Plasma Fractionation in Malaysia

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Introduction

Plasma fractionation has evolved from a medical service activity for the purpose of supplying products to the local community to a global manufacturing industry that has to comply with high quality standards (1). It involves sophisticated industrial process in licensed facilities and has the highest standard of hygiene and quality and conforms to the principles of Good Manufacturing Practice (GMP). To safeguard the public from unsafe blood products, there must be a system for licensing, regulation and control within the national authority (2). These requirements are beyond the means of developing countries like Malaysia (3).

Background

Malaysia is a country covering an area of 330,252 square miles. It consists of 2 major land masses, Peninsular Malaysia and the northern part of Borneo which separated by the South China Sea. The population of 28 million is made up of many races and ethnic groups. Thirty two percent are below 15 years old and only 4.5% are above 65 years of age. The annual population growth is about 2 %.

Malaysia is fortunate to have a very comprehensive range of the health services. The Malaysian government is very much committed to its principles of a universal access to high-quality health care, spending 4.6% of the total annual budget on health. Although the amount seems modest in comparison, through a wide nationwide networks of clinics and hospitals it provides 90% of healthcare in the country. However, in spite of the dedication of the government and staff of the Ministry of Health, there are still some problems that are unsolved, and one of those is the disparity in the availability of health services between regions.

Blood Transfusion Service in Malaysia

Ninety percent of the blood supply comes from 128 collection centres of the Ministry of Health (MOH). Screening and processing of the blood are done in 16 centres. In 2009 a total of 565,604 blood units were donated.

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From this more than 1.3 million units of components were prepared (4). A total of 274,746 units of Fresh Frozen plasma (FFP) were prepared and 14,417 units of recovered plasma were obtained. Nearly 9,600 units of apheresis plasma were donated.

The National Blood Centre in Kuala Lumpur is responsible for planning, coordinates activities, formulate policies and guidelines and conduct training as well as the Quality Assessment Programme.

Plasma Fractionation.

Malaysia went into contract fractionation with a modest start in 1990. Currently, there are 3 centres that provide the plasma for contract fractionation. Although potentially more plasma could be sent for fractionation, only 30,600 kg of plasma were able to be processed (4). This is because of budget constrain, and inability of the collection centres to meet the requirement of the regulators in which the fractionation plant is located.

Good Manufacturing Practice (GMP) principles are incorporated into the quality system to ensure safety, quality and reliability of the source plasma. The 'Plasma Master File' a document relating to the starting plasma was also introduced as required by the regulators. The introduction of the PMF was to simplify and reduce the burden of documentation as well as to improve harmonization of requirements and assessment of the starting material plasma for fractionation (6).

More than10,000 vials of 500 IU of factor IX concentrate, and 17,000 vials of 250 IU of factor VIII concentrate were produced (3). The yield for intravenous immunoglobulin is usually fairly good at approximately 49,564 vials of 3grams. In addition 28,634 vials of 20% albumin are produced.

Malaysia opted for contract fractionation for a number of reasons. There was a move towards component therapy in the 1980s that resulted in excess plasma. In the mid 1980s the MOH allocated budget for the purchase of factor concentrates for treatment of haemophilia (7). This added to the surplus of plasma which would be discarded if not used as storage space was limited. That would have caused a lot of wastage and would be detrimental to the blood donation programme. There was also a need to move towards self sufficiency in plasma derived products.

However, the amount of plasma available was too small to embark on establishing a fractionation plant in the country, not to mention the lack of expertise in the country. The regulatory agency did not have the expertise to provide adequate con-

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trol over the processing of plasma and the quality and safety of the fractionated products. Contract fractionation seemed to be the best option as the government need not provide the huge capital cost for building a fractionation plant and skill human resource for operating such a plant is not necessary.

Total dependency on commercial product can be avoided and there were times during global shortage of plasma derived products when the local products proved to be invaluable. Some cost savings was also possible.

Over the years there was huge progress in the quality management system of the blood transfusion service. The fractionation programmme had helped the blood centres to focus on the implementation of quality initiatives and expedite the progress made. Partnership developed between the fractionators and the plasma supplier. The improvement in the collection, processing, storage and transport of the plasma has not only helped in the yield of plasma derived products but also the blood components for clinical use.

Conclusion

The capacity of the current plasma suppliers for fractionation is limited and would not suffice to produce enough to cover global needs (8). Hence, all countries must make an effort to collect local plasma of acceptable quality and safety to meet their own requirements.

Although Malaysia is still a long way towards self-sufficiency in plasma fractionated products, the experience and the lessons learnt has helped the country to be more aware of the issues involved in the plasma industry and in particular understand the issues of safety and availability. The improvement in knowledge and skill of the blood centres has definitely profited the blood transfusion service.

However, contract fractionation needs be carried out as a national programme with clear vision and objectives. As it grew it has to be managed efficiently with proper planning and resources. It has to have a budget separate from the operations of the blood services. Ideally, it has to be an integral part of the national blood programme (9). It has to be visible and its contribution to patient safety and the healthcare system in general be recognized.

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