VACCINE OVERVIEW AND PROSPECTS FOR COVID-19

Information as we understand it today 11/12/2020

Strathmere Healthcare Partners

DISCLAIMER

We at Strathmere Healthcare Partners are licensed physicians, board-certified in our respective specialties with collective experience running medical practices and in leadership roles in healthcare administration and consulting. We are not infectious disease doctors nor do we speak directly for the CDC or any government or specific healthcare entity. The information in this presentation was obtained from official sources such as those highlighted below and we tapped our previous experience to interpret the evidence presented by experts. The information in this presentation is meant to inform in general and in no way is specific or individualized medical advice. We encourage individuals with specific concerns about their own health and that of their loved ones to reach out to their personal physicians for guidance and to stay apprised of information and recommendations that are available from the following organizations:

NIH National Institutes of Health
Turning Discovery Into Health

World Health Organization

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#vaccines-schedule

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

HHS.gov
Coronavirus

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VACCINES, A HISTORY

- The Chinese likely used “variolation” or inoculation to prevent smallpox as early as 1000CE
- Variolation was also used many years ago in Africa and Turkey before spreading to Europe and the Americas
- In 1796, an English doctor, Edward Jenner, overserved that milkmaids who had gotten cowpox did not show any symptoms of smallpox after variolation. This was the beginning of the era of “vaccination” or using matter similar to a specific virus to produce immunity to that virus
- In 1885, French scientist, Louis Pasteur successfully used an attenuated vaccine to prevent rabies in a 9 year old who had been bitten by a rabid dog
- In 1918-19, investigators attempted unsuccessfully to develop vaccines against the deadly Spanish flu. The Influenza virus was not isolated and identified until the 1930s with flu vaccines becoming licensed in the US in the 1940s. It is estimated that about 500 million people or 1/3 of the world’s population became infected with the Spanish flu with a worldwide death toll of at least 50 million (675,000 in the US)
- The mid 1900s saw the development of vaccines against polio, pertussis, measles, mumps and other diseases
- A typical child born in the US today is immunized against diphtheria, tetanus, pertussis, haemophilus influenza type B, hepatitis A, hepatitis B, human papillomavirus, influenza, measles, mumps, rubella, meningococcus, pneumococcus, polio, rotavirus and varicella
- The World Health Assembly declared the world free of smallpox in 1980, the only disease to date to be completely eradicated
- The Global Polio Eradication Initiative was launched with a resolution of the World Health Assembly in 1988. Although tremendous progress has been made, we are 99% of the way towards eradication, polio does still exist today and 2020 is an especially tough year for immunization efforts
- In 2019, the NIH reported that a decline in measles vaccination was causing a preventable global resurgence of the disease
- The CDC now warns of the effects of the pandemic on routine vaccine administration and states that ensuring that routine vaccination is maintained or reinitiated during the COVID-19 pandemic is essential for protecting individuals and communities from vaccine-preventable diseases and outbreaks

TYPES OF VACCINES AVAILABLE TODAY

- There are 4 main types of vaccines currently in widespread use:
  - Live-attenuated vaccines
  - Inactivated vaccines
  - Subunit, recombinant, polysaccharide, and conjugate vaccines
  - Toxoid vaccines

The vaccine that Pfizer is working on with reported preliminary results from a phase 3 trial suggesting that it may be up to 90% effective (on 11/9/20) is an *mRNA vaccine* using recombinant viral protein subunits. This type of vaccine has not been previously approved for widespread use in humans and is different from the subunit, recombinant, polysaccharide, conjugate category

TYPES OF VACCINES/EXAMPLES

	Description	Examples
Live attenuated vaccines	Use a weakened (attenuated) form of the germ that causes the disease	Measles, Mumps, Rubella (MMR) and Varicella vaccines
Inactivated vaccines	Use a killed version of the germ that causes a disease	Injectable form of Influenza and Polio vaccines
Subunit, recombinant, polysaccharide and conjugate vaccines	Use only specific pieces of the germ that cause the disease, such as the capsid (casing)	Hepatitis B, Meningococcal and Pneumococcal vaccines
Toxoid vaccines	Use a toxin made by the disease-causing germ creating immunity to parts of the germ	Diphtheria and Tetanus vaccines

MESSENGER RNA VACCINES

- mRNA vaccines work by delivering the genetic material or instructions for the recipient's cells to make an antigen that closely mimics a natural infection
- In the case of the mRNA vaccine for coronavirus, the antigen of interest is the spike protein the virus uses to bind and fuse with human cells. It is anticipated that the antibody response to that protein will be protective
- mRNA vaccines aren't grown in eggs or cells like other vaccines so they can be produced more rapidly and at lower cost
- mRNA vaccines aren't entirely new. German based CureVac and academic collaborators published phase1 results from an mRNA vaccine clinical trial for a rabies vaccine in 2018 and announced positive results in a low dose clinical trial earlier this year
- Potential mRNA vaccines have been studied in small early-phase trials against rabies, influenza, zika and others. Many of these trials are still underway
- Boding well for the safety of mRNA vaccines is the fact that mRNA can't cause infection, doesn't enter a cell's nucleus and the body breaks down mRNA and its lipid carrier within hours

https://jamanetwork.com/journals/jama/fullarticle/2770485

WHAT VACCINES ARE CURRENTLY IN CLINICAL TRIALS FOR COVID-19?

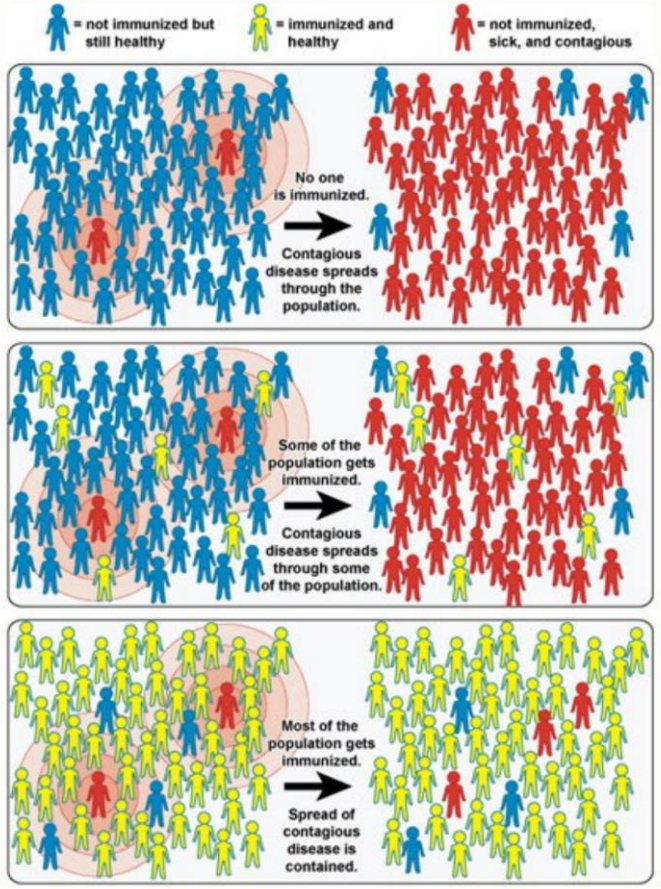
There are numerous vaccines on the WHO website (https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines) with links to much of the current research on www.clinicaltrials.gov . We are watching the following closely:

Covid-19 vaccine developer/manufacturer	Type of platform/vaccine	# or and timing of doses	Clinical Stage
University of Oxford/AstraZeneca	Non-replicating viral vector	2 doses: 0 and 28 days	Phase 3
Janssen Pharmaceutical Companies (Johnson & Johnson)	Non-replicating viral vector	2 doses: 0 and 56 days	Phase 3
Moderna/NIAID (National Institute of Allergy and Infectious Disease)	RNA, encapsulated mRNA	2 doses: 0 and 28 days	Phase 3
BioNTech/Pfizer	RNA, 3 LNP-mRNAs (lipid nanoparticle based)	2 doses: 0 and 28 days	Phase 3

Note: All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the US need two shots to be effective. We expect that for now a "2 shot" series is what we should plan on with hope for single dose solutions in the future.

HERD IMMUNITY

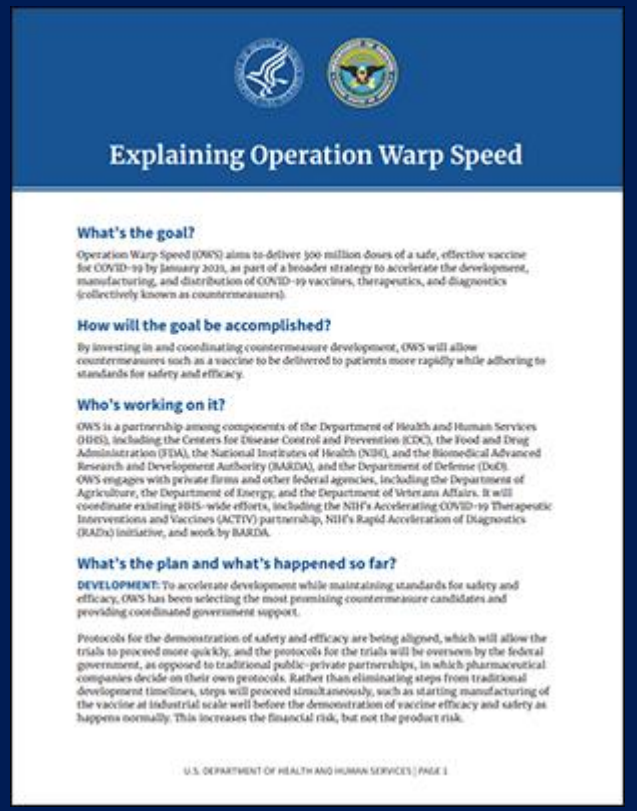
- *Herd Immunity* occurs when enough people in a population are immune to an illness to prevent its spread
- It occurs when a large portion of a community becomes immune to a disease, preferably **via vaccination**
- The percentage of a community that needs to be immune in order to achieve herd immunity varies from disease to disease
- When a subset of a community chooses not to be vaccinated against a particular illness, that subset not only puts themselves at risk but they put the other members of the community at risk by decreasing the likelihood that herd immunity will be achieved
- It is dangerous to assume we will reach herd immunity "naturally", we absolutely need strong vaccination compliance



https://www.pbs.org/wgbh/nova/article/herd-immunity/

OPERATION WARP SPEED

- Goal-to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics
- Operation Warp Speed, OWS, is a partnership among components of the Department of Health and Human Services, including the Centers for Disease Control and Prevention, the National Institutes of Health, the Biomedical Advanced Research and Development Authority and the Department of Defense
- OWS engages with private firms and other federal agencies
- OWS will coordinate existing HHS-wide efforts
- Click on the link below for Dr. Fauci's explanation on OWS and use the link in the bottom right for the full printable version of OWS explained



Explaining Operation Warp Speed

What's the goal?

Operation Warp Speed (OWS) aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).

How will the goal be accomplished?

By investing in and coordinating countermeasure development, OWS will allow countermeasures such as a vaccine to be delivered to patients more rapidly while adhering to standards for safety and efficacy.

Who's working on it?

OWS is a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. It will coordinate existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA.

What's the plan and what's happened so far?

DEVELOPMENT: To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support.

Protocols for the demonstration of safety and efficacy are being aligned, which will allow the trials to proceed more quickly, and the protocols for the trials will be overseen by the federal government, as opposed to traditional public–private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. This increases the financial risk, but not the product risk.

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https://youtu.be/Z06JQhyZLUI

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WILL WE TAKE THE VACCINE AND RECOMMEND IT TO OUR FAMILY?

In short, **yes,** when the FDA approves the Pfizer vaccine (or a similar one), we will gladly take it and will recommend our friends and family members do the same. We fully expect there to be a rollout that prioritizes those at higher risk to receive the first doses and we agree with that approach. It is important to understand that vaccination is one of the measures we should take but that we cannot stop wearing masks, avoiding crowds and using social distancing until the scientist experts tell us it is safe to do so.

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WE HOPE THIS HAS BEEN HELPFUL

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