

COVID-19 Vaccine Roundtable: Leadership Strategies & Myth-Busting



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Agenda

- Provide an overview of vaccine development and safety information
- Address and respond to common myths, concerns, and sources of vaccine hesitancy
- Offer leadership strategies for treatment providers and behavioral health employers
- Q+A



Vaccine Development

How Were COVID-19 Vaccines Developed So Fast?

- Scientists have been studying coronaviruses for over 50 years.
- Recent vaccine research was underway due to SARS epidemic in 2002 and MERS in 2012.
- Advances in genomic sequencing, researchers successfully uncovered the viral sequence of SARS-CoV-2 in January 2020 — roughly 10 days after the first reported pneumonia cases in Wuhan, China.
- Vaccine development is expensive and difficult to get funded but not during COVID – no time lost on small initial proof of concept studies or fundraising.
- Vaccine development is a process of trial and error; usually only one to a few trials at a time, but not during COVID – 87 animal studies and 55 human trials going simultaneously.
- Enormous funding allowed firms to do preclinical and phase I, II and III trials, as well as manufacturing, in parallel instead of sequentially.



How Were COVID-19 Vaccines Developed So Fast? (cont'd)



Goal for a COVID-19 vaccine is under 18 months

Pre-clinical trials			Emergency licensing
	Safety & dose selection trial	Safety & efficacy trial	
Small-scale production of clinical trial material & manufacturing scale-up		Large-scale manufacturing	

Governments will need to expedite their usual drug approval processes in order to deliver the vaccine to over 7 billion people quickly.

 It helped that COVID-19 was everywhere because firms need infections to show that vaccines work. It's hard to run efficacy trials when the diseases themselves aren't prevalent

Monitoring Vaccine Safety is a Regular, Ongoing Part of Vaccine Development

- Existing systems and data sources are used to monitor safety of vaccines after they are authorized or licensed, 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 are being developed to monitor vaccine safety, such as v-safe:
 - Active surveillance that uses text messaging to initiate web-based survey monitoring
 - Any clinically important events reported by a participant would be sent to VAERS for followup





These COVID-19 Vaccines are mRNA Vaccines

- Both are 95% effective at preventing Covid infections and the 5% that still get infected will not have a severe case
- mRNA vaccines teach our cells how to make a harmless piece of the "spike protein" for SARS-CoV-2
 - After the protein piece is made, the cell breaks down the instructions (the mRNA) and gets rid of them
- 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
- mRNA vaccines do not use the live virus that causes COVID-19. They CANNOT give someone COVID-19
- mRNA vaccines DO NOT affect or interact with our DNA in any way



Pfizer/BioNTech and Moderna Vaccines





Side Effects to mRNA Vaccines (Pfizer, Moderna)

- Symptoms
 - Pain at injection site red, tender, mild swelling
 - Fatigue
 - Headache
 - Muscle ache
 - Less common fever, chills, joint pain
- Often over in a day
- May be more severe after second dose
- Could be more accurately called "immune response" instead of "side effects"
- 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





What We Don't Know Yet

- How long will a COVID vaccination protect you from COVID?
 - Varies widely for other vaccines from just a year to a lifetime
- Can a vaccinated person who gets COVID infects others?
- Will there be any long-term adverse effects that don't show up until months to years later?
 - Long term adverse effects that don't show up until months to years later have not been a problem with other vaccines
 - There have been fears of this (vaccines causing Autism) but multiple large research studies have never found these fears to be correct





Myth-Busting

Vaccine Misinformation

- MYTH: Because of the pandemic, the pharmaceutical industry has been given permission to "skip the animal trials...we humans will be the guinea pigs."
 - <u>This is false</u>. The Pfizer BioNTech, Moderna and AstraZeneca vaccines have all been tested in animals as well as thousands of people, before they could be considered for licensing.
- MYTH: There are microchips in COVID-19 vaccines funded by Bill & Melinda Gates.
 - <u>This is false.</u> While the Bill & Melinda Gates Foundation has financially contributed to developing a COVID-19 vaccine, there is no evidence to claims that they are implementing microchips.
- MYTH: Vaccines are fake and press events showing people being injected have been staged. Fake syringes with "disappearing needles" are being used in an attempt by the authorities to promote a vaccine that doesn't exist.
 - <u>This is false</u>. Healthcare professionals are using a safety syringe, in which the needle retracts into the body of the device after use. Safety syringes have been in widespread use for over a decade. They protect medical staff and patients from injuries and infection.
- MYTH: There was a Facebook post that a nurse died in Alabama after taking the coronavirus vaccine.
 - <u>This is false</u>. After being alerted to the rumors, the Alabama department of public health contacted all vaccine-administering hospitals in the state and "confirmed there have been no deaths of vaccine recipients. The posts are untrue."



COVID Vaccines: The Facts

- COVID-19 mRNA vaccines will NOT give you COVID-19
 - None of the COVID-19 vaccines in use or under development use the live virus that causes COVID-19
 - The vaccines only have genetic information to make one part, the spike protein, not the whole virus
- COVID-19 mRNA vaccines will NOT cause you to test positive on COVID-19 viral tests
 - Vaccines currently authorized for use or in development won't cause you to test positive on viral tests, which are used to see if you have a current infection.
- COVID vaccines will NOT alter your DNA
 - mRNA stands for messenger ribonucleic acid and can most easily be described as instructions for how to make a protein or even just a piece of a protein
 - The mRNA from a COVID-19 vaccine never enter the nucleus of the cell, which is where our DNA are kept. This means the mRNA does not affect or interact with our DNA in any way.



Risk of Severe Reactions is Very Low

- As of January 6, only 21 of the first 1.9 million of Americans to receive the Covid-19 vaccine experienced the severe allergic reaction known as anaphylaxis
 - 17 had known risk factors for severe allergic reactions
 - 20 are known to have recovered and there are no known deaths
- By way of comparison
 - This rate of adverse reactions is 1.1 per 100,000
 - US Rate of death by motor vehicle crashes is 11.2 per 100,000
- CDC advises:
 - People with a history of drug allergies be observed for 30 minutes
 - All others be observed for 15 minutes after getting the shot
 - Vaccination sites should have emergency equipment on hand, including epinephrine



People Who Have Gotten Sick With COVID-19 May Still Benefit From Getting Vaccinated

- While more research is needed, available evidence suggests that reinfection with this virus is rare within 90 days of initial infection.
- Getting vaccinated may help to further strengthen natural post-infection immunity against COVID-19.
- Pfizer and BioNTech have studied their vaccine in people with and without a history of exposure to the virus. Data show that the vaccine is safe and likely effective in persons with previous evidence of SARS-CoV-2 infection.
- If someone currently has active symptoms of COVID-19, the CDC recommends they wait to get vaccinated until they've recovered and met the criteria for ending isolation.



Vaccination is One Measure to Help Stop the Pandemic

- While COVID-19 mRNA vaccines appear to be highly effective, additional preventive tools remain important to limit the spread of COVID-19.
- If you are one of the 5% who get COVID after vaccination, you could have an asymptomatic case and infect others.
- The combination of getting vaccinated and following CDC recommendations to protect yourself and others offers the best protection from COVID-19:
 - Cover your nose and mouth with a mask
 - Avoid close contact, maintain social distancing
 - Clean and disinfect
 - Wash your hands





Fear and Uncertainty are a Challenge

- In a recent US-consumer research, 63 percent of respondents are cautious about or unlikely to adopt COVID-19 vaccination.
 - The "cautious," who comprise 45 percent of respondents (the largest segment), are those who will wait and see how a vaccine performs in the "real world" before deciding if they will get vaccinated.
 - Another 18 percent say they are unlikely to vaccinate.
- In High-Risk Groups, only a portion reported being "interested" in getting vaccinated:
 - Elderly 65%
 - Black 31%
 - Hispanic 36%
 - Earning under \$25K/yr 31%
 - Earning over \$100K/yr 60%



Vaccine Hesitancy: What Do National Surveys Say?

- 59% worried about possible side effects
- 55% lack of trust in government to ensure vaccine safety & effectiveness
- 53% concern that the vaccine is too new
- 51% concern over the role of politics in the development process
- 43% risks of COVID-19 are being exaggerated
- 37% don't trust vaccines in general
- 33% don't trust the health care system
- 27% worried they may get COVID-19 from the vaccine
- 20% don't think they are at risk of getting sick from the virus
- <u>https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020/</u>



Persons of Color Have Real Reasons To Be Wary

- Historically, medicine has used Black bodies, without consent, for its own advancement.
- POC are less likely to receive treatments once proven effective.
- Reports of symptoms and pain from POC are not taken as seriously.
- POC experience higher rates of illness and death.
- This impairs the healthcare/patient partnership:
 - much less likely to report trust in their physicians and hospitals
 - less likely to seek treatment or be compliant with recommended treatment plans



POC were Included in the COVID-19 Vaccine Safety and Efficacy trials

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

Moderna

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

Subgroup analysis specific to POC showed both vaccines to be effective for preventing COVID in POC





Strategies for Employers

Leadership Strategies: Getting Staff Vaccinated

- Vaccine Rollout Experience To-Date
 - Challenges/Successes
 - Tips for Other Providers
- Vaccination Protocols for Treatment Providers: Require or Encourage?
 - What are the legal considerations?
 - What are the operational considerations?
 - What exemptions and/or accommodations may be made?



Addressing Vaccine Concerns with Your Staff

- Listen
- Vaccine hesitancy is not the same as being anti-vaccination
- Acknowledge the concerns and ask for more
- Acknowledge historical and current reasons for distrust Medical racism has left significant scars; we need to build trust
- Answer questions directly in as much detail as asked
- Share uncertainty be OK saying:
 - "We don't know yet"
 - "Let me look for more information on that and get back to you"
- Elicit hope toward helping one's community restore health & wellbeing
- Give time to decide later



Protect yourself, your family, friends, coworkers, patients, and community. Get vaccinated.

- Choose to get vaccinated yourself when it is available to you.
- Participate in v-safe and help CDC monitor for any health effects after vaccination.
- Share your experience with coworkers, friends, and family.
- Know the basics about the COVID-19 vaccine.
- Help answer questions from your family
- and friends.
- Visibly show you received a vaccine, such as
- by wearing a sticker or button.







Questions?

Thank you!