

Minipool technology to prepare immunoglobulins to fight viral infections in developing countries

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A study publishing February 26th, 2015 in *PLOS Neglected Tropical Diseases* describes a new, pragmatic, method for the production of immunoglobulin G (IgG) from human plasma in developing countries. IgG are therapeutic preparations on the WHO Medicine Essential List that are used to treat patients with primary immune immunodeficiency (PID) and to fight various infectious diseases. PID affects approximately 1 out of 5000 individuals. IgG are manufactured mostly in sophisticated facilities located in advanced economies and are produced from plasma collected in the USA or Europe. There are serious shortages of IgG worldwide, leaving PID patients in the developing world without treatment and therefore exposed to local viral and bacterial pathogens.

This simple methodology reported in *PLOS Neglected Tropical Diseases* allows the preparation of virally-inactivated IgG from small pool of plasma using disposable equipment and medical devices. It can be implemented to fractionate plasma from developing countries without the need to build a pharmaceutical facility. IgG made from local plasma have the ideal mix of antibodies suited to fight local viral and bacterial pathogens. The method could be ideal to prepare IgG from convalescent plasma, as is the case following the Ebola epidemics in West African countries.

Thierry Burnouf, corresponding author of the study and closely involved in the development of the procedure, also Director of the Graduate



Institute of Biomedical Materials and Tissue Engineering at Taipei Medical University (Taiwan), indicates that "making a technology simple, efficient, and cost-effective can often be more difficult than making it sophisticated. This minipool technology is a robust and pragmatic way to prepare IgG with good safety and purity levels; although initially targeting the treatment of PID, the technology can also be of value for preparing anti-Ebola virus IgG, or other IgG against emerging pathogens, using a minipool of 20 convalescent plasma donations."

"We have developed and implemented this technology with great success in our production center which is also preparing virally inactivated plasma and cryoprecipitate to treat patients with various bleeding disorders. The clinical studies performed in PID children are showing the safety and efficacy of the minipool IgG product to restore normal IgG levels and decrease the incidence of infections" said Magdy El-Ekiaby, first author of the study, Director of the Shabrawishi Hospital Blood Bank, and Egyptian Company for Biological Sciences in Cairo (Egypt), who has played a leading role in developing and implementing such minipool processes.

The authors note that the process could be implemented readily in blood establishments or national service centers after appropriate operator training and basic equipment acquisition. Critical parts of the process are performed in a closed-bag system and easy-to-use disposable equipment, do not present cleaning-related cross-contamination risks, and is affordable. It is far more feasible than current fractionation technologies for rapid implementation in low or medium income countries, therefore representing a pragmatic approach to address IgG shortages and to prepare convalescent IgG for passive immunotherapy against emerging infections.

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