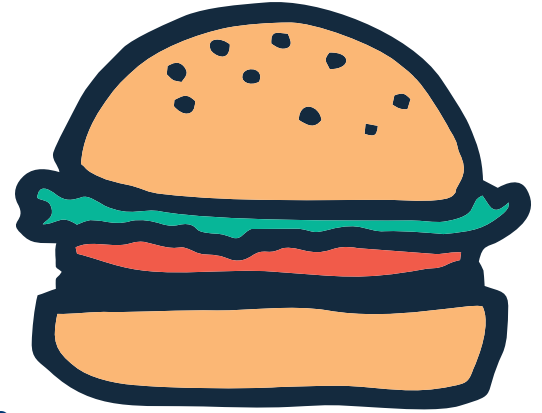


Were COVID-19 Vaccines Rushed?

By Lydia Greene, Back to the Vax

There is a difference between something being rushed and something being prioritized and expedited. The word "rushed" implies steps were missed. Say you are at a restaurant and you order a cheeseburger.



Somehow, your cheeseburger was forgotten while the kitchen made the rest of your table's orders. Panic ensues and they quickly throw your order together in hopes that everyone will get their food at the same time. You get your burger and it's missing the cheese, and it has pickles when you specifically said you didn't want them. That is "rushed". Let's take that same situation except this time they bring out everyone else's food and then tell you it will just be a few moments longer for your burger. In the kitchen, they have now chosen to prioritize this burger over the other orders, and when it gets to your table it's exactly as you wanted it. In both situations, the burger was desperately needed, but only in one case was it carelessly done with errors. I know this is an oversimplification, but words matter. COVID-19 vaccines were not carelessly rushed, they were expedited and prioritized over other things. If a job takes 1 person 10 hours, then 10 people can do it much faster. Not everything is like this in determining safety, as some things will take time no matter what, but those vital steps were not shortened.

The COVID-19 vaccine went through the same steps as other vaccines. None were skipped.

Exploratory Stage:

This step was already well underway in terms of mRNA technology decades beforehand. We had a lot of information to go off of.

Preclinical Stage:

This stage includes testing in-vitro on animals. Despite several myths that all of the animals died in preclinical trials, this is untrue. However, animals are destroyed after testing and tissue samples are further analyzed.



Clinical Stage:

This stage usually takes a long time. However, money, resources, and person-hours were devoted to getting this done efficiently. Trials were planned with overlap to save time. During the process, stage 1 overlapped with stage 2, and stage 2 with stage 3. Stage 4 is post-market and continuous, as with all new drugs and vaccines. This does not mean any steps were skipped, nor does it mean we don't know long-term side effects. Over 2 years have passed since stages 1-3: we have a lot of data. Resources were readily available, as there was no shortage of trial volunteers and scientists who chose to prioritize making COVID-19 vaccines. While vaccines are monitored for long-term effects indefinitely via post-market surveillance, vaccine trials show that long-term effects do not occur beyond 8 weeks. There is no more vaccine left in the body and the immune system has finished responding well before then.





Regulatory Review & Approval Stage:

During this step, we want to protect the most vulnerable, so the government and FDA issued an Emergency Use Authorization (EUA). First, the elderly, immunocompromised, and healthcare workers were given priority. When no major safety signals were identified, then other groups were encouraged to get vaccinated. Once each demographic of people had no major side effects, clinical trials were started for children. It began with older children and as each age group demonstrated safety, they started trials with younger populations. Now mRNA vaccines are fully approved and not under EUA. There are now traditional subunit vaccines (like Novavax) available for those still hesitant about mRNA technology and the side effect profiles of the vaccines are similar.



Manufacturing Stage & Quality Control Stage:

These last two steps I can personally speak to, as I used to work at a pharmaceutical manufacturing plant. Pharmaceutical plants must submit to a 3rd party auditor and get certified by current Good Manufacturing Practices (GMP). This applies to drug manufacturers that supply medications from outside the US as well. Plants must be fully inspected before manufacturing a new product and demonstrate their procedures from beginning to end. Everything is tested including starting materials, cleaning materials, and even containers used for packaging. My job was quality control. Every single task is documented. Documents must remain on site for a certain number of years and then they are moved to storage for another number of years. Before a plant can begin to manufacture, the manufacturing process must be approved. Then, constant quality control is done with thorough records. As a quality control chemist, I couldn't even write on scrap paper as everything had to be retained. All calculations are kept, and everything is documented and saved. If a GMP audit finds something that could potentially harm patients, the plant is shut down and the public will be notified if there is any risk to them no matter how small. FDA warnings can be alarming, but they are evidence of a system that catches issues. Though I am new to vaccinating as a formerly hesitant parent, I do trust the manufacturing process is being done with care.

Multiple vaccine monitoring agencies like VAERS, V-SAFE which was specifically made for COVID vaccines, and the Vaccine Safety Data Link which goes through the raw data from VAERS to determine both causation and safety signals. COVID vaccines were not rushed, they were expedited with great care.

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov


v-safeSM
after vaccination
health checker



Reviewed by: Melody Mitchell, Medical Oncology Researcher

This resource is a collaboration of Immunize Kansas Coalition and Back to the Vax.
Scan the QR code to see more Vaccine Fears Overturned by Facts.

