The Need for Plasma in Asia

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Asia has far and away the largest population of any continent, at 4.43 billion,[1] and a rising standard of living.[2] The percent of gross domestic product that most Asian countries are able to dedicate to health care is rising as well.[3] These factors, combined with a modest population growth rate (1.04 percent)[4] across the region, amount to one irrefutable fact—the clinical need for plasma protein therapies in Asia will increase. It is important that steps be taken in order to accommodate that clinical need, and advance the idea of Asia as a critical partner in a goal of global sufficiency of plasma.

Looking at numbers of people with hemophilia A (PWHA) and primary immunodeficiency (PID) show the stark gap between the numbers that might be statistically expected and how many have been identified. In India alone, we might expect to see 131,105 PWHA, but the World Federation of Hemophilia reports that 14,508 PWHA have been identified. In China, those numbers are 137,122 and 11,837, respectively. The estimated numbers of patients with a PID, compared to identified patients, are even bleaker. In India, we might expect to see 11,539, while 500 have been identified. A 2016 South East Asia Primary Immunodeficiency Network (SEAPID) study of Indonesia, Malaysia, the Philippines, Singapore, Thailand, and Vietnam shows that of an expected 46,461 patients with a PID, 489 have been identified.

What do these disparate numbers mean for the need for treatment in Asia? They mean that as health care systems and diagnosis improve and citizens are increasingly able to afford better medical care, previously unidentified patients will be diagnosed, which is a wonderful thing. It is important, however that there is a sufficient ability to procure the critical therapies they require. While there is a desire in many Asian countries to facilitate additional supply of plasma for fractionation, countries face a variety of hurdles to robust collection.

China, for example, has very strict regulations on collections, and while PPTA applauds China's efforts to maintain a safe supply of plasma, some of the measures taken put an undue burden on collection without any safety benefit. First and foremost among those is a prohibition against the use of recovered plasma, which means that much important plasma is lost as a result. Total demand for plasma to fully supply the Chinese market was 12,000 tons in 2016, while Chinese collection centers collected 5,480 tons.[5] Some of that shortfall is made up by albumin sales from foreign companies, but significant clinical need remains unmet. An additional restriction requires that

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plasma collection centers be owned by a fractionation company, which prevents the development of independent collectors which are a crucial piece of the systems enjoyed in the U.S. and European countries.

On the other hand, India's plasma collection is limited by a prohibition against the collection of source plasma. The country currently collects a small amount of recovered plasma—the Marketing Research Bureau estimates around one percent of the world's supply of plasma for fractionation in 2015, or around 425,000 liters. However, with the world's second largest population, also with an increasing standard of living, India has the potential to make a great impact on the world's supply of plasma should a well-regulated and safe source plasma collection system form in that country.

The Japan Blood Product Organization provides around 910,000 liters of plasma in 2015 to domestic manufacturers for processing into PPTs.[6] However, there is limited incentive to collect more due to the inclusion of PPTs in the Export Control Order, which prohibits their export, as well as the export of source plasma. An official report issued by a Ministry of Health task force in October of 2016 suggested removing PPTs from the Export Control Order and allowing the export of products made from "surplus" blood components on humanitarian grounds. While not concrete progress toward free trade in plasma, it is certainly a step in the right direction. Other challenges involving appropriate diagnosis and treatment of patients in Japan also warrant consideration, such as awareness of rare diseases, treatment, and the possibilities for suitable reimbursement policies that take such rare disease dynamics into account.

Indonesia is another country with great ambition but significant barriers to effective plasma collection. It was chosen as the pilot country for the 2013 World Health Organization (WHO) and European Commission project for enhancing the availability, safety and quality of blood products in low- and middle-income countries. As part of that project, three major fractionators reviewed Indonesia's current plasma collection practices and found a number of areas where critical deviations from established practices were observed.[7] However, more recent projects being developed in Indonesia may point the way to a more effective approach, with a new memorandum of understanding between the Indonesian Red Cross and PT Bio Farma. The Indonesian Ministry of Health has also recently approved PT Bio Farma to manage the production of immunoglobulins and albumin from plasma collected by the Indonesian Red Cross.[8]

PPTA tirelessly advocates for global sufficiency in plasma for fractionation. The countries mentioned here, as well as many others throughout Asia, show that there is certainly a strong regional will to contribute to that goal. We believe that through educating policymakers, doctors, patients, and industry leaders, and providing support wherever possible for those looking to help advance this goal, there is no reason that Asia cannot become an even more active contributor to the world's supply of plasma for fractionation. ●

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