Bioanalysis ZONE IN THE ZONE

PPD

How do we decide that a vaccine is effective?

1 Before dosing the first patient...

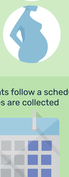
a. Safety must be assessed in animal model(s)

b. The composition and formulation of the vaccine is established at this stage

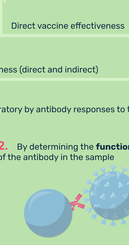
2 First-in-human

a. Volunteers are included or excluded based on certain criteria (e.g., pregnancy, age range, pre-existing medical conditions)

- Pre-existing medical conditions
- Unsuitable age range
- Pregnancy



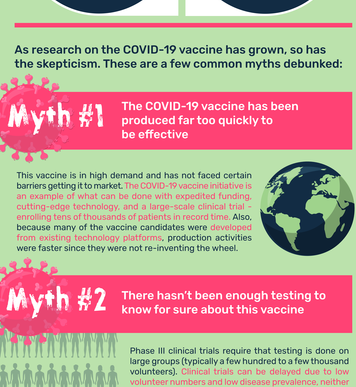
b. Enrolled patients sign a consent form and are assigned randomly to receive a vaccine or a placebo/control (e.g., a dose of saline)



c. Enrolled patients follow a schedule of visits where samples are collected

3 Determining if the vaccine is effective

a. Vaccine effectiveness is measured by comparing the frequency/severity of infection in the vaccinated and unvaccinated/placebo groups



b. It can also be measured in the laboratory by antibody responses to the vaccine, such as:

1. Antibody **detection** in the sample

or

2. By determining the **functionality** of the antibody in the sample

c. In addition, molecular assays can measure pathogen load through the use of laboratory methods such as RT-PCR

Vaccine efficacy

Vaccine efficacy refers to the percentage reduction of disease in a vaccinated group of people compared to an unvaccinated group, using the most favorable conditions, where vaccine storage and delivery are monitored and participants are usually healthy.

In their June 2020 guidance, 'Development and Licensure of Vaccines to Prevent COVID-19' the US FDA has conveyed their expectations that **a COVID-19 vaccine would prevent disease or decrease its severity in at least 50% of vaccinated people** when compared to the control group.

As research on the COVID-19 vaccine has grown, so has the skepticism. These are a few common myths debunked:

Myth #1 The COVID-19 vaccine has been produced far too quickly to be effective

This vaccine is in high demand and has not faced certain barriers getting it to market. The COVID-19 vaccine initiative is an example of what can be done with expedited funding, cutting-edge technology, and a large-scale clinical trial - enrolling tens of thousands of patients in record time. Also, because many of the vaccine candidates were developed from existing technology platforms, production activities were faster since they were not re-inventing the wheel.

Myth #2 There hasn't been enough testing to know for sure about this vaccine

Phase III clinical trials require that testing is done on large groups (typically a few hundred to a few thousand volunteers). Clinical trials can be delayed due to low volunteer numbers and low disease prevalence, neither of which are an issue here. The vaccines currently in market enrolled over tens of thousands of volunteers, for example >40,000 participants (Pfizer/BioNTech), in a very short period so there has been a significant amount of testing.

Myth #3 The vaccine is not safe

SAFE?

The technology used to develop all COVID-19 vaccine candidates (mRNA, virus vectors, etc.) has undergone the same safety testing in animals and has been studied for decades. In addition, the number of people who have a serious reaction to a vaccine is very small. Regardless of any emergency use authorizations (EUA) from the FDA, all COVID-19 vaccine candidates still must undergo all three phases of clinical testing.

Myth #4 Vaccines can alter genes/cause transhumanism

There is fear that a vaccine using mRNA technology may somehow change your DNA. The mRNA does not get into your DNA, it instead provides instructions to your body to produce a single protein from the virus that is then recognized by the immune system leading to production of protective antibodies. Injecting RNA into a person does not do anything to the DNA of a human cell, but instead turns your body into an antibody-producing factory that can fight the real infection later. While no mRNA vaccines have been approved yet, multiple clinical trials using mRNA vaccines have been conducted over the last few years with no evidence of genetic alteration whatsoever.

This infographic has been created as part of a Bioanalysis Zone feature in association with PPD.

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