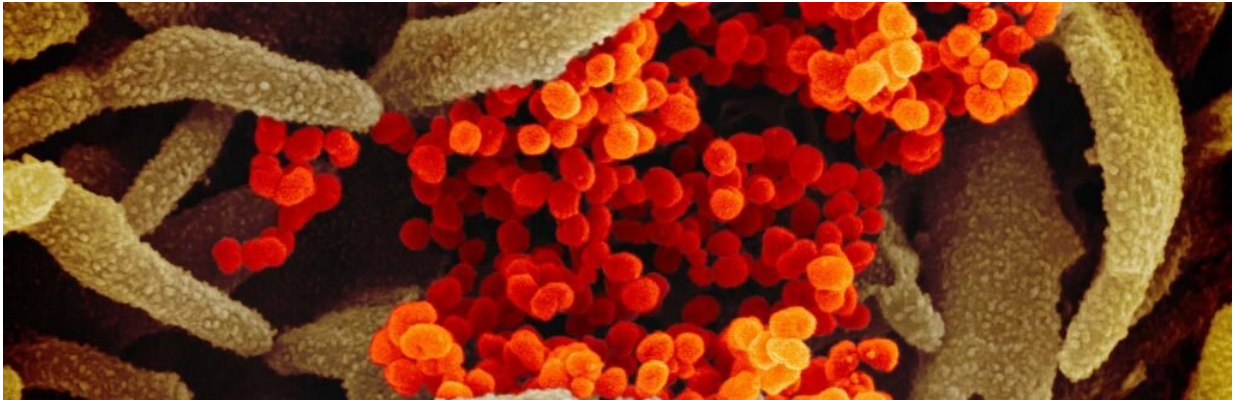


How long does it take to make vaccines?

December 17 2020, by Matt Shipman



Scanning electron microscopy image of SARS-CoV-2. Credit: National Institute of Allergy and Infectious Diseases-Rocky Mountain Laboratories, NIH

In this post, we focus on how long it takes to develop and manufacture vaccines—particularly those designed to protect against COVID-19.

To address those questions, we spoke with Jennifer Pancorbo, director of industry programs and research at NC State's Biomanufacturing Training and Education Center. Pancorbo is an expert in [vaccine manufacturing](#), with particular expertise in viral vector [vaccine development](#) and [production processes](#).

This post is part of [a series of Q&As](#) in which NC State experts address questions about the vaccines on issues ranging from safety to manufacturing to how the vaccines will be distributed.

The Abstract: How long does it take to make vaccines?

Jennifer Pancorbo: There are two ways to interpret this question. Do you mean actually manufacturing a vaccine that is already created? Or do you mean designing a new vaccine?

Developing a new vaccine from scratch takes considerable time. It depends a lot on how much information is available about the disease itself, how the disease infects people and spreads, and so on. But it traditionally has taken 5-10 years to get a new vaccine. That makes it truly amazing that we already have one authorized vaccine for COVID-19, and are evaluating stage 3 clinical trial data on others. It speaks volumes about the efforts put into pandemic preparedness and response.

As for actual manufacturing time, that can be affected by the type of vaccine being made—though this isn't really relevant for COVID-19, since all of the vaccines being considered for COVID-19 take about the same amount of time to manufacture.

If we are talking about a vaccine that has already been tested and approved, we could generalize and say that one batch of vaccine, consisting of a couple thousand doses, may take 2-6 weeks to go from starting with [raw materials](#) to being a completed vaccine in a vial or syringe.

TA: What types of vaccines are the most promising COVID-19 vaccine candidates?

Pancorbo: mRNA and adenovirus vaccines seem to be the most promising candidates at this time. Those two [production systems](#) lend

themselves well to rapid design and that is probably why those candidates are coming out first.

We may or may not see a candidate vaccine made with a more traditional technology in the future. It is hard to tell, and may depend a lot on how the initial vaccines work and how much room is left in the market for a different candidate.

TA: How long does it take to make conventional vaccines? And why does it take so long?

Pancorbo: Again there are two angles here.

First, from the stand point of design, it takes a while to understand the disease, its path of infection and spread, in order to find a way to stop it. Also, once an idea to alert the immune system of the invader is conceived, then you need to test the candidate to make sure the conceptual idea works. Once that is acceptable, then you need to establish a manufacturing process that lends itself to [large scale production](#)... all those steps take time.

Second, from the stand point of manufacturing, most vaccines are biologicals—meaning they are produced with help from a microorganism. And that means you need time for the microorganisms to grow and get the job done. Here's a general overview of the process:

To produce a vaccine using a biological system, you first select a suitable host. This is typically a well-known organism like bacteria or yeast. Then the genetic material of the host is engineered to provide instructions for the expression of the desired vaccine. In other words, you engineer the organism to make the vaccine for you. The newly engineered organism is then grown in sufficient quantities to be used for production purposes.

Once expression is completed by the organism, our vaccine is separated from everything else the organisms produce using operations like filtration. The last step is to mix the purified vaccine with the excipients –or those other components that add stability to the vaccine and allow us to safely transport and store it. The formulated vaccine is then filled into multi-dose vials or single-use syringes for administration.

And there is one more thing, once all the above is completed, then each batch produced must be tested for identity, purity and potency to make sure everyone receives a quality product. As you can imagine, all that takes weeks per batch.

TA: And how long does it take to make mRNA vaccines?

Pancorbo: I am not sure anyone knows this accurately at this point, since no mRNA vaccine has been manufactured before at any scale close to what will be required for COVID-19. I am going to dare say that it will take at least a couple of weeks per batch.

TA: What about adenovirus vaccines?

Pancorbo: Again, we don't have an adenovirus vaccine in the market, so my response is the same as what I said about mRNA vaccines.

TA: How long will it take manufacturers to scale up production once a vaccine has been approved by the FDA?

Pancorbo: Most of the companies you hear about on TV have already started doing this "at risk," so they can manage demand.

At-risk manufacturing means you don't have approval, or you don't know if the vaccine is going to work, but to reduce or eliminate waiting time to get to the market, you move forward with scale up, construction, manufacturing, etc. The risk is that the investment will not be returned if the vaccine is ineffective or if it is not approved.

It may take several years to scale up a production process like this to the levels required for COVID-19. It involves testing production in a larger vessel. Testing the purification equipment in a larger footprint—and this may get tricky as making soup for four people is not the same as making soup for 100 people. Another bottleneck is equipment and raw material availability. Once you find a device that works you cannot really go to your local grocery store to get one. The same is true for the basic raw materials and supplies—both need time to react to the larger demand.

TA: How much vaccine manufacturing takes place in the U.S.? Do we rely on importing vaccines, or do we have the capacity to make our own?

Pancorbo: Not much vaccine manufacturing takes place in the U.S., really. Traditionally, vaccines were manufactured in other places around the world. After the 2009 flu pandemic our government put a considerable investment into increasing vaccine manufacturing in the U.S., but the larger manufacturers—like Sanofi—are headquartered outside our borders.

TA: How long do you think it will take manufacturers to make enough vaccine to reach everyone who can be vaccinated?

Pancorbo: I would think it will take until late 2021 or mid-2022 to see a

significant amount of the population vaccinated.

TA: Will you get the vaccine once it's available?

Pancorbo: Yes. The approval process followed by FDA is very thorough and trustworthy. And, particularly for COVID-19, a lot of information about the vaccine candidates has been made public from early on, which gives me an additional confidence in the process.

Provided by North Carolina State University

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