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We hear a lot about a vaccine for Covid-19, but many of us still have lots of questions. Will one really be ready later this year? Why do they take so long to develop? Why should I consider being vaccinated? Read more below for some answers to your questions.

Why does a vaccine take so long to be approved and what's different with Covid-19?

The overall development of a vaccine consists of a discovery phase, a pre-clinical phase, the clinical development phase (phases I to III) and the post licensure phase (phase IV), and it takes on an average about 10 to 15 years. Vaccines are complex biological products that are given to healthy individuals to prevent an illness and so although efficacy is clearly needed, safety is of paramount importance.

When vaccine development is being undertaken outside of a pandemic, the companies performing that research and development, or in some cases a governmental institution, are bearing all the risk and cost of the development. The stages of development are done sequentially and investment into the next phase of work is only done upon positive results of earlier work. No company could normally afford to set in motion production of millions of doses of vaccine without being sure that the vaccine was safe, effective, and likely to gain regulatory approval. The other main reasons that vaccine development takes a long time are that it can be difficult to recruit the 30 000 volunteers needed for each phase 3 trial, and the way a trial measures success is by the number of volunteers who catch the disease. If the incidence of the disease is low, then it can take a long time to reach the number of cases required to show that the vaccine is statistically beneficial. As there are so many cases of Covid-19 and the disease is easily spread, this will not take as long as usual. Furthermore, a lot of people appear to be willing to enter these clinical trials.

Sometimes clinical trials must stop or slow down because the investigators see an unexpected and serious problem. These are usually exceedingly rare events that are only seen when thousands of people are treated. The trial will be put on hold while an independent panel of experts evaluates if the problem is related to the vaccine or if it is something that happened for another reason or by chance. Once they have worked that out the trial will re-start or be stopped. This is not unusual during the clinical trial process, but of course it adds to the time development takes.

Because of the seriousness of the Covid-19 pandemic, the US government under the guidance of Project Warp Speed, has made money available to the companies with the most promising vaccine candidates that enables them to invest in future work without waiting for read-outs from the earlier

research, thus minimizing risk to the companies and their investors, while ensuring that the most promising vaccine candidates can progress as quickly as possible. This is the main reason why it may be possible to have a vaccine for COVID-19 at the end of 2020 or in early 2021.

The Food and Drug Administration (FDA) issued guidance for the conduct of Covid-19 vaccine trials https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19. This guidance, that all companies developing vaccines in the USA should follow, is encouraging the sponsor companies to do certain things that can speed up development, while at the same time ensuring safety. For example, the guidance encourages a protocol (the document that lays out how the clinical trial will be conducted) to include several phases of development, for example a combined phase 2/3 trial. Normally the FDA would accept this if they were in agreement with the design, however, the sponsor company could be wasting millions of dollars if they recruited many volunteers into the trial, only to find that the vaccine had failed in the early part of the study. Therefore, companies do not normally follow this route.

The FDA can issue an Emergency Use Authorization (EUA) when "the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases, outweigh the known and potential risks of the product." An EUA can be based on interim data. This means that although the total duration of the vaccine trial is 2 years, that an interim statistical analysis will be done after all the volunteers have been treated for a few months. If the vaccine is seen to be safe and effective, then an EUA would be issued making the vaccine available. However, the clinical trials must be completed, and the FDA will continue to monitor the safety and efficacy of the vaccine. If serious issues occur then they would withdraw the EUA, otherwise upon completion of the phase 3 studies the complete dossier would be reviewed, and the vaccine approved for general use.

When can we expect a vaccine to be available in Pamlico County?

We hear and read that a vaccine could be available later this year or early 2021 and that is true.

BUT:

· Availability so soon depends on the trials successfully recruiting thousands of volunteers and the vaccine being safe and promoting the sort of antibody reaction that is expected to confer immunity.

· The vaccine will initially be available under an EUA, which may discourage some people from being willing to take it.

· It is expected that the vaccine will be rolled out first to front line workers, then to vulnerable populations and only last to the general population. This is the normal process for distributing a vaccine and since 1964, the United States has relied on the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices to make those decisions.

Why should I get vaccinated and how can my being vaccinated help protect others?

Scientists expect the vaccine to be 50-70% effective. So, some people may think that it's not worth getting, but it is. A vaccine like this would reduce your chance of getting Covid-19, a life-threatening disease, by 30-50%. Also, it will reduce your chance of passing Covid-19 to loved ones, who may be more vulnerable than you are, through age or underlying health conditions. With a large portion of the population vaccinated many economic activities and recreational activities could resume. It's possible that being vaccinated may make it easier to do some activities, such as travel.

A vaccine that is 50-70% effective plus a percentage of the population who have had Covid-19, helps us reach herd immunity. Herd immunity is when a population receives indirect immunity from an

infection due to a significant number of individuals in the population already having immunity. So, when a person comes into a community infected with Covid-19 they don't pass the infection on because those they come into contact with are immune. This is how diseases get stamped out, like smallpox, or become rare like measles.

CCTF COVID-19 COMMUNITY TASK FORCE

The COVID-19 Community Task Force (CCTF) is a volunteer organization established to engage the community in responding to the COVID-19 Pandemic and to support and augment the County's efforts. The information shared by the CCTF is not an official communication from Pamlico County, its Health Department or the Pamlico County COVID19 Task Force.