Expect Coronavirus Vaccine Failure and Reactions

Analysis by Dr. Joseph Mercola

Story at-a-glance -

- The earliest results from COVID-19 vaccine studies are starting to roll in, and they're far from reassuring
- In one vaccine, developed at the University of Oxford Jenner Institute and named ChAdOx1 nCoV-19, all of the vaccinated monkeys treated with the vaccine became infected when challenged
- Oxford scientists moved on to human trials of ChAdOx1 nCoV-19 anyway, vaccinating volunteers, then allowing them to mix with the public to see if they get infected, but COVID-19 cases are declining so quickly in the U.K. that scientists are worried they won't be able to determine if the vaccine works
- Moderna has partnered with NIAID to create its own experimental COVID-19 vaccine, called mRNA-1273; the vaccine hasn't been tested against a placebo, and specific numbers on antibody concentrations weren't released, nor were the exact ages of the eight people who developed neutralizing antibodies; there were four participants who had Grade 3 adverse reactions, but the study was too small and too short to determine if the vaccine is effective or safe
- Initially, public health officials had stated that a vaccine could be ready in an unprecedented 12 to 18 months; now, there's talk of accelerating vaccine delivery even further, with a target date of fall 2020

The race is on to develop the first vaccine for COVID-19, with competitors eager to roll out what's likely to be the most fast-tracked vaccine ever created. Initially, public health officials had stated that a vaccine could be ready in an unprecedented 12 to 18 months. Now, there's talk of accelerating vaccine delivery even further, with a target date of fall 2020.[1]

Dr. Anthony Fauci, director of the National Institute for Allergy and Infectious Diseases (NIAID),[2] and Bill Gates are among those who have stated that life cannot return to normal until there is a vaccine against COVID-19.

"Humankind has never had a more urgent task than creating broad immunity for coronavirus,"

Gates wrote on his blog in April 2020. "Realistically, if we're going to return to normal, we need to develop a safe, effective vaccine. We need to make billions of doses, we need to get them out to every part of the world, and we need all of this to happen as quickly as possible."[3]

The earliest results from COVID-19 vaccine studies are starting to roll in, however, and they're far from reassuring. In addition to failing to prevent COVID-19, the experimental vaccines may still allow those who are vaccinated to spread the illness, and unforeseen serious side effects, even death, are a real possibility.

Monkeys Given Oxford's COVID-19 Vaccine Harbor Virus

One vaccine, developed at the University of Oxford Jenner Institute and named ChAdOx1 nCoV-19, uses a "replication-deficient chimpanzee adenovirus to deliver a SARS-CoV-2 protein to induce a protective immune response."[4] It was tested on six rhesus macaque monkeys, which received the experimental vaccine, then were infected with SARS-CoV-2, the virus that causes COVID-19, 28 days later.

The study revealed that monkeys that received the vaccine had the same amount of coronavirus in their noses as three nonvaccinated monkeys used as the control.[5,6] William Haseltine, a former professor at Harvard Medical School, wrote in Forbes:[7]

> *"All of the vaccinated monkeys treated with the Oxford vaccine became infected when challenged, as judged by recovery of virus genomic RNA from nasal secretions. There was no difference in the amount of viral RNA detected from this site in the vaccinated monkeys as compared to the unvaccinated animals. Which is to say, all vaccinated animals were infected."*

Also concerning, a titer of neutralizing antibody, which stop viruses from entering cells, was extremely low. While neutralizing antibodies from effective vaccines can be diluted by 1,000-fold and still be active, the neutralizing antibody in the study could only be diluted by four- to 40-fold before becoming inactive.

"[W]e know in the case of SARS and other coronavirus infections that even high titers of neutralizing antibodies fade quickly over time. How long can we expect weakly neutralizing antibodies to protect?" Haseltine questioned.[8] Despite the serious concerns raised by the trial, the authors promoted it as a success, stating that it protects monkeys against COVID-19 pneumonia[9] and moderates some effects from COVID-19.

When comparing breathing rates, three of the six vaccinated monkeys were clinically ill, but three of them were indistinguishable from the control group. When the amount of virus in the lungs was measured, viral RNA was found in two of the six vaccinated animals and all three of the unvaccinated animals, which suggests only partial protection.

As for lung damage, while two of the three unvaccinated animals had some degree of pneumonia in the lungs, no such damage was found in the vaccinated monkeys.[10] The researchers took this and ran, stating, "The vaccinated animals showed no signs of virus replication in the lungs, significantly lower levels of respiratory disease and no lung damage compared to control animals."[11]

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Vaccine Moves on to Human Trials With 50% Chance of Success

Oxford's vaccine trial results were less than stellar, yet they've teamed up with drug maker AstraZeneca and moved on to testing in humans anyway. A Phase 1 trial of the vaccine, funded by the U.K. government, began April 23, 2020, in healthy volunteers in the U.K.[12] "Time will tell if this is the best approach. I wouldn't bet on it," Haseltine said.[13]

The first two human volunteers were injected with the vaccine in late April 2020. In all, about 1,100 volunteers are expected to receive the vaccine and then mix with the general population to see if they end up catching COVID-19.

As of May 25, 2020, about one month since the human trial began, problems are already arising — namely, COVID-19 cases are declining so quickly that scientists are worried they won't be able to determine if the vaccine works.

"At the moment, there's a 50% chance that we get no result at all," Adam Hill, director at Oxford University's Jenner Institute, told The Telegraph,[14] adding that they may need to "chase" COVID-19 around Britain or internationally.

Ironically, the number of people with COVID-19 is falling so quickly that those who are vaccinated may not even come in contact with enough infected people to determine if it works — yet the vaccine, which allowed monkeys to still contract COVID-19, is still being fast-tracked at an unparalleled rate. Jonathan Ball, professor of molecular virology at the University of Nottingham, expressed further doubts, tweeting May 17, 2020:[15]

> *"That viral loads in the noses of vaccinated and unvaccinated animals were identical is very significant. If the same happened in humans, vaccination would not stop spread. I genuinely believe that this finding should warrant an urgent reappraisal of the ongoing human trials of the ChAdOx1 vaccine."*[16]

Moderna Vaccine Maker Withholds Key Data

Moderna has partnered with NIAID to create its own experimental COVID-19 vaccine, called mRNA-1273. In February 2020, its stock price increased 78.1% when it announced that its messenger RNA vaccine was ready for clinical trials.[17] "The company's CEO has become a new billionaire overnight," wrote Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center (NVIC).

Its stock soared again in May, hitting $29 billion, even though the company currently doesn't sell any products,[18] when it released early results from its Phase 1 study of 45 healthy volunteers

between the ages of 18 and 55 — the first released from a study involving human volunteers.

Moderna's press release[19] is overwhelmingly positive, stating that 25 participants who received two doses of its low or medium dose vaccine had levels of binding antibodies — the type that are used by the immune system to fight the virus but do not prevent viral infections — at levels approximating or exceeding those found in the blood of patients who recovered from COVID-19.[20]

Data for the more significant neutralizing antibodies was reported for only eight people, with Moderna stating that levels in each of these initial participants met or exceeded antibody levels seen in recovered COVID-19 patients. Moderna added that "mRNA-1273 was generally safe and well tolerated," and Dr. Tal Zaks, chief medical officer at Moderna, stated in their news release:[21]

> *"These interim Phase 1 data, while early, demonstrate that vaccination with mRNA-1273 elicits an immune response of the magnitude caused by natural infection starting with a dose as low as 25 µg.*

> *When combined with the success in preventing viral replication in the lungs of a pre-clinical challenge model at a dose that elicited similar levels of neutralizing antibodies, these data substantiate our belief that mRNA-1273 has the potential to prevent COVID-19 disease and advance our ability to select a dose for pivotal trials."*

During Phase 2 trials, 600 people will receive the vaccine, while a Phase 3 trial is expected to start in July 2020 — an unprecedented move in terms of typical vaccine development timelines — but a number of experts are questioning even the Phase 1 results.

For starters, the vaccine hasn't been tested against a placebo to determine if it's effective in preventing infection. Further, specific numbers on antibody concentrations weren't released, nor were the exact ages of the eight people who developed neutralizing antibodies.

Those antibodies were tested for just two weeks after vaccination — another red flag. "That's very early. We don't know if those antibodies are durable," Anna Durbin, a vaccine researcher at Johns Hopkins University, told STAT News.[22]

Severe Systemic Symptoms Triggered by High-Dose Shot

"While Moderna blitzed the media, it revealed very little information — and most of what it did disclose were words, not data. That's important: If you ask scientists to read a journal article, they will scour data tables, not corporate statements. With science, numbers speak much louder than words," STAT News reported.[23] Far more than 45 people will need to be tested before results can be trustworthy, and there are also safety concerns.

During the trials, subjects received two doses of the Moderna vaccine about a month apart at dosage levels of 25, 100 or 250 micrograms (µg). The low or medium doses of the vaccine in the Phase 1 clinical trial were associated with a mostly mild reaction, but three of those who received higher doses of the vaccine had more severe systemic symptoms.[24]

There were four participants who reported adverse reactions to the experimental mRNA-1273

vaccine in the Phase 1 clinical trials.

As reported by The Vaccine Reaction on May 24,[25] one the participants who received doses of between 25 μg and 100 μg experienced a "Grade 3 adverse event" after receiving the mRNA-1273 vaccine that included erythema or a rash around the injection site, which means the reaction could have included blistering, open ulcers, wet peeling (moist desquamation) or a serious rash over large areas of the body.

Three other participants in the clinical trial who received a vaccine dose of 250 μg reportedly experienced "Grade 3 systemic symptoms" following administration of the second dose. Moderna described these as the "most notable" of the adverse events, but that they were "transient and self-resolving."

A Grade 3 adverse event is described by the U.S. Department of Health and Human Services as "severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; limiting self-care" such as "bathing, dressing and undressing, feeding self, using the toilet, taking medications."[26]

Ian Haydon was one of the three trial volunteers to suffer from a systemic adverse reaction to the vaccine, which occurred after his second dose. According to STAT News:[27]

> *"Twelve hours after receiving his second dose, he developed a fever of more than 103 degrees, sought medical attention, and, after being released from an urgent care facility, fainted in his home … His girlfriend caught him and kept his head from hitting the floor.*

> *She then called one of the doctors working in the study, and asked what they should do. The doctor told them he could go back to urgent care, or call 911, and reminded them that all his medical costs would be covered by the study … Haydon said the experience left him as sick as he'd ever felt."*

Longer, Larger Studies Necessary to Reveal Side Effects

Even vaccination proponent Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia, stated that longer testing on a larger group of patients is needed, as, "You don't know about uncommon side effects." He further told BioPharma Dive, "We're in the 'science by press release' age. I just wish there were more data before people step up to the microphone."[28]

Not only did Moderna and NIAID conduct human trials of the experimental mRNA-1273 COVID-19 vaccine without first conducting animal trials,[29] but its vaccine uses new RNA technology. "No RNA drug or vaccine product has ever been certified for public use. Other companies have tried and failed, mainly because safety was a serious problem," wrote journalist Jon Rappoport, adding:[30]

> *"Fauci, Gates, and others are itching to get an RNA product approved for public use. In the area of vaccines, the manufacturing process is far quicker and easier than the traditional approach. Thus, they can flood the world with all sorts of new vaccines at the drop of a hat. That's what they want: a massively vaccinated planet under the gun."*

So, not only are they dealing with a novel virus, the mechanics of which are still not thoroughly understood, they're also using a novel RNA-based vaccine that has never been used before, and attempting to fast-track it through testing and development faster than any vaccine before it. As I said in May, what could possibly go wrong?