations

Sales of human plasma-based hyperimmune preparations occurred mainly in Europe (39% of global sales), and North America (34%). Asia & Pacific sales were 13% of the world market (2). In units, the geographical distribution of these products would be quite different. In recent years, several fractionators have attempted to manufacture various hyperimmune globulin products against recent epidemics, including SARS (3, 5), H1N1, and earlier, against HIV (5). These efforts have been fruitless, due to a variety of obstacles.

3) Manufacturing Issues pertaining to Hyperimmune Globulin: Plasma Donor and Production Risks

Adequate plasma donors must be identified: they must have the proper profile, and in the case of voluntary donors apheresis donors in the United States and other countries, they must consent to be inoculated – if this is the way the specific plasma is to be obtained (6). They must consent to donate by plasmapheresis, and to return to the blood or plasma center to subsequent donations. A high degree of commitment is required from these donors, and the observation has shown that they are strongly motivated by the good cause they serve regardless of whether they are compensated or not.

As regards the production of hyperimmune preparations, the first requirement to manufacture the product is to ensure that the plasma has

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a sufficient titer. In recent years, it has been difficult to secure appropriate vaccine for donor immunization. Reportedly, the vaccine manufacturers have produced new vaccines that adequately protected individuals, but their potency was insufficient for the production of specific plasma, and the immunized donors did not generate sufficient antibody titers. In the case of high infectious diseases, such as HIV and hepatitis B, the risk of contamination is vital.

4) Conclusion

An issue which has recently come up is the fact that the general population, from which blood and plasma donors are drawn, has a low antibody titer against specific viruses, notably hepatitis B because of vaccination campaigns. Therefore, the hyperimmune preparations directed against these viruses may be needed in higher quantities in the future.

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