

Current Vaccine Guidelines for Adults

The scientific community has debated the nature of viruses for over one-hundred years. Viruses are single cell organism, able to evolve or mutate. Initially they were seen as poisons, then life forms, then biological chemicals. Today we consider viruses to be in a spectrum of living and nonliving entities because they are only able to replicate once they infect a host's living cells.

Viral infections can cause very different reactions depending on the tissue they infect. The virus called varicella zoster initially causes blisters on the skin, referred to as Chicken Pox. The blisters may be painful and itchy but typically heal well once the virus runs its course. Unfortunately the virus remains active and moves into the nerve tissue near the spinal cord where it lies dormant. Later it may "wake up" and cause a more severe, painful rash known as shingles or herpes zoster.

The virus called poliomyelitis, which causes polio, also attacks the nerve tissue near the spinal cord however the effect can be much more severe. Before the polio vaccine was developed, in 1955, epidemics were common and affected infants and children most severely. The majority of individuals fully recover, however the virus can cause varying degrees of paralysis and death.

There is no cure for most viral infections and many cause serious health problems. Vaccines are one of the safest, effective, preventative treatments available to reduce the incidence of many diseases.

Recommended Adult Vaccines

- Tetanus, diphtheria and pertussis (T-dap)
- Measles, mumps and rubella (MMR)
- Pneumococcal polysaccharide is recommended for adults over age 65 years old
- Influenza is recommended for anyone older than 6 months
- Hepatitis B is recommended for adults in high-risk groups
 - Healthcare workers
 - Those in contact people who have chronic hepatitis B
 - · People with a recently acquired sexually transmitted disease
 - Adults under age 60 who have diabetes
 - · People who have or have had multiple sex partners
- Hepatitis A is recommended for adults in certain high-risk groups
 - · Healthcare workers
 - Travelers to countries where hepatitis A is common
 - People with chronic liver disease or clotting-factor disorders
- Zoster (Varicella) is a vaccine which prevents shingles
 - People aged 60 and older, especially for adults who have not had chickenpox or been immunized
- Human papillomavirus (HPV) is recommended for
 - Young adults, through age 26. Not recommended for women while pregnant

Adult Vaccines Schedules

- Measles, mumps, rubella 1 dose
- Pneumococcal 1 dose
- T-dap Vaccine 10-year intervals for adults
- Influenza Vaccine Yearly due to the annual appearance of new strains of the virus
- Hepatitis B Vaccine In 3 doses over a 6 month period
- Hepatitis A Vaccine 2 doses are needed to ensure long-term protection
- Varicella Vaccine 2 doses are recommended for those over age 13

For a complete listing of all recommended adult vaccinations visit https://www.cdc.gov/vaccines/schedules/index.html



COVID-10 Vaccine and Drug Treatment Research Update

The COVID-19 virus has triggered a pandemic with unprecedented challenges for global public health and the healthcare industry. This new strain of virus, commonly referred to as the "novel coronavirus", primarily infects the respiratory system. Infections in people first emerged in China at the end of 2019. It is a subgroup associated with SARS (severe acute respiratory syndrome) which emerged in 2003. Given that the novel coronavirus and SARS viruses are closely related, the presentation and duration of symptoms are similar. Unfortunately, there are currently no FDA-approved drug treatments or vaccines available for COVID-19. New vaccine development typically take 5-7 years however the FDA is allowing a "fast track" process to speed testing.

While this is a disheartening situation, it has opened many opportunities for collaboration across medical, pharmaceutical (Pharma) and employer health organizations. Researchers are working with unprecedented speed and focus to develop an effective treatment. They are sharing intelligence and technology which has expanded partnerships with other countries. These new and expanded partnerships are focused on sharing intelligence, technology and resources with manufacturers and researchers across the globe.

The non-profit organization, <u>Coalition for Epidemic Preparedness Innovations</u> (CEPI), has been instrumental in efforts to finance and coordinate COVID-19 vaccine development. Their investments, and others like the Gates Foundation, are allowing scientists to work with greater speed and efficiency. Several organizations have committed significant donations toward global support of healthcare worker, research and relief efforts.

AstraZeneca donated 9 million masks to healthcare workers around the globe. They set aside work on other drugs in order to fully focus on advancing their COVID-19 research. Amgen has committed \$12.5 million to support global relief efforts and will also match donations made by Amgen staff around the globe.

Gates Foundation is funding a collaboration, **COVID-19 Therapeutics Accelerator**, to review current drugs with potential to treat this new virus. Pharma manufacturers, including Novartis, Lilly, Gilead, Johnson & Johnson and Pfizer, have agreed to share their proprietary molecular compounds with the organization in support of efforts to conquer the pandemic.

World Health Organization (WHO) announced a global trial, named **Solidarity**, to test 14 existing antivirals, which show promise, in thousands of patients Their initial study will include remdesivir, chloroquine, Kaletra, and interferon-beta. Kevzara, used to treat rheumatoid arthritis, was jointly developed by Sanofi & Regeneron. They are testing its ability to reduce severity of the symptoms of COVID-19. The FDA has already approved a clinical trial for further exploration.

China, France and Australia recently publicized outcomes studies using hydroxychloroquine, an anti-malaria drug, and azathioprine, an antibiotic to treat COVID-19. This combination appears to have potential to reduce the duration and severity of infection. Further investigation is necessary to ensure safety, otherwise there is a risk that the treatment could cause a worsening of symptoms.

Recent news broadcasts about these small studies has unfortunately caused concerns about safety and drug shortages as many people are already seeking this combination therapy. Most states have adopted strict quantity limits and prescribing parameters to prevent people from taking the drugs if they are not positive for COVID-19. This is vitally important in order to maintain a sufficient supply to treat those who test positive, once they have been approved by the FDA, specifically for COVID-19.



Types of Vaccines

Pharmaceutical manufacturers across the world are developing vaccines and drug treatments that have the potential to treat the COVID-19 virus. Several vaccine candidates are currently being developed through what is referred to as "FDA fast-tracked" however each one will need to be tested for efficacy and safety. While the FDA has ways to speed projects, any action to omit scientific evidence and give an unproven vaccine to healthy people, has the potential to worsen patient symptoms and progression of the infection. More than 35 companies and institutions are working to develop a vaccine and four have already begun to conduct animal testing.

There are 6 basic types of vaccines, including killed viruses, weakened viruses, and viral proteins. Each exposes the body to a form of virus to increase the natural immune response to attack and kill the original virus. Genetically modified vaccines, called mRNA vaccines, are promising because once a process is determined they can use the same technology to alter other genes. This would improve the speed to market tremendously.

mRNA-1273 vaccine by Moderna & Vaccine Research Center

Moderna, in partnership with Vaccine Research Center, was the first manufacturer to gain approval for a vaccine to test in a human trial. They gained approval in just 42 days through cooperation with the **National Institutes of Health (NIH)** & the **Coalition for Epidemic Preparedness Innovations (CEPI)**. On **March 16th**, **2020** the new vaccine was administered to a healthy, 44 year old female, volunteer at Kaiser Permanente Washington Research Institute in Seattle. China was instrumental in speeding this development by sharing their development of a vaccine for SARS-CoV-2. They used genetic modification technology, used previously for influenza virus, to boost the immune response. Changing a portion of the genetic code made it effective against COVID-19.

Phase 1 clinical trials for mRNA-1273 begin in April, with 45 healthy volunteers, to determine safety and immune response. Researchers will monitor healthy volunteers to see when they begin to produce antibodies against the virus and ensure all adverse reactions are fully documented. If the safety test goes well they could begin Phase 2 trials by summer to determine whether vaccinated people are protected from the virus. While this is exceptional progress, realistically, a vaccine will not be available for 12–18 months due to the vigorous testing required.

The table below summarizes several other vaccines and drug therapies currently being researched and tested. The following page is a summary of more recent considerations for treatment potential.

Manufacturer	Product Name	Mechanism	
Noravax	MERS	Recombinant nanoparticle vaccine technology binds surface proteins	
Invio	INO-4700	DNA immunotherapy effective against MERS-CoV in 94% of patients	
Biocryst	Galidesivir	Antiviral which disrupts viral replication & is effective against Ebola, Zika	
AbbVie	Lopinavir	HIV protease inhibitor combined with ritonavir to reduce viral replication	
Regenron	REGN3048-3051	Antibodies which bind to the S-protein of MERS coronavirus	
Medicago	Virus Like Particles	Antibodies which attack the virus. Research funded by Canadian Institutes for Health	
Takeda	Plasma Derived	Concentrated pathogen specific antibodies derived from plasma of recovered patients	
Pfizer	Antiviral	Third party to screen & identify potential compounds by end of March, testing in April	
Altimmune	Intranasal Vaccine	Designed using technology similar to NasoVAX. Animal testing will follow	
Medicago	VLP	Virus-Like Particles (VLP) are used to develop antibodies against SARS-CoV-2	
Airway	AT-100	Human recombinant protein boosts immunity and reduces inflammation in the lungs	
Tiziana	TZLS-501	Monoclonal antibody blocks IL-6R, preventing lung damage by reducing inflammation	

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Developer	Mechanism	Candidates
Zydus Cadila	DNA Replicating Viral Vector	
WRAIR/USAMRIID	Protein Subunit	
Vaxil	Protein Subunit	
Vaxart	Non-Replicating Viral Vector	Influenza, Chikungunya, Lassa, Norovirus, Ebola Hepatitis-B
Univ. of Queensland, GSK	Protein Subunit	Nipah, Influenza, Ebola, Lassa
Univ. of Oxford	Non-Replicating Viral Vector	Influenza, TB, Chikungunya, Zika, Meningitis
Tonix Pharma, Southern Research	Replicating Viral Vector	Smallpox, Monkey pox
Takis, DNA Sciences, Evivax	DNA	
Sinovac	Inactivated	SARS
Sanofi Pasteur	Protein Subunit	Influenza, SARS
Novavax	Protein Subunit	RSV, HPV, Varicella Zoster, Ebola
Modern, NIAID	RNA	Multiple Candidates
Janssen	Non-Replicating Viral Vector	Ebola, HIV, Respiratory Syncytial Virus
Institute Pasteur	Replicating Viral Vector	West Nile, Chikungunya, Ebola, Lassa, Zika
Inovio	DNA	Multiple Candidates
Imperial College London	RNA	Ebola, Lassa, Marburg, Avian Influenza, Rabies
iBio/CC-Pharming	Protein Subunit	
Heat Biologics, Univ. of Miami	Protein Subunit	HIV, Malaria, Zika
Greffex	Non-Replicating Viral Vector	MERS
GeoVax, BravoVax	Non-Replicating Viral Vector	Lassa, Ebola, Marburg, HIV
Generex, EpiVax	Protein Subunit	Influenza, HIV, SARS
Fudan Univ., Shanghai RNACure, JiaoTong Univ.	RNA	
Fudan Univ., Shanghai JiaoTong Univ., RNACure	RNA	
ExpreS2ion	Protein Subunit	
EpiVax, Univ. of Georgia	Protein Subunit	Avian Influenza
Curevac	RNA	Rabies, Lassa, Yellow Fever; MERS, Influenza, Zika
Codagenix	Live Attenuated Virus	Hepatitis A, Simian Virus, RSV, Dengue, RSV
Clover, GSK	Protein Subunit	HIV, Respiratory Syncytial Virus, Influenza
China CDC, Tongji Univ., Stermina	RNA	
CanSino Biologics	Non-Replicating Viral Vector	
Baylor College of Medicine	Protein Subunit	SARS
Arcturus, Duke-NUS	RNA	Multiple Candidates
Altimmune	Non-Replicating Viral Vector	Influenza
AJ Vaccines	Protein Subunit	

References

1.WHO COVID-19 Dashboard

2. The Lancet COVID-19 Resource Centre

3. https://www.cdc.gov/coronavirus/2019-ncov/summary.html

4.<u>https://coronavirus.jhu.edu/map.html</u>

5.https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance

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patients-with-severe-COVID-19



Potential Immune System Boosters

There are currently no FDA-approved vaccines available for COVID-19 however several pharmaceutical manufacturers are working with unprecedented focus to develop an effective treatment and ultimately a vaccine which provides long-term protection. There are ways to improve our immune response to fight infection. A healthy diet of vegetables, fruits and lean protein is the first step. Consistent exercise and good sleep habits strengthen immunity as well. Vitamins and supplements can provide additional nutritional benefits and some are very powerful in their ability to protect at a cellular level.

Anti-oxidants are naturally occurring substances that are extremely important to protect our cells from free radicals which are known to cause many health issues due to cell damage. Free radicals can be introduced from outside the body through smoking, inhaling environmental pollutants, or exposure to ultraviolet radiation. Once they enter a cell they oxidize (add an oxygen molecule) causing a genetic alteration which damages the cell and may lead to cancer, degenerative disorders such as Alzheimer and Parkinsonism and plaque formation which develops into coronary artery disease.

Anti-oxidants are found in many natural foods like olive oil, berries, green tea, spinach and kale. Hydroxytyrosol, derived from olive oil, is a very effective anti-oxidant due to its ability to be absorbed in the central nervous system. Examples of anti-oxidants are listed below. Zinc, Glycyrrhizin and Andrographis paniculata are being studies to assess their effectiveness in preventing severe viral or bacterial infections. This information should not be taken as medical advice. Please contact your physician prior to taking any medication to ensure safety.

Hydroxytyrosol

CoQ10

- Zinc Beta-Carotene
- Vitamin A, C, D, E
- Niacinamide
- Turmeric,
- Spirulina
- Glutathione

Zinc is an essential micronutrient which supports a healthy immune system by increasing lymphocytes (white blood cells). Lymphocytes are the body's main defensive mechanism against viral infections. Zinc's antiviral effect is due to its ability to reduce viral replication by blocking RNA polymerase. This can reduce the duration and severity of the disease.

Glycyrrhizin, known as black licorice, stimulates the immune system by increasing white blood cells. China has used it in combination with antiviral drugs to treat hepatitis and HIV. Patients demonstrated a decrease in viral replication and liver enzymes, which is an indicator progression of the infection. Studies have also noted its ability to increase lymphocytes and interleukins which boost the immune system. There is no human research to confirm that this extends to COVID-19.

Andrographis paniculata is a supplement which has the ability to lessen the severity of symptoms and reduce the duration of upper respiratory infections by increasing lymphocyte production. Recent studies show promise of its ability to inhibit several key infectious enzymes, making Andrographis a potential candidate in the development of drugs to treat COVID-19.

References

- 1. Information from the World Health Organization (WHO)
- 2. Information from the World Health Organization (WHO)
- 3. The Lancet COVID-19 Resource Centre
- 4. WHO COVID-19 Dashboard

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