Convalescent Plasma Transfusion and Hyperimmune Globulin
Understanding the Differences

The CoVIg-19 Plasma Alliance welcomes a wide range of efforts to fight COVID-19, including vaccines and other treatments. In the plasma category, we believe both convalescent plasma (CP) transfusion and hyperimmune globulin (H-Ig) potentially have important roles to play.

Since both treatments use plasma from recovered patients and are currently being studied as potentially effective responses to COVID-19, it is important to understand the two approaches.

	Convalescent Plasma Transfusion	Hyperimmune Globulin*
DEFINITION	**Plasma that has been collected from recovered patients and is transfused directly to people experiencing serious complications from COVID-19.**	**Plasma that has been collected from recovered patients and is further processed into a medicine called hyperimmune globulin. It is a potential treatment for people at risk for serious complications from COVID-19.**
PROCESS	**Donated plasma directly transfused.** Plasma from a donor is transfused directly to a patient. The process includes viral inactivation and blood-group matching between CP and recipient.	**Donated plasma pooled and processed.** Plasma donations from many people who have recovered from COVID-19 are sent to manufacturing facilities. There, the plasma is pooled together and processed to remove or inactivate viruses and concentrate the antibodies.
TIMING	**Shorter-term use.** Minimal processing means faster availability. Can be available for use the same day plasma is collected, but must be infused or frozen within 24 hours.	**Longer-term use.** Because it requires more processing, it will take longer for H-Ig to be available. However, it has a longer shelf life (from 24-36 months), which could make it easier to distribute and store for use in future outbreaks.
SAFETY	**Limited viral inactivation.** Scientists must first ensure that donated plasma does not contain other viruses. Blood typing needs to be confirmed or tested to ensure compatibility.	**Extensive viral inactivation.** All H-Ig preparations have at least three dedicated viral inactivation or removal steps. Blood typing is not required.
STANDARDIZATION	**Antibody levels vary by donor.** Because the amount and range of antibodies in a unit of plasma provided to a patient is dependent on an individual donation, it is challenging to deliver a standardized dose.	**Consistent antibody potency.** Because it is made from pooled convalescent plasma that has been purified and concentrated, H-Ig is standardized so it has a consistent level of antibodies in each unit.
POTENCY	**Less potent antibody concentration.** Because plasma is minimally processed, it has a broad range of virus-specific antibodies per unit of volume.	**More potent antibody concentration.** Because it is highly concentrated through the manufacturing process and contains antibodies from many donations, H-Ig contains more virus-specific antibodies per unit of volume.

*These attributes are based on our knowledge of current plasma-derived therapies. However, because the FDA and other regulatory authorities are the final arbiters of what is ultimately approved, we cannot guarantee that an investigational therapy would have the same or similar attributes.

Summary

There is a long history of using convalescent plasma (CP) transfusion and hyperimmune globulin (H-Ig) to treat new diseases. Convalescent plasma transfusion is currently a treatment approach for COVID-19 as there are very limited treatment options and because it can be available more quickly. But its individual and variable nature make it difficult to produce at a large scale.

Hyperimmune globulin may take longer to develop due to a more complex manufacturing process. However, the additional processing allows it to be standardized so it has a consistent level of virus-specific antibodies in each unit, and significantly reduces the risk of transmitting any kind of virus (not just coronavirus) from donors to patients. H-Ig also has a longer shelf life, which could make it easier to distribute and store for use in future outbreaks.

Both of these approaches are experimental. Convalescent plasma transfusion has received temporary authorization for emergency use, while H-Ig needs to be tested in clinical trials to determine whether it is safe and effective. The efficacy and safety of convalescent plasma transfusion could be confirmed through clinical trials.

Numerous research initiatives on each approach are currently underway. The CoVIg-19 Plasma Alliance is a group of world-leading plasma companies who believe that H-Ig is a promising approach for a potential large-scale treatment for COVID-19. We are working together to accelerate its development, improve our overall probability of success, and increase the supply of a potentially life-saving treatment.

The Alliance's effort to develop an H-Ig depend on unknown factors such as the availability and collection of convalescent plasma, clinical trial outcomes, and regulatory approval. However, if we are successful, we believe our H-Ig has the potential to be one of the earliest approved scalable treatment options.

About the CoVIg-19 Plasma Alliance

In an effort to help fight against the COVID-19 pandemic, a new alliance was created in April 2020 to help develop a potential plasma-derived therapy for people at risk for serious complications from COVID-19.

The CoVIg-19 Plasma Alliance brings together world-leading plasma companies to work on the development of an investigational unbranded polyclonal anti-SARS-CoV-2 hyperimmune globulin medicine with the potential to treat patients who are at risk for serious complications from COVID-19.

The “I” and “g” in CoVIg-19 stand for immune globulin, which the CoVIg-19 Plasma Alliance will use to concentrate the antibodies into a potential medicine.

The Alliance, formed by CSL Behring and Takeda, also includes the leading-edge expertise of Biotest, BPL, LFB, and Octapharma. The Bill & Melinda Gates Foundation is providing advisory support. Microsoft is providing technology including the Alliance website and the Plasma Bot for donor recruitment. Experts from the Alliance are collaborating across key aspects such as plasma collection, clinical trial development, and product manufacturing.

bpl Bio Products Laboratory · Biotest · CSL Behring · LFB Biomédicaments · octapharma · Takeda