



The Challenges of Rapidly Developing & Distributing COVID-19 Vaccines

Thursday, January 28, 10:00-11:00

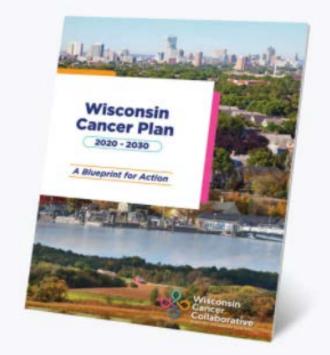
Who We Are

The Wisconsin Cancer Collaborative is a statewide coalition of 140 organizations working together to reduce the burden of cancer for everyone in Wisconsin.

Join Us!



Wisconsin Cancer Plan 2020-2030



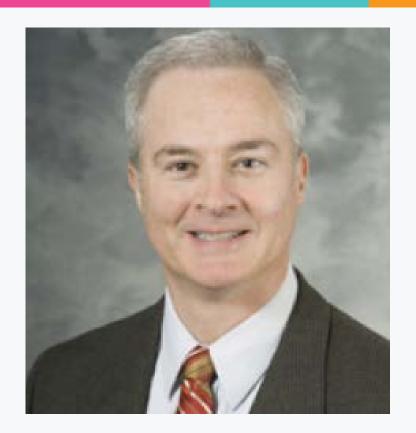
www.wicancer.org

Agenda

- Welcome
- Presentation by Dr. James
 Conway
- Questions







Dr. James Conway *Medical Director for UW Health Immunization Programs*



The Challenges of Rapidly Developing & Distributing COVID-19 Vaccines



James H. Conway, MD FAAP

Professor of Pediatrics – Division of Infectious Diseases
Medical Director – UW Health Immunization Programs
Director, Office of Global Health
Associate Director, Global Health Institute





12/31/2019: cluster of atypical pneumonia cases reported in Wuhan 1/4/2020: first WHO confirmation

THE LANCET

12/1/2019 estimate of first case (November? September?)

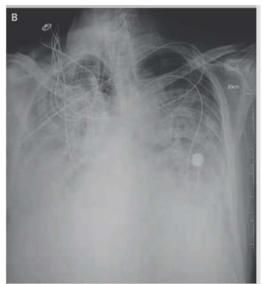


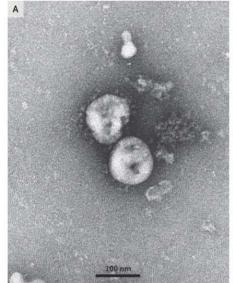
ORIGINAL ARTICLE BRIEF REPORT

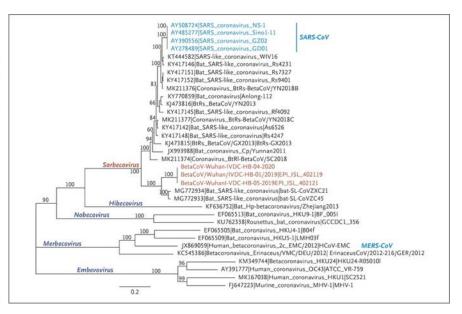
A Novel Coronavirus from Patients with Pneumonia in China, 2019

Na Zhu, Ph.D., Dingyu Zhang, M.D., Wenling Wang, Ph.D., Xinwang Li, M.D., Bo Yang, M.S., Jingdong Song, Ph.D., Xiang Zhao, Ph.D., Baoying Huang, Ph.D., Weifeng Shi, Ph.D., Roujian Lu, M.D., Peihua Niu, Ph.D., Faxian Zhan, Ph.D., Xuejun Ma, Ph.D., Dayan Wang, Ph.D., Wenbo Xu, M.D., Guizhen Wu, M.D., George F. Gao, D.Phil., and Wenjie Tan, M.D., Ph.D.et al., for the China Novel Coronavirus Investigating and Research Team

January 24, 2020 DOI: 10.1056/NEJMoa2001017 1/12/2020 China first released the virus sequence 1/24/2020 initial publication of clinical description, virus isolation, sequence analysis







WHO statement on novel coronavirus in Thailand

1/13/2020: First case outside of China

13 January 2020 | News release

1/30/2020: WHO declares COVID-19 a Public Health Emergency of International Concern



WHO Director-General's opening remarks at the media briefing on COVID-19 -11 March 2020

11 March 2020

Good afternoon

In the past two weeks, the number of cases of COVID-19 outside China has increased 13-fold, and the number of affected countries has tripled.

There are now more than 118,000 cases in 114 countries, and 4,291 people have lost their lives.

Thousands more are fighting for their lives in hospitals.

3/11/2020: WHO declares COVID-19 a Pandemic

SARS CoV1 (2002-2003)



Horseshoe bat (Sciencephoto.com)



Civet "cat" (Voanews.com)



(BBCnews.com)

MERS CoV (2012)



Bamboo bat (ecologyasia.com)



Dromedary camel



(BBCnews.com)

SARS CoV2 (2019+)



Horseshoe bat (bio.bris.ac.uk.com)



Pangolin (USAToday.com)



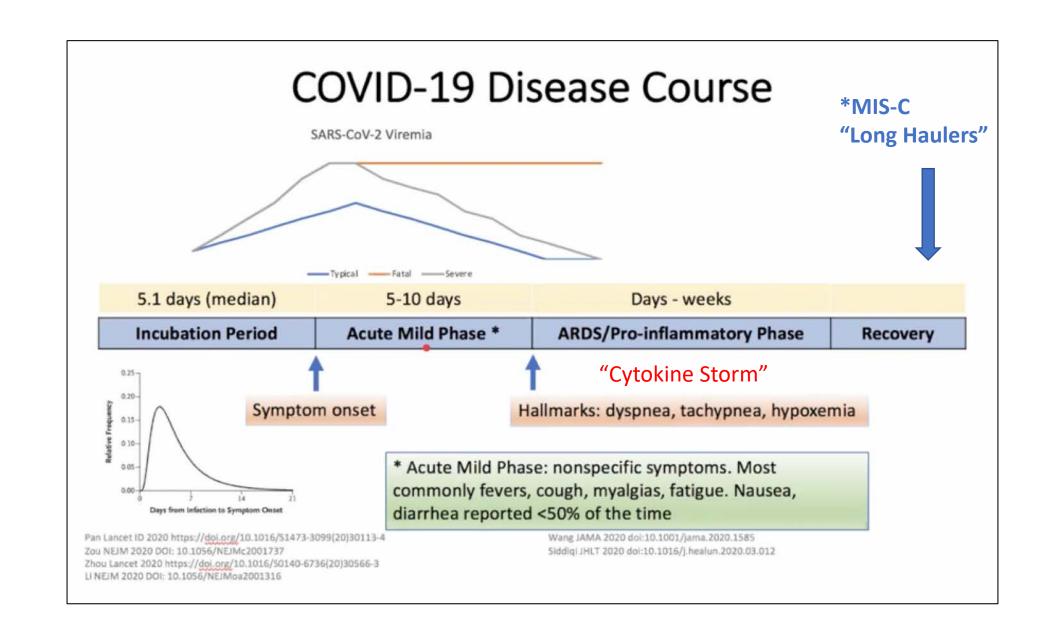
(BBCnews.com)

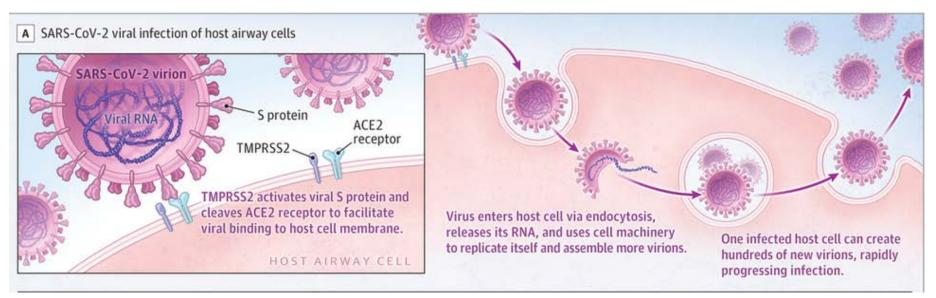


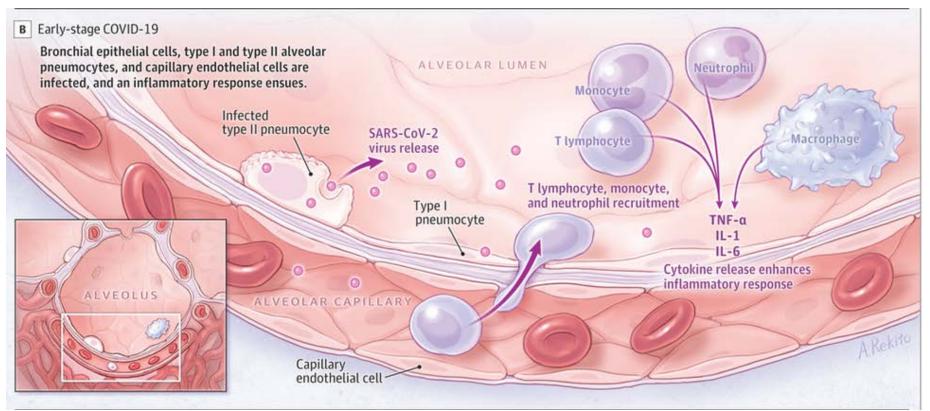
Coronavirus Disease 2019 (COVID-19)

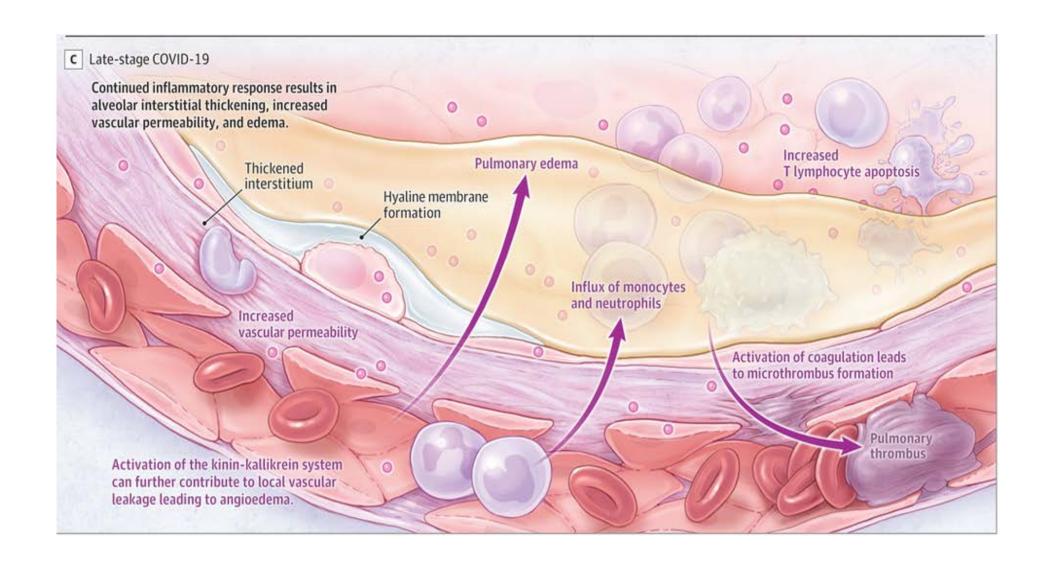
Clinical Presentation

- Over the course of the disease, most people with COVID-19 experience one or more of the following:
 - Fever or chills
 - Cough
 - Shortness of breath or difficulty breathing
 - Fatigue
 - Muscle or body aches
 - Headache
 - New loss of taste or smell
 - Congestion or runny nose
 - Nausea or vomiting
 - Diarrhea









SARS-CoV2 severity

81% Mild minimal or no pneumonia

14% Severe dyspnea, hypoxemia, >50% lung involvement on CXR

5% Critical respiratory failure, shock, multi-organ system failure

The Importance of Co-Morbidities

- AGE >65years
- Conditions that impact heart/lungs, small blood vessels or immune system
- People of any age with the following conditions are at increased risk of severe illness from COVID-19:
 - Cancer
 - Chronic kidney disease
 - COPD (chronic obstructive pulmonary disease)
 - Immunocompromised state (weakened immune system) from solid organ transplant
 - Obesity (body mass index [BMI] of 30 or higher)
 - Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
 - Sickle cell disease
 - Type 2 diabetes mellitus

Coronavirus Treatment Acceleration Program (CTAP)



560+

Drug development programs in planning stages¹



370+

Trials reviewed by FDA²



5

COVID 19 treatments currently authorized for Emergency Use³



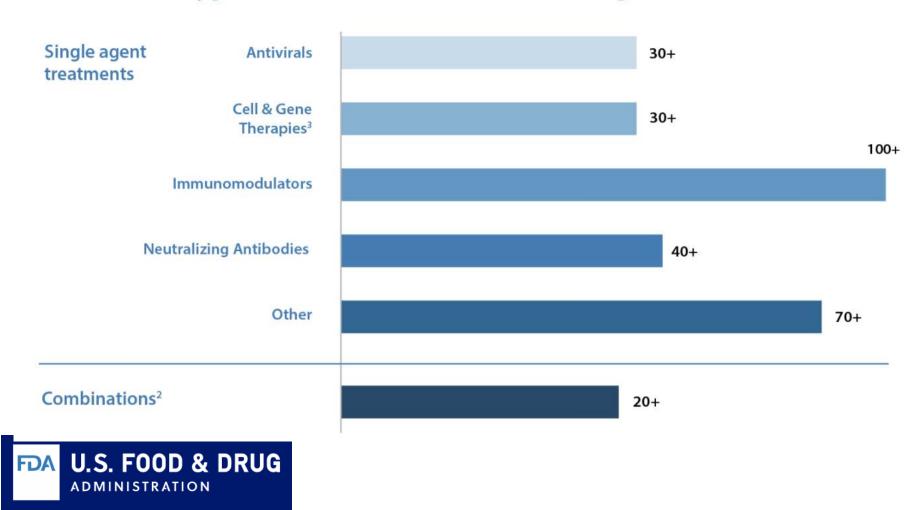
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Treatments currently approved by FDA for use in COVID-19

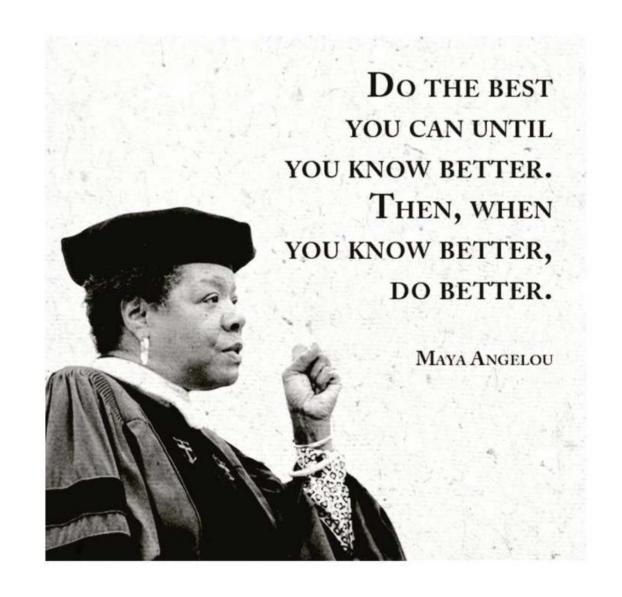


Coronavirus Treatment Acceleration Program (CTAP)

Type of COVID-19 Treatment Being Studied¹



Public Health = PREVENTION!





Initially....

- Mainly droplet transmission person to person
 - Hence *initially* limited mask recommendations
 - Hand hygiene, surface cleaning
 - Stay home when sick
 - Social distancing
- Later.....role of aerosols recognized as more significant
 - Routine masking & enhanced PPE
 - Limiting indoor contact
 - Limiting group sizes
 - Attention to air circulation



Developing a Vaccine for COVID-19 & Eventual 'Herd Immunity'



What do we know about Coronaviruses & immunity following infection?

- Found worldwide, winter/spring URIs
- Approximately 60% of children and 90% of adults
 >50 yo are seropositive
 - "Development of a nucleocapsid-based human coronavirus immunoassay and estimates of individuals exposed to coronavirus in a U.S. metropolitan population. Severance et al. *Clin Vaccine Immunol 2008*
- SARS & MERS IgG persist longer up to 1 year
- However mucosal immunity declines quickly
 - Only 8-31% have detectable secretory antibody
 - Reinfection is common
 - "Prevalence of Antibodies to Four Human Coronaviruses Is Lower in Nasal Secretions than in Serum" Gorse et al.
 Clin Vaccine Immunol 2010.

Ideal Vaccine Candidates



- EFFICACY: Produce immune protection that prevents infection
 - Long lasting & easily boosted
 - Prevents shedding & transmission to others
 - Activates both T-cells and B-cells
 - Superiority over wild-type infection?

• SAFETY:

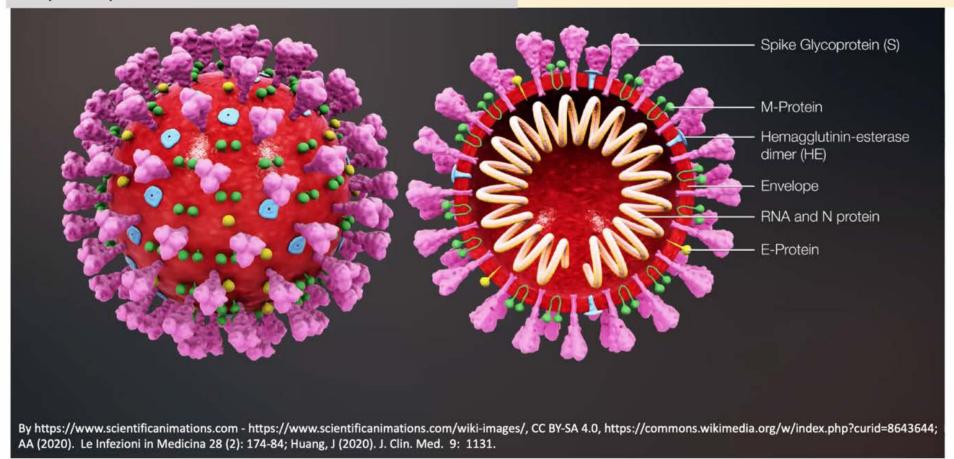
- Does not cause enhanced immune response during infection
- Minimal side effects after injection
- No long term side effects

functional targets

- RNA-dependent RNA polymerase (RdRp)
- heterogeneous nuclear ribonucleoprotein A1 (hnRNP A1)
- glycogen synthase kinase 3 (GSK3)
- cysteine proteases

structural targets

- M protein
- Spike protein
- Envelope proteins



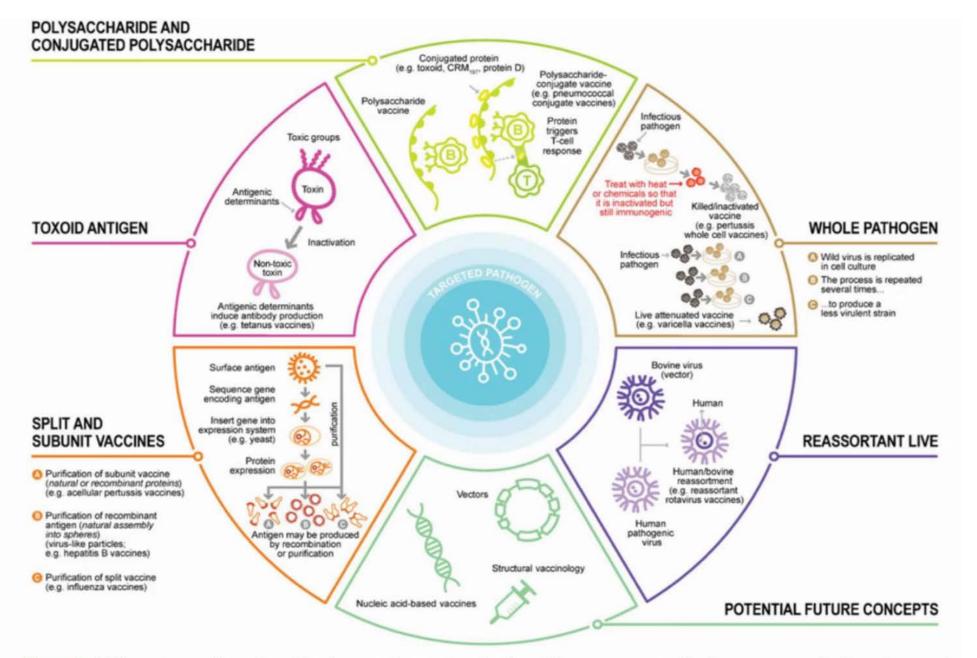


Figure 1. Different types of vaccines. Vaccines can be produced using different processes. Vaccines may contain live attenuated pathogens (usually viruses), inactivated whole pathogens, toxoids (an inactivated form of the toxin produced by bacteria that causes the disease), or parts of the pathogens (e.g. natural or recombinant proteins, polysaccharides, conjugated polysaccharide or



CHALLENGES to a COVID-19 vaccine

- Natural immunity to coronaviruses appears to be short-lived
 - serum neutralizing antibodies detection ≠ mucosal immunity
- Unclear surrogate marker of immunity
 - How do we assess vaccine efficacy?
 - Ethics of challenge trials?
- Best target antigen(s)?
- Anticipating progressive mutations?
- Optimal route of delivery?



CHALLENGES to a COVID-19 vaccine

- Enhanced disease after vaccine?
 - Multisystem Inflammatory Syndrome-Coronavirus = MIS-C

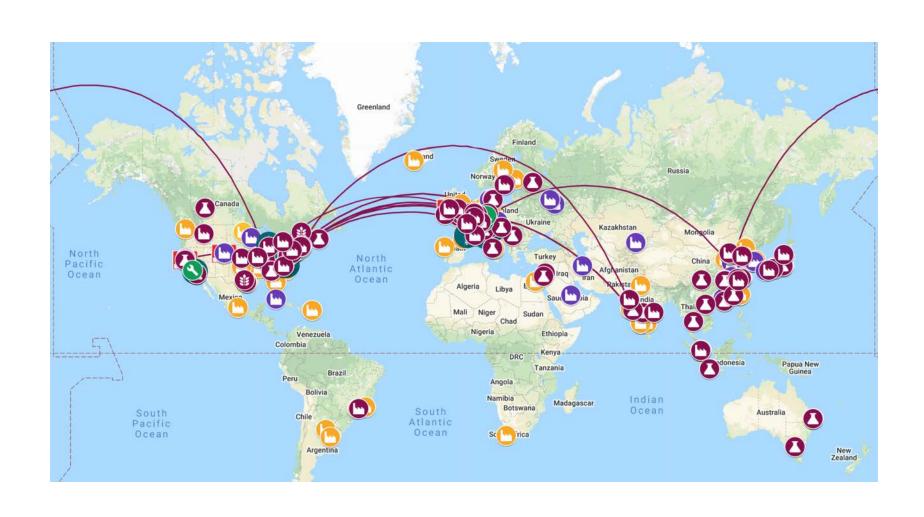


- Durability of immunity? Need for boosters?
- Testing population vs. target population?
- Bypassing the usual progressive process for product development
- Mass manufacture & delivery
- Targeted & equitable distribution challenges

Reasons for (modest) optimism

- An unprecedented GLOBAL effort to develop a vaccine!
 - Collaboration between companies
 - Widespread sharing of information including pre-prints
- MANY potential candidate vaccines & novel technologies
- \$\$\$ being put into R & D
- National competition?
- Novel approaches to R & D and production
- Prior efforts to develop MERS & SARS-CoV1 vaccines
- Novel approaches to clinical studies & enrollment
 - Inclusion of >65yo, comorbidities, women of childbearing age

http://vaxmap.org/



How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

PHASE 1



20-100 healthy volunteers

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

PHASE 2



several hundred volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

PHASE 3

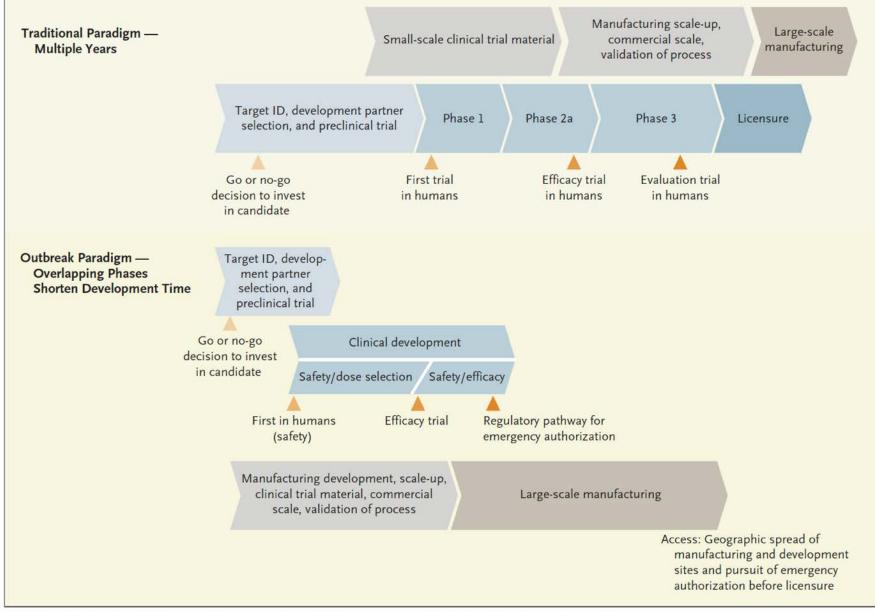


hundreds or thousands of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks



Difference between Traditional Vaccine Development and Development Using a Pandemic Paradigm.

Developing Covid-19 Vaccines at Pandemic Speed

Nicole Lurie, M.D., M.S.P.H., Melanie Saville, M.D., Richard Hatchett, M.D., and Jane Halton, A.O., P.S.M.



Emergency Use Authorization

Type of authority by FDA to allow use of medical products to prevent serious or life-threatening diseases when certain safety criteria are met and there are no alternatives.

COVID-19 - Landscape of novel coronavirus candidate vaccine development worldwide

Summary Information on Vaccine Products in Clinical Development

1. - Number of vaccines in clinical development

63

2. - Number of vaccines in pre-clinical development

173

3. - Candidates in clinical phase

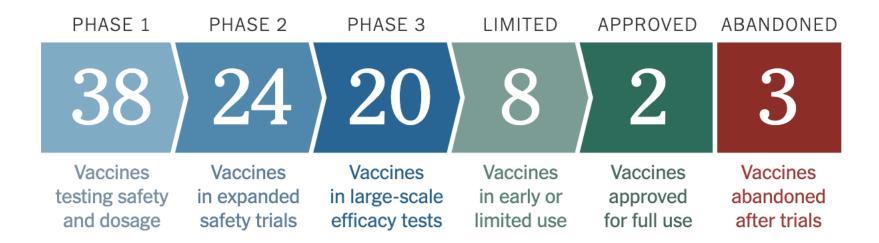
Filter All

Select phase of development (default is all)

atform		Candidate vaccines (no. and %)
PS	Protein subunit	20	32%
VVnr	Viral Vector (non-replicating)	10	16%
DNA	DNA	8	13%
IV	Inactivated Virus	9	14%
RNA	RNA	7	11%
VVr	Viral Vector (replicating)	3	5%
VLP	Virus Like Particle	2	3%
VVr + APC	VVr + Antigen Presenting Cell	2	3%
LAV	Live Attenuated Virus	1	2%
VVnr + APC	VVnr + Antigen Presenting Cell	1	2%
	*	63	

Coronavirus Vaccine Tracker

By Carl Zimmer, Jonathan Corum and Sui-Lee Wee Updated Jan. 26, 2021

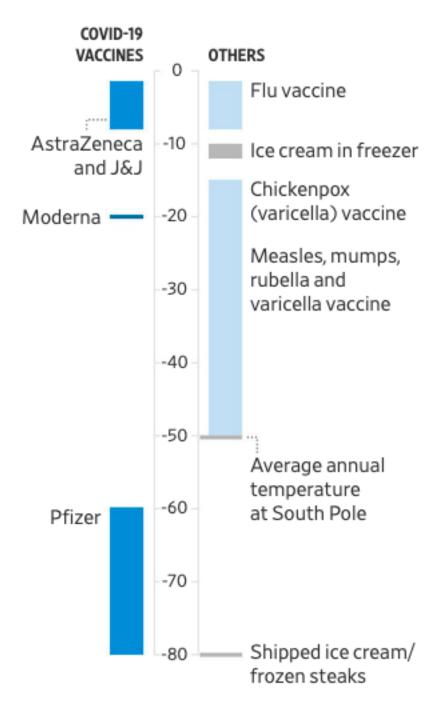


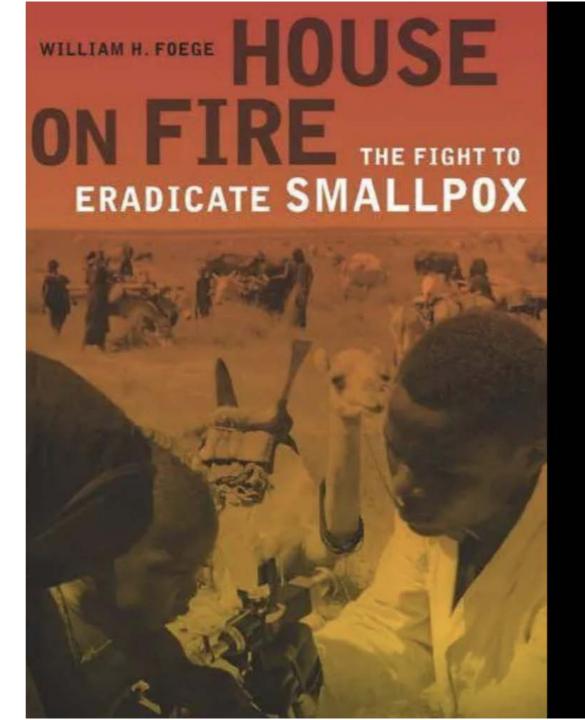
SARS-CoV2 Vaccines in US trials

Candidate	Manufacturer	Туре	Phase	Schedule	Age	Size	Recruiting
mRNA-1273	Moderna	mRNA	III	2 doses (0, 28d)	≥18 years	30,000 participants	Enrollment complete
mRNA- BNT162	Pfizer, Inc./ BioNTech	mRNA	III	2 doses (0, 21d)	12-85 years	44,000 participants	✓
AZD1222	Oxford/ AstraZeneca	Viral vector (non- replicating)	III	2 doses (0, 28d)	≥18 years	40,000 participants	✓
Ad26COVS1	Janssen/ Johnson & Johnson	Viral vector (non- replicating)	III	1 dose	≥18 years	30,000 participants	✓
NVX- CoV2373	Novavax	Protein subunit	1/11	2 doses (0, 21d)	18-84 years	1,400 participants	Enrollment complete
_	Sanofi/GSK	Protein subunit	1/11	1 dose or 2 doses (0, 21d)	≥18 years	440 participants	✓
V591	Merck	Viral vector (replicating)	1/11	2 doses (1, 57d)	≥18 years	260 participants	✓
VXA-CoV2-1	Vaxart	Viral vector (non- replicating)	I	2 doses (1, 29d) *Oral	18-54 years	48 participants	✓
INO-4800	Inovio	DNA plasmid	I	2 doses (0, 4w) *Electropora tion	≥18 years	120 participants	Active, not recruiting
AV-COVID-19	Aivita	AuDendritic cell	1/11	1 dose	≥18 years	180 participants	Not yet recruiting

Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	2 3	Approved in Saudi Arabia, Bahrain, Switzerland. Emergency use in U.S., E.U., other countries.
Moderna	mRNA	3	Emergency use in U.S., U.K., E.U., other countries.
Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
Oxford- AstraZeneca	ChAdOx1	2 3	Emergency use in Britain, India, other countries.
CanSino	Ad5	3	Limited use in China.
Johnson & Johnson	Ad26	3	
Vector Institute	Protein	3	Early use in Russia.
Novavax	Protein	3	
Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in Egypt, Jordan.
Sinovac	Inactivated	3	Emergency use in China, Brazil, other countries.
Sinopharm-Wuhan	Inactivated	3	Limited use in China, U.A.E.
Bharat Biotech	Inactivated	3	Emergency use in India.





If a house is on fire, no one wastes time putting water on nearby houses just in case the fire spreads. They rush to pour water where it will do the most good – on the burning house.

William H. Foege

Phase 1 Phase 2 Phase 3 Phase 4

Phase 1a "Jumpstart Phase"

- High-risk health workers
- First responders

Phase 1b

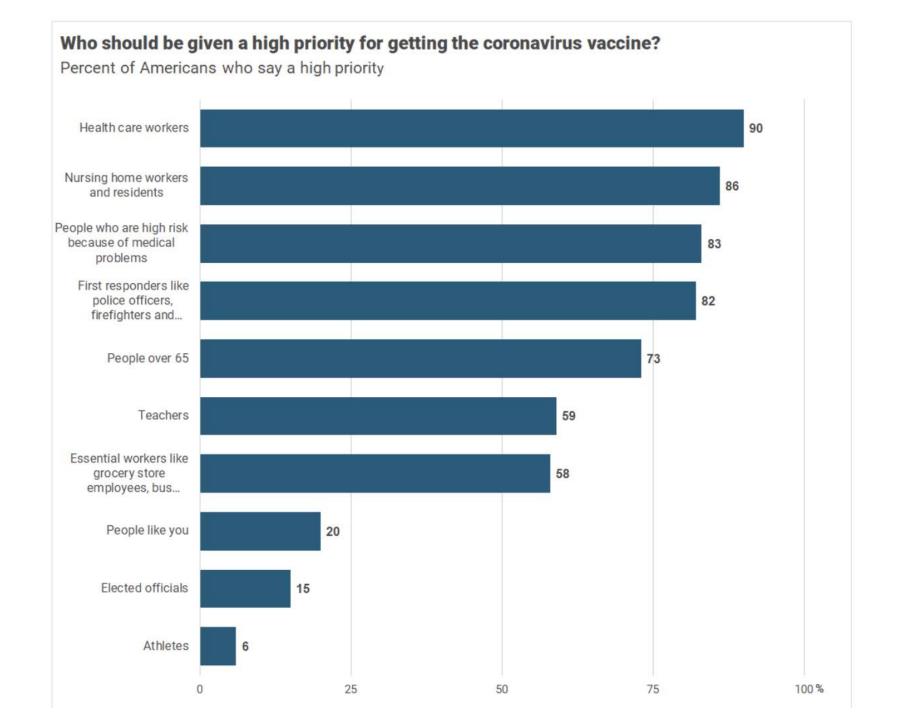
- People of all ages with comorbid and underlying conditions that put them at significantly higher risk
- Older adults living in congregate or overcrowded settings

- K-12 teachers and school staff and child care workers
- Critical workers in high-risk settings—workers who are in industries essential to the functioning of society and at substantially higher risk of exposure
- People of all ages with comorbid and underlying conditions that put them at moderately higher risk
- People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, developmental and intellectual disabilities, and physical disabilities or in recovery, and staff who work in such settings
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
- All older adults not included in Phase 1

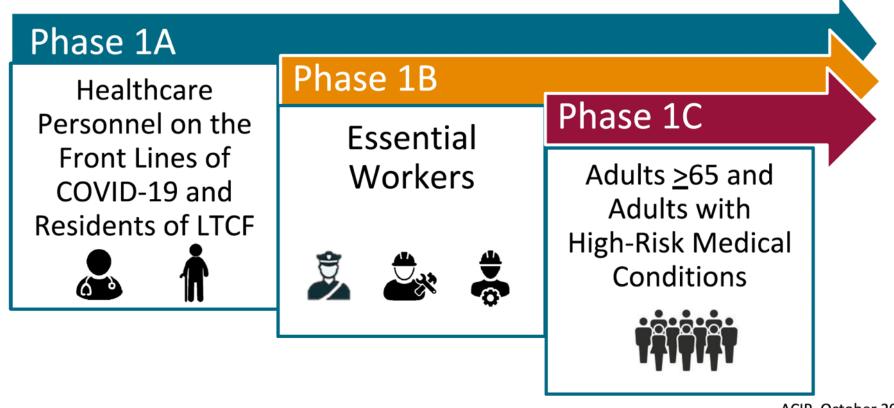
- Young adults
- Children
- Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

 Everyone residing in the United States who did not have access to the vaccine in previous phases

Equity is a crosscutting consideration: In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.



Evolving US Vaccine Allocation Framework



ACIP, October 2020

Preliminary Recommendations of the NCCN COVID-19 Vaccination Advisory Committee

- Patients with cancer should be prioritized for vaccination (CDC priority group 1b/c) and should be immunized when vaccination is available to them.
- Immunization is recommended for all patients receiving active therapy, with the understanding that there are limited safety and efficacy data in these patients.
- Reasons for delay of vaccination:
 - recent exposure to COVID-19 (quarantine period)
 - Documented recent SARS-CoV2 infection (30-90 days)
 - Recent administration of COVID monoclonal Abs or plasma (90 days)
 - 14 days within administration of other vaccines (unless cannot be avoided)
- Vaccination should be delayed for at least 3 months following HCT or engineered cellular therapy (e.g. CAR-T cells) to maximize vaccine efficacy.
- Caregivers and household/close contacts should be immunized when possible.

A note to the wise...

• Don't assume that acceptance will be automatic and widespread

THE SACRAMENTO BEE



'No masks. No vaccines.' Battle is brewing over coronavirus immunizations in California

BY HANNAH WILEY





U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine

Concerns about the safety and effectiveness of possible vaccine, pace of approval process

The Washington Post

Anti-vaccination leaders fuel black mistrust of medical establishment as covid-19 kills people of color

The memory of the horrific Tuskegee syphilis study makes some African Americans suspicious of a coronavirus vaccine



Even before a coronavirus vaccine becomes available, some activists are ready to attack it; this woman attended a "Reopen Virginia" protest in Richmond in April. MATTHEW RODIER/SIPA USA/AP IMAGES

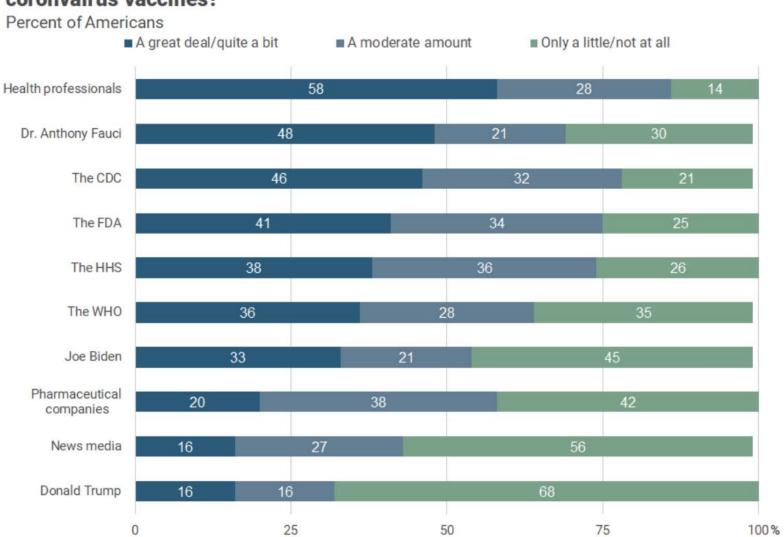
Just 50% of Americans plan to get a COVID-19 vaccine. Here's how to win over the rest

By Warren Cornwall | Jun. 30, 2020, 4:25 PM

Science's COVID-19 reporting is supported by the Pulitzer Center.

Within days of the first confirmed novel coronavirus case in the United States on 20 January, antivaccine activists were already hinting on Twitter that the virus was a scam—part of a plot to profit from an eventual vaccine.

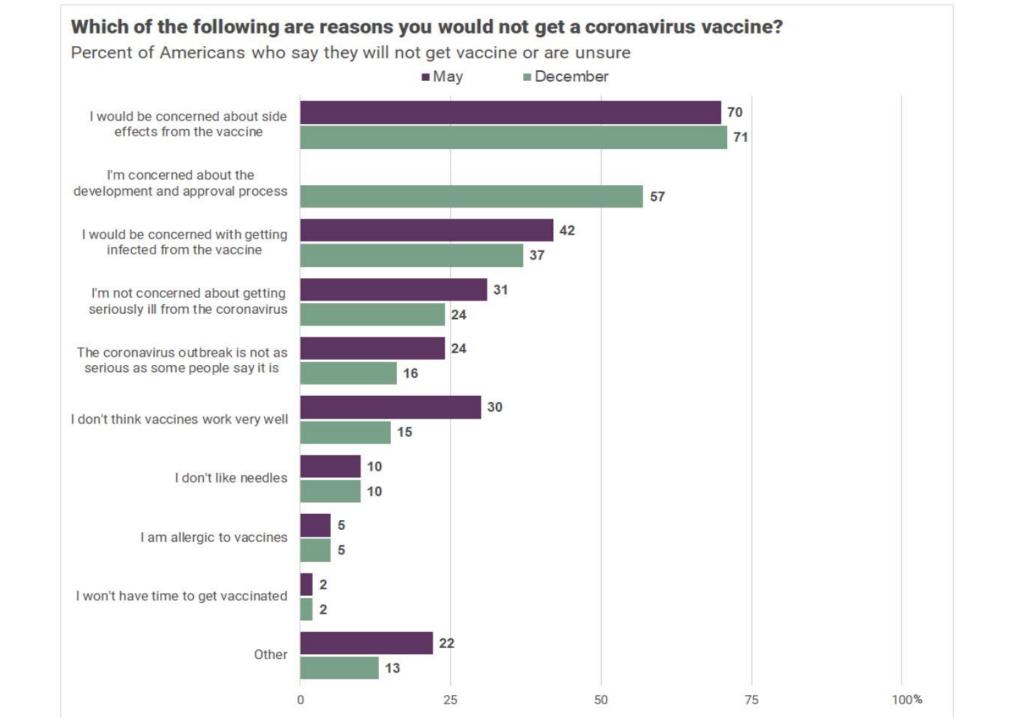
How much do you trust each of the following sources of information about coronvairus vaccines?



Question: How much do you trust each of the following sources for information about coronavirus vaccines? Source: AP-NORC poll conducted December 3-7, 2020, with 1,117 adults

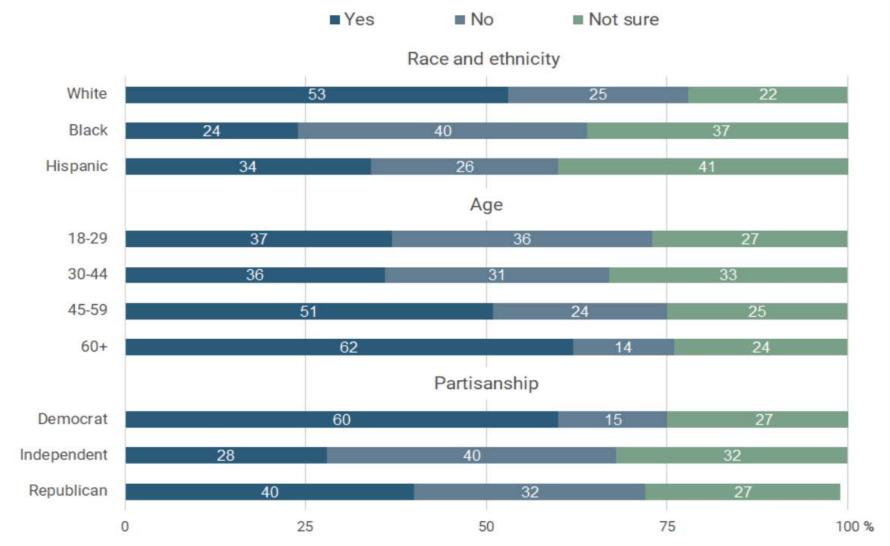






Do you plan to get vaccinated against the coronavirus?

Percent of Americans

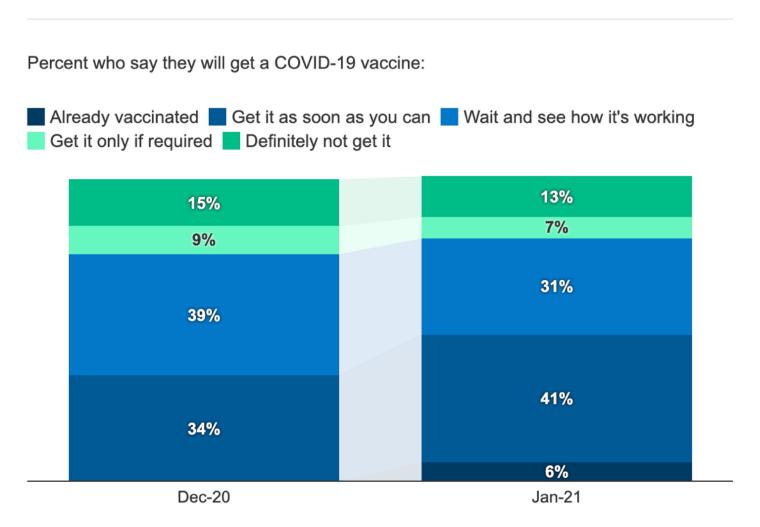


Question: When a vaccine against the coronavirus becomes available to you, do you plan to get vaccinated, or not? Source: AP-NORC poll conducted December 3-7, 2020, with 1,117 adults





Compared To December, Larger Share Now Want COVID-19 Vaccine "As Soon As Possible," Fewer Want To "Wait And See"



https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor/

In the meantime...



Cancer Talking Points

- Healthcare workers play a key role in building vaccine confidence, ensuring the safety of their patients, and increasing patient comfort level with medical appointments and necessary treatment during the pandemic.
- Cancer patients should ask their healthcare provider before receiving the vaccine to better understand when they should receive the vaccine, especially if their treatment compromises their immune system.

In the meantime... recommendations:

- Stay home if you're sick
- Hand hygiene!
- Maintain physical distance from others
- Wear a mask especially when in confined public places, both for the protection of others & yourself
- GET IMMUNIZED AGAINST INFLUENZA!
- Activate MyChart & be sure contact information in EMR is accurate
 - Encourage creation/maintenance of email



ante Thank you Cnacuo - Are Cro Dziękuję Euxapioto Kiitos Tak Dziękzie 有り難う Obrigado 谢谢 Hvala 有り難う ふん Tack nin Merci Danke Terma kasih D 射謝 Grazie Thank you Gracias ขอบคุณ Kitt ありかとう 감사합니다 かぬ 謝謝 Cnacubi inte Multumesc Cnacubi Cnacubo Dankon kon Xbana Brazodapa Asante Děkuju Obri 割割 شكراك Teşekkür ederim 大のSZÖNÖM Obrige

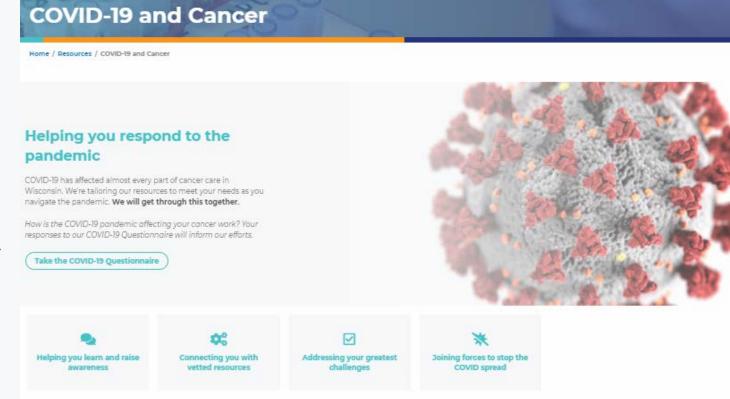
Questions? Comments?

Please take our poll! Will pop up on your screens shortly.



Check out our COVID-19 & Cancer Resource Page

- Social media toolkits
- Links to research articles
- Past COVID-19 webinars
- Tips for local governments & businesses





https://wicancer.org/resources/covid19/

Preliminary Recommendations of the NCCN COVID-19 Vaccination Advisory Committee

The National Comprehensive Cancer Network (NCCN) released guidance on the COVID-19 vaccinations in people with cancer, recommending that this patient group be prioritized for immunization.

This document goes over recommendations.

Link: https://www.nccn.org/covid-19/pdf/COVID-19 Vaccination_Guidance_V1.0.pdf



NCCN: Cancer and COVID-19 Vaccination

Version 1.0 1/22/2021

Preliminary Recommendations of the NCCN COVID-19 Vaccination Advisory Committee*

- Patients with cancer should be prioritized for vaccination (CDC priority group 1b/c) and should be immunized when vaccination is available to them.
- Immunization is recommended for all patients receiving active therapy, with the understanding that
 there are limited safety and efficacy data in these patients.
- Reasons for delay of vaccines are similar to the general public (e.g., recent exposure to COVID-19), and cancer-specific factors. Vaccination should be delayed for at least 3 months following HCT or engineered cellular therapy (e.g. CAR-T cells) to maximize vaccine efficacy.
- · Caregivers and household/close contacts should be immunized when possible.

Table 1. COVID-19 Vaccination Recommendations for Cancer Patients

Patients	
Treatment/Cancer Type	Timing ^{†,‡}
Hematopoietic Cell Transplantation (HCT)/Cellular Therapy	
Allogeneic Transplantation	At least 3 months post-
Autologous Transplantation	HCT/cellular therapy ^{a,b}
Cellular therapy (e.g., CAR-T cell)	
Hematologic malignancies	
Receiving intensive cytotoxic chemotherapy (e.g. cytarabine/anthracycline-	Delay until absolute neutrophil
based induction regimens for AML)	count (ANC) recovery ^c
Marrow failure from disease and/or therapy expected to have limited or no	When vaccine available
recovery	
Long-term maintenance therapy (e.g., targeted agents for chronic	When vaccine available ^c
lymphocytic leukemia or myeloproliferative neoplasms)	
Solid tumor malignancies	
Receiving cytotoxic chemotherapy	When vaccine available ^{c,d}
Targeted therapy	When vaccine available
Checkpoint inhibitors and other immunotherapy	When vaccine available*
Radiation	When vaccine available
Major surgery	Separate date of surgery from
	vaccination by at least a few days
Caregivers and Household/Close Contacts (≥16 years of age)	
Any time eligible to receive the vaccines	

†COVID-19 vaccines should be prioritized over other needed vaccines, as data on dual vaccination is not available to date. 14 days recommended between COVID-19 vaccines and other approved vaccines.

Discussion with clinical trial leads should be considered in advance to prevent protocol violations or exclusions.

RIORITIZATION AMONG CANCER PATIENTS IN THE SETTING OF LIMITED VACCINE AVAILABILITY

New Resource!

"Cancer Tests & Screenings: How to Safely Get Tested for Cancer during COVID-19"

 Developed in partnership with the Wisconsin Well Woman Program and **Covering Wisconsin**





Cancer Tests & Screenings

How to Safely Get Tested for Cancer during COVID-19

Have you been afraid to get care because of COVID-19?

It is safe to go to your doctor for check-ups and tests.

Some tests can even be done at home. Ask your clinic what tests you need.

What are screenings?

Cancer screenings are tests to check for cancer

Many cancer tests are covered by health insurance.

What are clinics doing to keep you safe?

- · Exam rooms and wait areas are carefully cleaned
- Doctors use masks and protective equipment
- Patients are checked for COVID symptoms at



COVID-19 safety basics to protect your health:

- Wear a mask in public
- Keep 6 feet apart
- Wash hands often or use hand. sanitizer

What's free with health insurance?

What's free with most insurance?

For all adults:

- Lung cancer tests
- · Colon cancer tests
- Help to stop smoking
- Help to stop drinking

- Breast cancer tests
- Cervioal cancer tests

If you don't have health

You can go to a free clinic or community health center for low-cost options.

Call the 2-1-1 helpline and ask for health insurance help or a free clinic near you.

Call your insurance company for a complete list of free screenings and ask about the cost of follow up care.

It's best to find and treat cancer fast

Don't wait to get a cancer test!

Finding cancer early can:

- Save your life
- Prevent the spread to other body parts
- Be easier to treat
- Cause less health issues







February Networking Webinar - Registration Open!

"Cancer in the LGBTQ+ Community"

The executive director of the National LGBT Cancer Network will join us to share tools and strategies for improving outcomes for LGBTQ+ populations across the cancer continuum. (Note: This webinar is 90 minutes long.)

Register here: https://wicancer.org/events/webinars/





10:00-11:30

https://wicancer.org/events/webinars/

Thank you!

Thank you for joining! Stay well!

