HIV, COVID-19 and Vaccinations



Bells and candlelight honor 400,000 dead from COVID-19







- "I have decided to stick with love. Hate is too great a burden to bear."
- "Be a bush if you can't be a tree. If you can't be a highway, just be a trail. If you can't be a sun, be a star. For it isn't by size that you win or fail. Be the best of whatever you are."
- "Life's most persistent and urgent question is, 'What are you doing for others?"

COVID-19 – worldwide cases





COVID-19 – Cases by WHO Regions





COVID-19 – Deaths by WHO Region





Data may be incomplete for the current day or week.

COVID/CT: Estimated Newly Infected Subjects (per Day)

2 Compare

Map Map

~ Trend

Daily infections and testing

Estimated infections are the number of people we estimate are infected with COVID-19 each day, including those not tested.

=== Current projection === Universal masks === Rapid vaccine rollout

Source: Dr. Ian M. Mackay's Twitter

Phases of clinical trials

There are four phases of clinical trials

Source: https://covid19community.nih.gov/resources/understanding-clinical-trials

- Researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials.*
- Manufacturing started while the clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.
- mRNA vaccines are faster to produce than traditional vaccines.
- FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines.

COVID-19 vaccine trials by the numbers

Pfizer/BioNTech

- 43,931 enrolled
- 150 clinical sites
 - 39 U.S. states
- Racial/ethnic distribution
 - 13% Hispanic
 - 10% African American
 - **6% -** Asian
 - 1% Native American
- 45% ages 56-85

Sources: <u>https://www.pfizer.com/science/coronavirus/vaccine;</u> <u>https://www.modernatx.com/cove-study</u> For more information, visit <u>www.clinicaltrials.gov</u>

Moderna

- 30,000 enrolled
- 89 clinical sites
 - 32 U.S. states
- Racial/ethnic distribution
 - 63% White
 - 20% Hispanic
 - **10% -** African American/Black
 - **4% -** Asian
 - 3% All others
- 64% ages 45 and older
 - 39% ages 45-64
 - 25% ages 65+

COVID-19 vaccines expected to receive FDA Emergency Use Authorizations

- Two vaccines received FDA Emergency Use Authorizations (EUAs) :

 Pfizer/BioNTech (BNT162b2) 95% effective (manufacturer data)
 Moderna (mRNA-1273) 94.5% effective (manufacturer data)
- Both are mRNA vaccines with a 2-dose schedule.
- Duration of protection is not yet known.
- Both vaccines were tested in diverse adult populations, including older adults and communities of color.
- For the latest information about authorized vaccines, visit <u>www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-</u> 2019-covid-19/covid-19-vaccines.

What are messenger RNA (mRNA) vaccines?

- Carry genetic material that teaches our cells how to make a harmless piece of "spike protein," which is found on the surface of the SARS-CoV-2 virus.
 - Genetic material from the vaccine is destroyed by our cells once copies of the spike protein are made and it is no longer needed.
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies. This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies.
- Do not affect our DNA; mRNA does not enter the cell nucleus.
- Cannot give someone COVID-19.
- Use technology that is new but not unknown. mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV).

About these COVID-19 mRNA vaccines

- These mRNA vaccines produce side effects after vaccination, especially after the 2nd dose.
 - Side effects may include:
 - Fever
 - Headache
 - Muscle aches

- No significant safety concerns were identified in the clinical trials.
- At least 8 weeks of safety data were gathered in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.

Safety of COVID-19 vaccines is a top priority

- COVID-19 vaccines are being held to the same safety standards as all vaccines.
- FDA's <u>Vaccines and Related Biological Products Advisory Committee</u> (VRBPAC) reviews applications for EUAs.
- The <u>Advisory Committee on Immunization Practices (ACIP)</u> considers safety and efficacy data before recommending use.
- VRBPAC and ACIP are independent committees composed of scientific and clinical experts.
- FDA and CDC monitor vaccine safety and side effects once vaccines are in use.

Robust vaccine safety monitoring systems exist

- Existing systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:
 - Vaccine Adverse Event Reporting System (VAERS)
 - Vaccine Safety Datalink (VSD)
 - <u>Clinical Immunization Safety Assessment (CISA)</u>
 - Biologics Effectiveness and Safety System (BEST)
- New systems have been developed to monitor COVID-19 vaccine safety, such as v-safe:
 - Active surveillance that uses text messaging to initiate based survey monitoring.
 - Will provide telephone follow up to anyone who reports significant adverse events.

The Problem: Patients may be hesitant to receive COVID-19 vaccine

• Only 58% of the general public said they would receive a COVID-19 vaccine

(as of an October 2020 Harris poll)

Factors weighing on acceptance:

Are there side effects?

Does it work? Is it safe?

How much does it cost?

COVID-19 vaccine more acceptable if: Healthcare team said it was safe No costs to the individual It would help get back to school and work They could get it easily

Tyson, A, Johnson, C, & Funk, C. (2020, September 17). *U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine*. Pew Research Center. <u>https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/</u>

Jackson, C., & Newall, M. (2020, September 29). *Despite COVID-19 spike, few individual behaviors are changing*. Ipsos. <u>https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index</u>

COVID-19 Myths Debunked

- COVID-19 vaccines were 'rushed,' so they could still be unsafe.
- You can get COVID-19 from the vaccine.
- The vaccines can change your DNA.
- The COVID-19 vaccines cause infertility.
- You don't have to get vaccinated if you've already had COVID-19.
- Once you've been vaccinated, you can no longer spread the virus.
- Severe reactions to the COVID-19 vaccines are common.
- You should wait until you can choose the exact type of vaccine you'd like.

Source: Huffington Post

Additional COVID-19 Vaccine Side Effects Reported

- A warm glow inside from knowing you are making your neighbors, friends and family safer
- A feeling of doing your part to stop the global pandemic

COVID-19 Vaccine: Supporting Our Community Connecticut

- Connecticut Children's is supporting the state's vaccine program with our clinics
- Phase 1b in progress: State residents who are 75 and older
- Phase 1b will soon be expanded:
 - o Front line essential workers
 - $\circ~$ Individuals, ages 64 to 74 $\,$
 - o Individuals, ages 16 to 64 with underlying health conditions that put them at greater risk
 - Connecticut residents and staff in congregate settings
- When eligible, your friends and family members can get details on how to register at ct.gov/covidvaccine