

Multilayer-strategy to enhance optimal safety of the blood supply: The role of pathogen inactivation/reduction for optimizing recipient safety and helping health care cost containment

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Over 100 million units of blood are collected yearly. The need for blood products is greater in developing countries, but so is the risk of contracting a transfusion-transmitted infection. Without efficient donor screening/viral testing and validated pathogen inactivation technology, the risk of transfusion-transmitted infections correlates with the infection rate of the donor population. The World Health Organization has published guidelines on good manufacturing practices to ensure a strong global standard of transfusion and blood product safety. Sub-Saharan Africa is a high-risk region for malaria, human immunodeficiency virus (HIV), hepatitis B virus and syphilis. Southeast Asia experiences high rates of hepatitis C virus. Areas with a tropical climate have an increased risk of Zika virus, Dengue virus, West Nile virus and Chikungunya, and impoverished countries face economical limitations which hinder efforts to acquire the most modern pathogen inactivation technology. These systems include Mirasol® Pathogen Reduction Technology, INTERCEPT®, and THERAFLEX®. Their procedures use a chemical and ultraviolet or visible light for pathogen inactivation and significantly decrease the threat of pathogen transmission in plasma and platelets. They are licensed for use in Europe and are used in several other countries. The current interest in the blood industry is the development of pathogen reduction technologies that can treat whole blood and red blood cells. The Mirasol system has recently undergone phase III clinical trials for treating WBC in Ghana and has demonstrated high efficacy toward malaria inactivation and low risk of adverse effects. A 2nd-generation of the INTERCEPT® S-303 system for WBC is currently undergoing a phase III clinical trial. Both methodologies are applicable for WB and components derived from virally reduced WB or RBC. The implementation of such technologies enhances not only optimal recipient safety and also bring about considerable cost containment in health care system, in long terms, by removing some of the multilayer safety tests currently in practice.

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