COVID-19, MUTATIONS, AND VACCINES

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I am working on updates to the coronavirus material I posted last year; I will get it up on the blog as I get it together. This post addresses mutation dynamics and vaccines as well as a few other things. Note: getting accurate information and data has proved difficult, in part because material is often slanted to try and reduce social panic and polarization so as to get the economy (such as it was) going again. Far too much of the functioning of American culture depends on people with too little money and gig work spending it rather than the government doing its job to maintain infrastructure, functioning institutions, and social safety nets. Because of this it is very hard to find any accurate material that does not minimize some of the dangers we are facing.

Covid-19 Mutations

Like all microbes, and most especially viruses, Sars-CoV-2 is a master of mixing its genome. It is a very adaptable organism. Viruses, when they move into large populations of people, enter new ecological territories. Just as we do, they learn the new terrain and adapt to it.

Viruses are immeasurably older than the human species; they have a great deal of experience altering their genomic structure to better facilitate their surviving in new ecological niches. Regrettably, researchers often speak of viruses as having trouble reproducing identical copies of themselves. They often say that viruses make "typos" or "copy-and-paste" errors or engage in bad "proofreading" when reproducing. (Note: viruses are not machines or editors, they are highly adaptable and intelligent living beings; these metaphors are extremely misleading.) These kinds of comments make the viruses seem rather stupid: "Oh, the poor things. Can't even reproduce correctly."

What is more ecologically accurate is that viruses are a form of swarm intelligence – the individual members are not the important thing – the swarm entity is. One of the primary adaptation patterns viruses use is to generate millions of slightly different offspring very quickly in order to produce more highly adaptable forms. The viral swarm also possess the capacity to create new genomic forms through highly sophisticated examination and analysis of their new hosts' ecologies. They *respond* to our responses to them – both our immune responses *and* our social responses, which includes the vaccines we create. They do this in a number of ways.

An important, recent, finding is that during the pandemic Covid-19 viruses worldwide took up residence in a number of immuno-compromised people. They did not kill the people, or even make them very ill, instead they spent their time studying the human immune system. Then they recombined genomes, creating more efficient immune-adaptable forms. As Molecular epidemiologist Emma Hodcroft has said, "It becomes almost like a training course for how to live within the human immune system."

The creation of a great many different virus forms ("proofreading errors") gave the viral swarm more adaptable forms to choose from. These genomic innovations were then combined to create even more efficient immune-survivors. There is also increasing evidence that our medical responses to them, including vaccines, are also stimulating adaptation. The viruses, as they commonly do, are also gathering genomic information from other coronaviruses (such as the corona common cold virus) that have already adapted to the human immune system. (Then there is the potential problem, of the SARS-CoV-2 coronavirus sharing what it learns with any of the

thousands of wild coronaviruses that exist; should they gain a spike protein adaptation that allows human infection new pandemic forms can arise.) When these variants encounter each other in new hosts they immediately share what they have learned and form even more adaptable variations. This promiscuous genetic sharing and innovation are the reasons why similar-toidentical variants have emerged, nearly simultaneously, in many different countries.

These are adaptation strategies of long ecological duration. All microbes, despite what we were taught in school, are highly intelligent and they have been surviving and adapting far longer than our species has.

Currently, three innovated forms (aka mutations) are especially worrying (more will emerge as time goes by and yes, they know where we live). Shorthand: they are the UK, South African, and Brazilian variants. (There are three others that may become serious problems as well: one in Spain, another in Brazil, and a new one in California that appears to be *very* infectious.) The genomic innovations in the three variants are not identical, though they are very similar. But in one respect they are identical. Each possesses an alteration in a particular spike protein (N501Y). This alteration allows the virus to attach to ACE2 receptors more easily, making infection more likely.

Initially, a wild form of CoVid-19 found a way to attach itself to ACE2 receptors on human cells. Here's a bad analogy: the virus (male) and the cell (female) formed a kind of male/female attachment point. The fit wasn't perfect but it worked well enough. The human immune system responded by creating an antibody that "capped" the spike on the virus (condom), making it more difficult or impossible for the virus to attach and thus penetrate the cell. Over time the virus adapted to this immune response (the new variants). They changed the shape of the spike so that it could not be capped by the antibody. At the same time the innovation created a much firmer, tighter fit to the ACE2 receptors.

Other alterations made the new forms far more transmissible. (Viral loads in the infected are up to 1000-fold higher.) And still more innovations (the E484K mutation) enable them to more easily avoid immune system antibodies, especially so in the South African and Brazilian forms.

Large numbers of previously infected Brazilians are now succumbing to their new variant. The same dynamic appears to be playing out in South Africa. The take away from this: *Previous infection does not confer immunity to adapted forms*. Nor does donor plasma seem to work against the new variants. Given these adaptations, it may be more accurate to think of the new coronaviruses as similar to the flu virus, which needs a different shot each year. A number of researchers are now saying *that herd immunity is unlikely*. The only good news is that the variants (on average) seem to be causing milder infections in most people. Nevertheless, some people will still become very ill and others die.

These new variants are becoming dominant everywhere they take hold, including in the U.S. New variants will continue to emerge and it is becoming extremely likely that CoVid-19 will adapt well enough that it can't be eliminated entirely, that it will be with us for a very long time. The important question is, can we adapt to it?

The Vaccines

Despite common assumptions, COVOD-19 vaccines are not actually vaccines in the way most people think of them. They are not like the smallpox vaccine which prevents all future infection.

More properly, most current vaccines activate the immune system which enables it to better respond to the virus. Thus, some people won't develop an infection, for others it will be less severe than it might have been otherwise. Unfortunately, the current vaccines were designed to enhance responses to the original or wild form of the virus. They were not designed for the newer variants. Reports are emerging that people who were previously vaccinated, irrespective of country or vaccine, are now being infected with the new forms.

Apparently, there are some 240 different vaccines now in development. At present, six vaccines are officially approved or authorized in various countries (22 others are in phase three trials, 23 in phase two, 18 in phase one). The approved/authorized vaccines are: the Moderna mRNA-1273 vaccine, the Pfizer-BioNTech BNT162b2, the AstraZeneca AZD1222, the Sinovac Biotech and Sinopharm vaccines from China, the GAM-COVID-Vac (Sputnik V), the Novavax NVX-CoV2372, and the Johnson & Johnson/Janssen Ad26.COV2.S vaccine.

The Pfizer and Moderna vaccines are made using messenger RNA (mRNA) which delivers the genetic code for the spike protein into the body. This stimulates the immune system to make antibodies for the spike protein, which are activated when the virus enters the body. The Johnson & Johnson vaccine uses a different approach, creating what is called a viral vectored vaccine. A relatively benign adenovirus is altered to carry the SARS-2 spike protein into the body which, again, stimulates the immune system to produce antibodies. The Pfizer vaccine is only for people 16 and older, the other two 18 and older.

The Novavax vaccine delivers the actual spike protein (boiengineered via moth cells) into the body to stimulate the immune system. It also has an additive that "soups up" the immune response, a saponin from the Chilean soapbark tree. (Technically it is considered to be adjuvanted recombinant protein nanoparticles). The Sinovac Biotech and Sinopharm vaccines use an inactivated virus – similar to flu shots. (There is some concern about this approach, given the rush to market, in that early vaccine trials with inactivated dengue and RSV viruses caused serious side effects in large numbers of people.) The Sputnik V and AstraZeneca vaccines are what is known as vector vaccines similar to the Johnson & Johnson vaccine. (There is some evidence that vectored vaccines are more effective and longer lasting than other approaches.) There is also a Sinofi/GlaxoSmithKline vaccine which is apparently somewhat similar to the Johnson & Johnson vaccine and which may be available in late 2021 in the U.S.

Efficacy Versus Effectiveness

As usual, academicians' convoluted language (which the media endlessly repeats, often incorrectly) has created confusion about how effective the vaccines are. In truth there are two words being used, often interchangeably (which they should not be). During trials what is being looked for is efficacy. This is the degree to which a vaccine prevents disease (and sometimes transmission) *under controlled circumstances*. Effectiveness refers to how well it does *in the real world*. These are *not* the same things. Here is the ridiculous, and somewhat confusing, explanation, and why it matters.

Pfizer and BioNTech say their vaccines are 95 percent efficacious; Moderna's is 94.5 percent; Sputnik V is over 90 percent, the Johnson & Johnson single shot is (on average) 66 percent efficacious (but 85 percent against severe disease), Novavax is 89 percent efficacious in general but only 50 percent against the South African variant. The problem is that when those percentages are reported in the media the word *they* use is "effective."

When people hear that a vaccine is 95 percent effective, they, rightly, assume it means that only five out of every 100 people will get sick, 95 people will not. However, efficacy percentage *in a clinical trial* works like this . . .

Using the Pfizer vaccine as an example, here's what happens. That company recruited 43,661 people for the vaccine trials. (More on this in a moment.) They were split into two groups. One received a placebo, the other the vaccine. Then they sat around and waited for 170 people to become ill, specifically: *to show symptoms*.

Yes, this is a strange number. Apparently it was a suggestion from a statistician as being the lowest meaningful number in a trial . . . or something.

Once 170 people were sick, they looked at *who* got sick. Of the 170, 162 received the placebo and eight received the vaccine. They figure percentage of efficacy like this: If people in the placebo and vaccine groups become ill in the same numbers, the efficacy of the vaccine is zero. If no people in the vaccine group get sick then the efficacy is 100 percent. What they usually get, however, is a relational number. The 95 percent figure that is being cited represents the relation between the numbers who got sick in the placebo and vaccine groups. Specifically: eight divided by 162 gives you 0.05 (close enough) which comes out to five percent. In other words, the numbers of those in the vaccine group who got sick is five percent of 162, therefore the vaccine has 95 percent efficacy. This makes sense in the world researchers live in but not to people who live in the real world. And of course the media using the word "effective" instead of "efficacy" while failing to make the distinction clear has caused serious misunderstanding. Worse, what

happens in the trials might not actually have anything to do with what happens in the real world.

This is because the trials worked with a very limited number of people compared to the billions that will eventually be given. The general population is *very* different in health and genetic make up than those chosen for the trials. In consequence, the efficacy percentage is not directly translatable to the real world. No one knows what it will actually be until it is used in the real world and there is enough time distance to analyze what happens. A further problem is that some people who become infected show no symptoms. To get their efficacy percentage the trials only counted people who showed symptoms. It was not adjusted for lack of symptoms.

Very early, back of the envelope studies (Israel) are showing that there is definitely a reduction in symptomatic infections in the real world with the use of the Pfizer vaccine (a 30 percent reduction after the first shot, 75 percent after the second). Symptomatic infections do still occur, there are just fewer of them. There is no word yet on non-symptomatic infections after vaccine.

Five further points: 1) The shots *only* reduce severity of the disease if you become infected, *they do not prevent* infections as the smallpox vaccine does. *They are not vaccines* but should be thought of as more of a "dampener on the virus's ability to replicate inside you" as one researcher put it. No one knows yet if death rates will be reduced; the speculation is that they will be. 2) The doses are delivered into muscle tissue. This stimulates overall immune responses but it doesn't necessarily stimulate immune responses in the nasal tissues where the virus first takes hold. So it is possible that people may be carriers while not getting sick themselves. 3) Most of the vaccines stimulate antibody production. Antibody levels fall over time, so that shots may be necessary every six months to one year. (No one knows.) 4) Unexpected side effects will also

appear, often very different than those found during the trials. (This is true of *all* vaccines.); 5) The current vaccines will most likely not have the same efficacy percentage for mutant forms. (Current research is showing they do not; the Novavax vaccine is only 50 percent efficacious against the South Africa variant.) Emerging viral forms are becoming dominant worldwide which is going to reduce both efficacy and effectiveness. It is highly likely that new vaccine forms will have to be continually developed. This means that the virus may be with us for a very long time. The new normal is probably going to be very different than the old normal.

Vaccine Side Effects

The primary side effects of the vaccines (so far) appear to be pain (sometimes severe) at the site of the injection, possible temporary loss of use of the arm in which the injection occurs, and overall feelings of having the flu for a few days (chills and fever, nausea, aches and pains, fatigue). People are reporting that these symptoms are far more severe after the second Pfizer injection.

But, as expected, reports are emerging (as of March 2021) that the range of side effects from the shots are going to be far broader than first thought. Because the vaccines are only now going into the general population, reports are sparse so far: 1) Mild to severe, potentially deadly allergic reactions; 2) Headaches, fatigue, dizziness; 3) Tremors; 4) Immune thrombocytopenia (very serious); 5) Bell's palsy; 6) Death, mainly in older patients. (Norway recently reported 23 deaths in elderly, frail patients after they received the vaccine.)

A CDC report found that between December 14, 2020 and January 13, 2021 there were 6,994 reports of mild to severe adverse reactions to the Pfizer and Moderna vaccines out of

13,794,904 million injections. There were substantially more adverse events with the Pfizer than the Moderna vaccines. The CDC classified 6,354 as nonserious and 640 as serious. The most common side effects reported were severe: headache, fatigue, dizziness, chills, pain at injection site, and nausea. There were 113 deaths, 78 of them among long term care facilities (LCTF). The remaining 35 were ages 29 to 91. Pfizer vaccine deaths were 16, Moderna 19. Approximately 50 people reported anaphylaxis. Side effects beyond those that are listed here were not clarified.

This is a rather early report. It does show that the vaccines are pretty safe. Nevertheless, after 30 years of exposure, I no longer trust CDC figures to be complete or entirely accurate. As only one example, despite decades of solid research showing that at least 100,000 people per year were being infected with Lyme disease organisms, the CDC continually insisted that only 10,000 a year were infected. This kind of problem with CDC numbers has to do, in part, with CDC reporting requirements (often bearing little relation to the real world) but also reflects physician bias as well as political and PR pressures to under-report. (In general, I always multiply CDC figures by ten to get a more realistic sense of things.) As with Lyme infections, the coronavirus pandemic has put tremendous pressure on the medical community to get people safely vaccinated so the economy can reopen and life can go back to "normal." Media articles continue to downplay vaccine risks – and to be fair, reports are only now coming in and experience is showing them to be, in general, very safe. However, while it is true that only a small percentage of people are dying or becoming seriously ill from the vaccines, the fact remains that some people have very serious responses. That it is rare does not to help those who become very ill or die. ("Yeah, well, sorry don't do no good now, does it?").

Physician Paul Offit, whose work I admire, had some comments on vaccines and his

concern about the rush to market in September, 2020.

I think when you have no commercial experience with a vaccine strategy and you're using that as a way to stop a new virus, there will be something of a learning curve.... I wish there was a little more humility from some of these companies.... You're only going to know about rare adverse events once these vaccines are out there, because even in a best case scenario, they are tested on 20,000 or 30,000 people, not 20 million or 30 million people. So you are only going to know about a rare adverse event post-licensure.... Let's say we have a vaccine that is theoretically 75% effective against moderate to severe disease, and we know that it's been given to 20,000 people and that your group has been represented. And let's assume that the virus is still killing 1000 people a day and causing people to be hospitalized and suffering.... When do you know enough to say that a vaccine's benefits outweigh its theoretical risks? You have to also make sure people know what you don't know. You don't know how long protection is going to last. You're only going to know that afterwards. You don't know whether it causes a rare side effect. You're only going to know that afterwards. ... I just think we have to be honest and transparent about what we know and what we don't know.... Once we know the characteristics of these vaccines, it'll be much easier to try to explain what we know and what we don't know.

There is no easy answer to whether or not any individual should get vaccinated. (This is very

different than masks and social distancing; these are inconvenient but they don't disable people for life. They are a form of cultural caring for others and the social body as a whole.) As always, I believe that the use of medical technology should be a personal decision. I have simply heard too many thousands of horror stories to suggest that anyone use the medical world without seriously exploring the procedures or drugs their physicians are suggesting they use and then determining to the best of their ability whether or not they should go ahead. It appears that most people will do fine with the Pfizer and Moderna vaccines, for example, and that the worst effects will be feeling as if you have the flu for a few days. But I can't be so cavalier as to say that the relatively few people who die or are disabled from the vaccine don't matter because of the "greater good."

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continue to adapt, necessitating more alterations to the vaccines. And so on, as nauseum.)