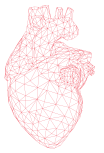




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Now That I'm Vaccinated...

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It has now been a year since the COVID-19 pandemic wreaked havoc on our health and totally disrupted our lives. The threat of unimaginable death has been realized, with over 525,000 fatalities due to COVID recorded at the time of this writing. For the fortunate among us who escaped infection, almost no aspect of daily living has remained unaltered by COVID. From the beginning, we were assured by experts that the answer to overcoming the pandemic was a vaccine that, once available, would enable a return to normal life. To that end, enormous amounts of money were devoted, not only to the development but also to the production of vaccines.

In contrast to the generally dismal response to the infection in the U.S., a clear outstanding accomplishment was the creation of a number of effective vaccines. The U.S. government and some private entities such as the Gates Foundation gambled that at least one of the several possible vaccine candidates would be found to be effective. They sponsored not only research into the development of a vaccine but also the production to scale so that it could be administered shortly after approval. Large clinical trials were initiated with the goal to achieve a vaccine that was at least 50% effective against the SARS-CoV-2 virus.

When the clinical trials were done, our expectations were exceeded when not one but two candidates were found to be 94–95% effective. A collective sigh of relief went out that, perhaps now, there was a light at the end of the tunnel. The anticipation was that our lives would quickly return to normal after vaccination. It was thought that masks could be abolished, social distancing eliminated, and families could once again get together and exchange hugs. We yearned for the return of restaurants, and movies, and concerts, and carefree travel, etc., etc., etc. Medically, we longed to return to in-person meetings and conferences. Of perhaps greater importance, we desperately looked forward to the reopening of schools. Working at home and distance learning had taken their toll. A vaccine could not come soon enough as “COVID fatigue” increasingly led people to disregard some of the public health measures to avoid disease. It was no surprise, therefore, that there was substantial jockeying to be in the first groups to get vaccinated.

As a health-care worker, I was in one of the earliest groups to be vaccinated. Shortly thereafter, my wife also received the vaccine. So several weeks ago, we were both beyond the 14-day period after receiving the second dose that had been found to produce 95% efficacy against the virus. We had not seen two of our children or seven of our grandchildren for over a year (other than Zoom or FaceTime). As we sat down

and considered what to do first and how to open up our lives, it occurred to us that the vaccine may not actually have changed much in our lives.

Following trials that reported positive results, it has been dogma that clinical application of the drug, device, or procedure tested be applied exactly as it had been in the trial. In fact, this has generally been the policy of regulatory agencies that grant approval for use. It is entirely rational and intuitive to believe that, to obtain the results of a clinical trial in a practice setting, you should apply the therapy as it had been in the protocol. Among the requisites would be choosing similar patients to those in the trial and subjecting them to the same conditions as the study population. That this same thinking should apply to the application of a vaccine trial seemed obvious.

As I thought about how life was going to change now that I was vaccinated, I took stock of the details of the clinical trials. First and foremost, I considered the population enrolled in the trials. They were surely a relatively extraordinary group of individuals. Not only did they volunteer for a study for which the safety and efficacy of the agent were uncertain, but they did so when they were in excellent health. Many patients who are afflicted with a disorder volunteer for investigational protocols, and these patients are indeed heroes. However, they already are ill and potentially have something to gain. The volunteers for the vaccine trials were risking what was at the time good health. So I regard these subjects as somewhat unique. I assume that they were motivated to accept an experimental vaccine in part since they were very impressed by the deleterious effects of COVID. Therefore, I further assumed that these subjects would be highly observant of the lifestyle recommendations to avoid infection. They would be extremely likely to wear masks, keep 6-ft. distance from others, avoid crowds and confined spaces, and wash their hands frequently. They were not likely to let their guard down under any circumstances. My guess is that these volunteers are likely on one end of the spectrum in terms of behavior that adheres to public health recommendations.

An additional factor in considering the application of the trial results to myself was the uncertainty involved in the protocol. To begin with, the volunteers had no knowledge of whether they received the vaccine or were in the control group. Moreover, even had they received the vaccine, they had no idea of whether or not it would be effective. Therefore, not knowing whether or not they had obtained an effective



vaccine, the only rational action was to behave during the course of the trial as if they had never received one. In aggregate, I envision that the patient population of the vaccine trials was comprised of individuals who were highly motivated to adhere to public health measures and behaved as if a vaccine never existed in the first place.

In view of the foregoing considerations, it would seem clear that, to duplicate the results of the trials, and achieve 95% efficacy, one would have to behave as if they were never vaccinated. Needless to say, this was a bit of a downer. When friends who had not yet been vaccinated asked me how life had changed now that I was vaccinated, I had to tell them “not much”. I was convinced that the best way to duplicate the results of the trials was to reproduce its conditions as closely as possible, admitting that I was not likely to be as adherent as the volunteers. I continued to mask, to avoid

crowds (especially in confined spaces), and to wash my hands until they were chafed. Of course, I do have a sense of confidence that was not present before, especially when with others who have been vaccinated. But I suspect that a return to normal will require either herd immunity or a tremendously effective therapy for the virus. Until then, it appears that the changes that I imagined would occur now that I am vaccinated will have to be much smaller in scope.

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