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Introduction

In order to help communicate with the citizens of Moore County, county Health Director Robert Wittmann, MPH has partnered with Paul Kuzma, MD to prepare a series of articles meant to inform the public about Covid-19 and public health. Dr. Kuzma has practiced medicine in Moore County for over 20 years and is currently completing his Masters of Public Health degree at Johns Hopkins University. This is the sixth in a series of articles prepared by Dr. Paul Kuzma to further public understanding of Covid-19.

Vaccine Challenges

Once we get a vaccine approved, this whole COVID pandemic will just go away, right? Everyone can get a shot and we can go back to our normal lives, right?

Since the start of the COVID-19 pandemic, there has been a race to develop the first vaccine to the SARS-CoV-2 virus, the virus that causes COVID. As of Oct 26, this virus has killed over 1.15 million people worldwide, including over 225,000 Americans. It has disrupted our lives, damaged our economies, closed schools and businesses, and affected almost every aspect of our social interactions. We are tired of social distancing, we miss visiting freely with friends and families, miss going out to a crowded bar or restaurant to watch a game or celebrate one of life's events. Kids can't be kids and run around at school. Hugs and handshakes are suddenly considered risky behavior. We all want to put this pandemic behind us and get back to living. Give us a shot and let us go!

If only it was that simple…

The development of potential COVID vaccines has taken place at a pace that is faster than ever before and is on pace to produce a vaccine in less than 1 year. This is an amazing accomplishment and an incredible example of what can be accomplished by today's scientists if they are given a mandate and enough money to pursue their work. Up until today, the fastest vaccine ever developed was for the mumps and it took 4 years. We are hopeful that the first COVID vaccine will be approved in December or January.

Several vaccines are in late stage, large-scale human trials and once the data from these trials are analyzed, the manufactures will request FDA approval to begin production. The manufacturers will have to demonstrate that the vaccine is safe for use in people and that it causes us to develop an effective immune response and therefore some

degree of protection against the virus. Many of these vaccines will only be partially effective and the FDA has set the bar at 50% efficacy. So even an approved vaccine may only protect half the people that receive the shot!

Then what?

The challenges involved in quickly vaccinating the world against this virus are immense. There are approximately 7.8 billion people alive today, and about 330 million of us live in the United States. The logistical and practical challenges are enormous. Let's focus on the United States. We are a wealthy, advanced and developed nation. What do we need to do to get our citizens vaccinated?

We need to manufacture enough doses of the vaccine. Since most of these vaccines require 2 shots spaced several weeks apart, we need 660 million doses of vaccines. These vaccines are produced under strict manufacturing conditions and require labs, specialized equipment and trained staff to produce the vaccine. Many companies are taking early steps to develop this capacity, but are hesitant to fully invest in manufacturing capacity until they have approval to move forward. If they don't get FDA approval, those manufacturing plans will not be used.

These vaccine doses need to be packaged and readied for distribution. This requires the production of millions (or billions) of vials, rubber stoppers, caps, labels, boxes etc. Manufacturers of these products will need to increase capacity and delivery to the vaccine producer. Specifications will need to be appropriate for the particular vaccine. We will also need billions of additional syringes, needles, anti-septic wipes, gloves and other supplies needed to administer the vaccine.

Most of these vaccines need to be stored at a constant very cold temperature to remain safe and effective. That means that from the time of production through the time they are administered, they need to be kept in specialized freezers with careful temperature controls. This includes the shipping, handling and distribution, as well as the storage at the pharmacy, hospital or office that will administer the shot. This type of "cold-chain" distribution is complex and expensive and many distributors and facilities don't have this type of equipment.

Since there will not suddenly be 660 million doses available, we need to decide where the first doses of vaccine are distributed. Once they arrive, what happens next?

People will need 2 doses of a vaccine, and the vaccines are not interchangeable. For every dose administered, one dose will need to be held in reserve for the second inoculation. This is crucial, since each vaccine is different the person inoculated with a first dose must get the exact same vaccine for their second dose. Therefore, if 1000 doses are delivered, only 500 people can be vaccinated.

Who get the vaccine first?

The federal government will initially determine where the vaccine is sent. Some states or localities will be felt to be of higher priority and get the first doses. The details of this distribution plan have not been revealed.

Every state has developed a vaccination plan that it has submitted to the Federal Government. North Carolina's plan has multiple phases based on the availability of vaccine. It includes a prioritization of populations to decide who gets the vaccine first. The first people offered the vaccine will be health care providers at high risk for exposure and who are vital to the COVID vaccine efforts and staff in long term-care facilities .People at high risk for clinical severity and high risk of exposure come next. This includes nursing home residents and others in congregate living as well as anyone with two or more chronic conditions that are high risk for COVID complications. Moore County has developed a plan to vaccinate our community once the vaccine makes it here.

After vaccinating these populations and as vaccine availability increases, the vaccine will be offered to more people. If a vaccine is approved before the end of this year, it will likely be mid to late 2021 before there is enough vaccine available to offer it to the general population. Based on our historic rate of flu vaccination being less than 50%, and legitimate caution about a new vaccine, it is unclear how many people will get the vaccine even if it is available. If the vaccine is only 50% effective, only half of those vaccinated will develop effective immunity. Since most experts believe that it will take at least 60-70% of the population to have some immunity either through vaccination or recovering from an infection, it seems likely that we will be dealing with COVID for the foreseeable future.