PERSPECTIVE

A Nursing Researcher's Experience in a COVID-19 Vaccine Trial

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I was scrolling through Instagram in early August 2020 when I saw an advertisement that caught my attention. Usually, I swipe past these without a second glance, but this was for the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine trial. It was recruiting participants for the highly publicized phase 3 trial of a new vaccine, BNT162b2, that had shown promising results earlier in the year. As a nurse and researcher who has encountered social media recruitment in my own work—and has closely followed the COVID-19 vaccine trials—I was curious to see how Pfizer planned to convince 30 000 people in the US to volunteer. I clicked on the advertisement.

The recruitment website (https://www.covidvaccinestudy.com/) was nicely designed with bright photos and thoughtful messaging about the trial. I intended to look at the recruitment approach, but found myself instead thinking about how important it is for people to participate. In the US, as of September 2020 COVID-19 had been diagnosed in nearly 7 million people and had killed more than 200 000.[1] A vaccine could save lives and stop the spread of the virus. Volunteering for the trial felt like an honorable thing to do—and the 50% chance to be randomized to the vaccine early seemed equally compelling to me as a practicing nurse. Before I left the website, I entered my contact information to be considered for participation.

A few days later, I was in a parking lot loading groceries into my car when I received a phone call from the study coordinator.

"Hi, is this Kristen? I'm calling from the COVID-19 vaccine study. I'd like to go through a screening and schedule you for the first visit, assuming you still want to participate, that is." He went on to ask me questions about my health and lifestyle. When I passed the screening, he continued, "Let's check the schedule for your first visit… It looks like I have an opening today. Can you come in today?"

I responded, "Um, sure. Yes. Send me the time and place and I'll be there."

As a researcher myself, I had an idea of what to expect when I arrived. I read through an informed consent, signed paperwork, and answered questions about myself and my health. I chatted with the medical assistants and research nurses about what it was like to be a nurse during the pandemic. I gritted my teeth through the dreaded nasopharyngeal swab for severe acute respiratory syndrome coronavirus 2.

Nearing the end of the visit, I found myself alone. Waiting for the actual injection, I thought about how strange it felt to be a research participant. Randomization is considered the gold standard in clinical research, necessary for omitting all possible bias and determining causality. I had studied the ethics of randomization and why it can be unappealing or even unacceptable to people. But the disconcerting *feeling* of randomization surprised me. I thought about why getting the experimental vaccine rather than the placebo mattered for me as a health care worker—and then, even those stakes seemed low when I thought about what randomization must feel like for patients.

I sent up a final prayer for the active vaccine as the research nurse finally administered the blind-to-me injection. A visit for the second injection was scheduled for 1 month later. My arm was sore, but I did not notice anything out of the ordinary. I could not begin to guess whether I had received the vaccine or the placebo.

I returned to the research clinic the next month. It was easier and faster this time, although I was dismayed to find that there was another nasopharyngeal swab test. I received the injection and returned home.

The experience after the second injection was different. My arm quickly became painful at the injection site, much more than the first time. By the end of the day, I felt light-headed, chilled, nauseous, and had a splitting headache. I went to bed early and fell asleep immediately. Around midnight, I woke up feeling worse—feverish and chilled, nauseated, dizzy, and hardly able to lift my arm from muscle pain at the injection site. My temperature was 99.4 °F (37.4 °C). I tossed and turned, sleeping little during the rest of the night.

When I woke up again at 5:30 AM, I felt hot. Burning. I took my temperature and looked at the reading: 104.9 °F (40.5 °C). This was the highest fever I can ever remember having, and it scared me. I took acetaminophen and drank a glass of water. When the research office opened at 9 AM, I called to report my reaction to the injection. Thankfully, my fever had come down to 102.0 °F (38.9 °C) by then. The research nurse said, "A lot of people have reactions after the second injection. Keep monitoring your symptoms and call us if anything changes." My fever hovered around 99.5 °F (37.5 °C) for the rest of the day. By the next morning, all my symptoms were gone except a sore, swollen bump at the injection site.

I cannot be certain, but based on my reaction, I have a strong suspicion that I received the experimental vaccine, not the placebo. While waiting for the research office to open that morning, I had read the research report[2] on the earlier Pfizer-BioNTech trial. To my surprise, the nurse was right about how common my symptoms were. In the phase 1 trial of BNT162b2, the following adverse effects were observed in the intervention arm of adults aged 18 to 55 years after receiving the second dose of BNT162b2: fatigue (75%), head-

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ache (67%), chills (33%), muscle pain (25%), fever (17%), and joint pain (17%).[2] If this vaccine is approved, it is possible that most people receiving the vaccine could have 1 or more reactions to the vaccine like I did. Fortunately, my experience of having all symptoms together seems to be rare.

The adverse effects of the vaccine—even if, at worst, they all happen at once—are transient and a normal sign of reactogenicity signaling an effective immune response. But I worry that they could be a major barrier to vaccine uptake. Clinicians will need to be prepared to discuss with patients why they should trust the vaccine and that its adverse effects could look a lot like COVID-19. They will need to explain that fatigue, headache, chills, muscle pain, and fever are normal, reactogenic immune responses and a sign that the vaccine is working, despite the unfortunate similarities with the disease's symptoms.

Despite the extensive information I had on the research process and vaccine, on a personal level I did not get the message that I should anticipate a reactogenic response. I was scared when I saw that I had a fever, and my gut reaction after months of scrutinizing myself for all the possible COVID-19 symptoms was: Do I have COVID-19?

I texted a few friends about my experience, and their response was the same: "Wait, does this mean you have COVID-19? Are you contagious?" I assured them I did not and was not, but every physician and nurse in the US needs to be prepared to have a conversation about adverse effects with patients. I can already see the wrong message about the COVID-19 vaccine going viral.

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