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The Plasma Shot (Passive Vaccine)

The Problem

Now that we are thankfully seeing a lower level of infection in the tri-state area and many other areas across the USA, the vulnerable among us are wondering when they can resume normal life. Grandparents long to kiss their grandchildren and children of the immunocompromised yearn to play with their peers. How can we protect the at-risk as we return to normal?

The Solution

Hyperimmune globulin (HiG) may be the solution to this problem. HiG consists of concentrated antibodies from convalescent COVID-19 plasma which may protect vulnerable individuals from infection. Concentrated antibodies have been used to <u>treat many diseases</u> over the past century, such as diphtheria, polio, measles, and rabies [1].

Vaccines for a specific disease elicit immunity in individuals by stimulating their immune system to <u>provoke a response to that disease</u> [2]. A COVID-19 vaccine may not be available for <u>many months</u> [3]. Concentrated COVID-19 antibodies (HiG) may serve as a substitute by <u>providing passive immunity</u> so that individuals need not be concerned about infection for 1-4 months after injection [4].

HiG Intramuscular Injection

HiG can theoretically be administered as an intravenous infusion (into the vein) or as an intramuscular injection (into the muscle). While the <u>CoVIg-19 Plasma Alliance</u> is developing an intravenous HiG product [5], we are focusing on intramuscular HiG injections. We believe that intramuscular HiG has superior applications, since intramuscular injections require less training to administer and can easily be implemented outside the hospital/clinic setting (e.g. in nursing homes, etc.).

We are working with researchers at the Mayo Clinic, Columbia University, Case Western University, Johns Hopkins University, and multiple hospitals to perform clinical trials on the efficacy of the HiG shot. Additionally, we are supporting multi-center trials that will be evaluating an HiG shot manufactured by Kamada, Ltd. and Kedrion Biopharma. We have also discussed the possible manufacturing of HiG injections with <u>ADMA Biologics, Inc.</u>, a well-regarded, public company with years of experience in manufacturing HiG products [6].

Clinical Trials

Clinical trials are focused on the following three areas:

- 1. *Pure Prophylaxis*: injections are administered in any high-risk population (e.g. elderly, nursing homes, front-line workers, schoolteachers in districts providing in-person learning) to provide passive immunity for 1-4 months.
- 2. Post-exposure Prophylaxis: injections are administered to those who have been exposed to COVID-19 to prevent active COVID-19 infection
- 3. *Mild Treatment*: injections are administered to treat those who have become ill with mild COVID-19 Additionally, <u>HiG has been used</u> to treat severe infection in a young COVID-19 patient in Israel with highly promising results [7].

Nursing Homes

Since nursing home residents are at high-risk for severe COVID-19 (<u>some estimate that a third of COVID-19</u> <u>deaths in the US are of nursing home residents or staff</u>) [8], nursing homes are eager to prevent illnesses among their residents. We have several nursing home industry chains who will participate in clinical trials to



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given to close contacts of infected individuals to prevent further outbreaks. This approach is similar to the ring vaccination strategy of vaccinating close contacts of infected patients, which has been successfully used to <u>eradicate smallpox</u> [10].

Community Voucher Program

Plasma donors would like to be assured that their relatives are able to receive convalescent plasma if they become ill and that their high-risk relatives are able to receive the HiG shot.

Economists Scott Kominers, Parag Pathak, Tayfun Sönmez, and Utku Ünver have produced an <u>incentive scheme</u> that would allow plasma donors to receive community credits for each plasma donation [11]. The community credits can be used by family members or friends of the donor for priority access to HiG products. By donating plasma, you may receive a passive vaccine credit to allow your parent and/or grandparent to live normally.

Additionally, potential plasma recipients (e.g. ill patients) can pledge to donate plasma when they recover, and thereby receive priority access for HiG.

- [1] https://ccpp19.org/healthcare_providers/hyperimmune_globulin/index.html
- [2] https://academic.oup.com/occmed/article/57/8/552/1474357
- [3] <u>https://www.cnbc.com/2020/05/07/timeline-on-covid-19-vaccine-and-treatments-under-development-now.html</u>
- [4] https://academic.oup.com/occmed/article/57/8/552/1474357
- [5] https://www.covig-19plasmaalliance.org/en-us#recruitment
- [6] https://www.admabiologics.com/
- [7] https://vosizneias.com/2020/06/23/hadassah-becomes-worlds-first-hospital-to-use-igg-serum-on-covid-19-patients/
- [8] https://nypost.com/2020/05/16/blame-governors-for-coronavirus-deaths-in-nursing-homes-goodwin/
- [9] https://www.wsj.com/articles/eli-lilly-studies-experimental-covid-19-drug-in-nursing-homes-11596451502
- [10] https://pubmed.ncbi.nlm.nih.gov/1083309/
- [11] https://www.tayfunsonmez.net/wp-content/uploads/2020/06/WhitePaper-ConvalascentPlasma.pdf

