COVID-19 CONVALESCENT PLASMA

OUR ONLY HOPE UNTIL A VACCINE IS READY

Since the beginning of March, I have been waiting for Governments worldwide to announce that they would order the manufacture of Covid-19 Hyperimmune Immunoglobulin from convalescent plasma by the Cohn fractionation process. The product would be used in its intravenous form to give immediate passive immunity to treat seriously ill patients with Covid-19 and to give in its intramuscular form to Front line health workers, Care Home Staff and residents, the BAME community, the immunocompromised and all other vulnerable groups to be used in a prophylactic manner. From the experience of using other viral immunoglobulins, in this latter form, passive immunity can last for several months or more. During the second world war, Edwin J Cohn, an American Harvard University Scientist, was asked to develop a process that would separate albumin from human plasma to be used to treat soldiers suffering from shock and burns. The process that he developed was not only successful in separating albumin but a whole range of plasma proteins including immunoglobulin. The Cohn fractionation process is still used today in plasma fractionation facilities around the world. The one of most importance for todays' coronavirus covid-19 pandemic is called specific hyperimmune immunoglobulin. It is called specific because plasma is collected from blood donors that have recovered from a specific viral infection, examples being Hepatitis, Measles, Varicella-Zoster, Rabies etc. The plasma, known as convalescent plasma, is high in antibody (hyperimmune) to the viral infection from which they have recovered. Specific immunoglobulins have been manufactured from convalescent plasma for more than 50 years and this very safe and efficacious product has saved thousands of lives.

It is the same product that a vaccine stimulates our immune systems to produce when we are infected by a live virus. To be clear, a vaccine is a virus that has been neutralised in such a way that its antigenic properties activate our immune system without being infectious. Our immune systems produce antibody and memory cells to the vaccine and so when we are infected by the live virus our memory cells immediately produce antibody to destroy the live virus. If we take convalescent plasma from patients having recovered from covid-19 then it will have high levels of antibody to the virus that we can separate and on injection can be used to help save the lives of those whose immune systems are not so robust.

From the end of March, The US Department of Health and Human Services announced that they, in cooperation with the FDA, were approving the use of convalescent plasma for direct infusion into patients suffering with covid-19. This would continue until their plasma fractionators had enough convalescent plasma to pool and manufacture the specific covid-19 hyperimmune immunoglobulin to treat patients. One plasma fractionator, Grifols, was given an upfront payment of $14.5 million to make the product. It takes approximately 5 weeks from pooling the convalescent plasma to having a batch ready for release.

The US are moving quickly. The country's first convalescent plasma transfusion trial results have been published and show 19 out of 25 patients improved with the treatment, and 11 were discharged from hospital. With no adverse side effects caused by the plasma transfusion, the study concluded that convalescent plasma is a safe treatment option for patients with severe COVID-19 disease. Patients were first treated under emergency use guidelines (eIND) from the FDA and then received approval on April 3 from the FDA to open the trial to more patients as an investigational new drug (IND). This extraordinarily

rapid approval granted by the FDA gave access to convalescent plasma treatment for COVID-19 patients. Not all plasma recipients transfused were part of this first trial. Since late March, when the first patients were infused with convalescent plasma, of 74 critically ill COVID-19 patients, 50 have been discharged from the hospital and are recovering.

The UK do not seem to be going so fast. A paper written by NHSBT - Understanding the convalescent plasma trials for COVID-19 published on 21 May 2020 has the last sentence "We hope to have results from these trials by Spring 2021".

The French fractionator is working with the alliance of plasma fractionators from around the world and their first clinical trial is expected in summer 2020.

The US clinical trial results are not a surprise. Studies of the use of convalescent plasma and hyperimmune immunoglobulin in previous SARS outbreaks have been reported as reducing the Case Fatality Rate.

Until a vaccine is ready and this could be a long way off, there are tens of thousands of people that have recovered from Covid-19 across countries in Europe and who are ready to donate their blood plasma to save lives. Furthermore, there is always the concern of a second wave. If all plasma fractionators are prepared to manufacture the specific covid-19 hyperimmune immunoglobulin now then not only could covid-19 infected patients be treated and the "at risk groups" be given prophylactic passive immunity but stocks of the product could be built up to save us from a potential second wave.

I simply do not understand why our European Governments are not forcing the manufacture of this product to save lives.

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