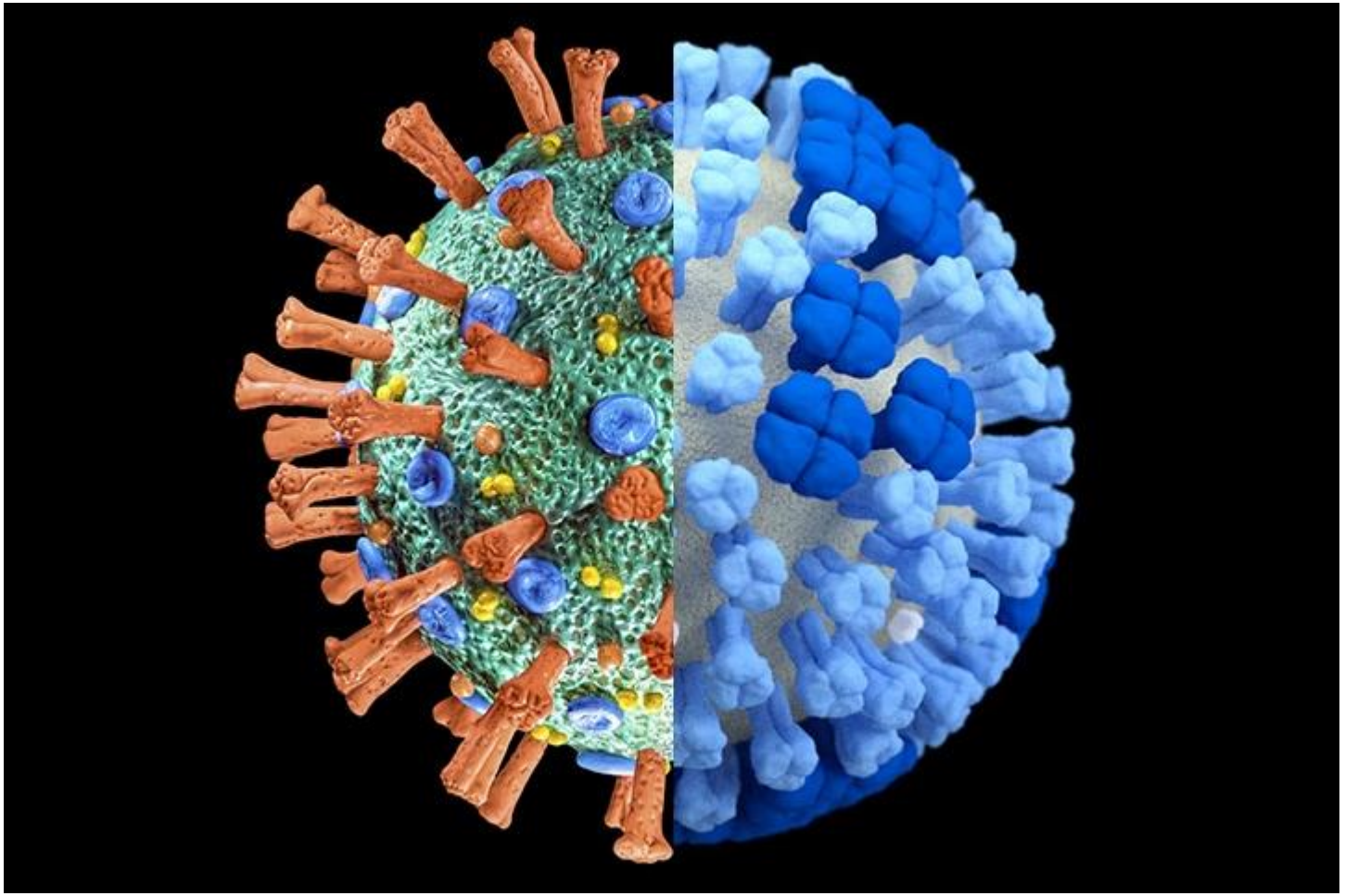
dhec
Healthy People. Healthy Communities.

South Carolina Department of Health and Environmental Control

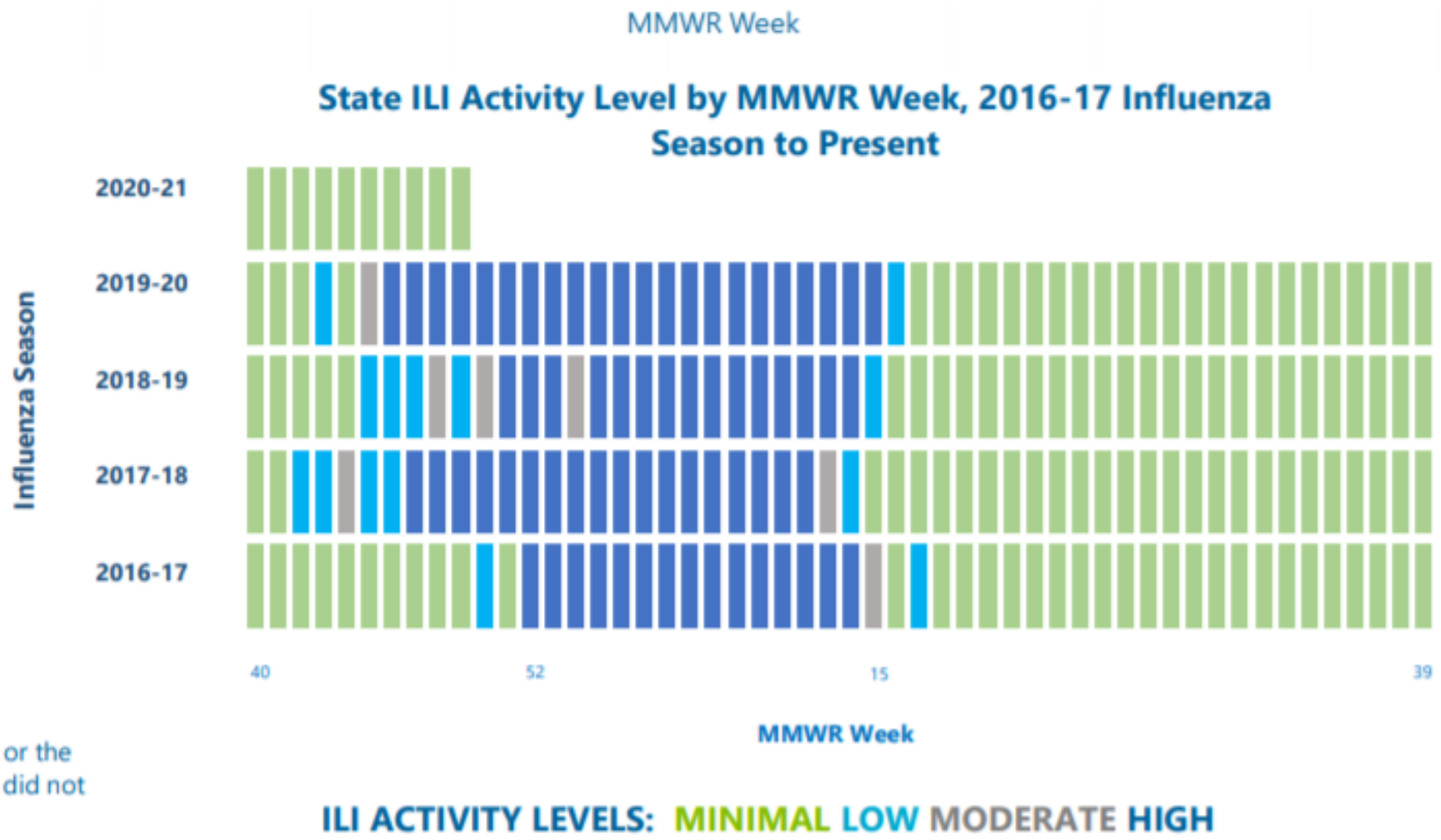
Twindemic: Influenza and COVID-19

Jane Kelly, MD
Assistant State Epidemiologist
SC DHEC
December 15, 2020

COVID-19 and Influenza Co-Infection

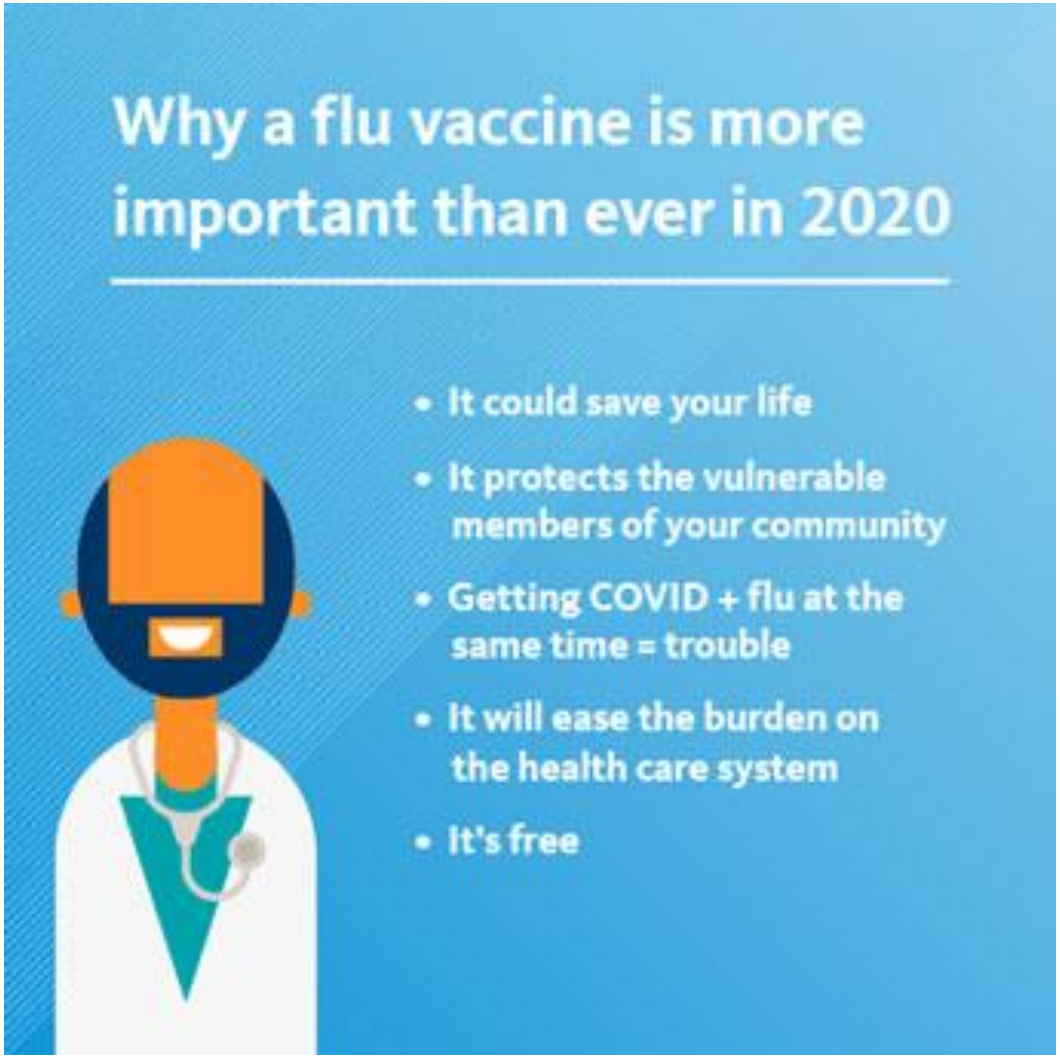


Influenza-like Illness (ILI)



ty or the
ty did not

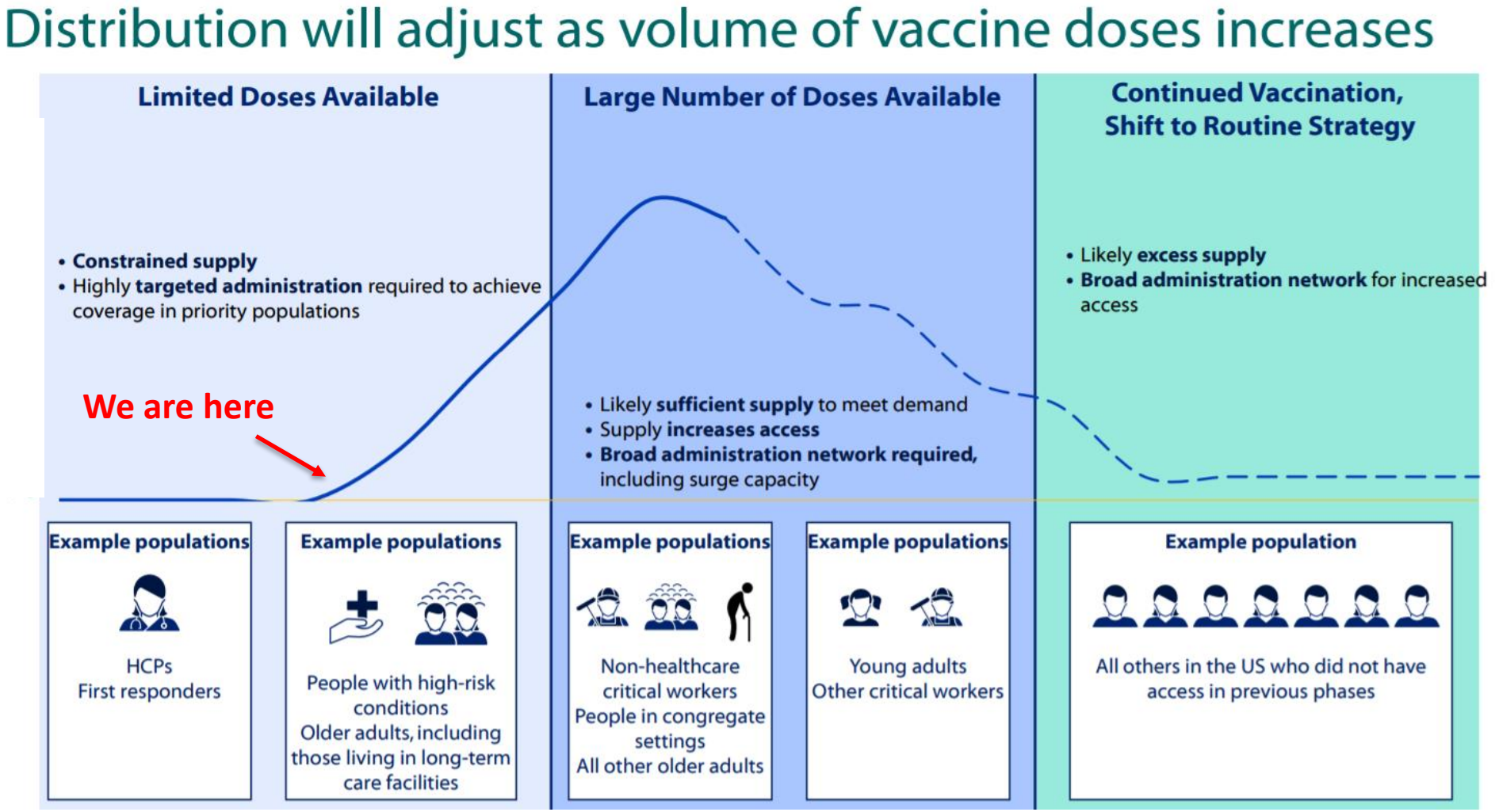
This may be the most important flu vaccine in your life

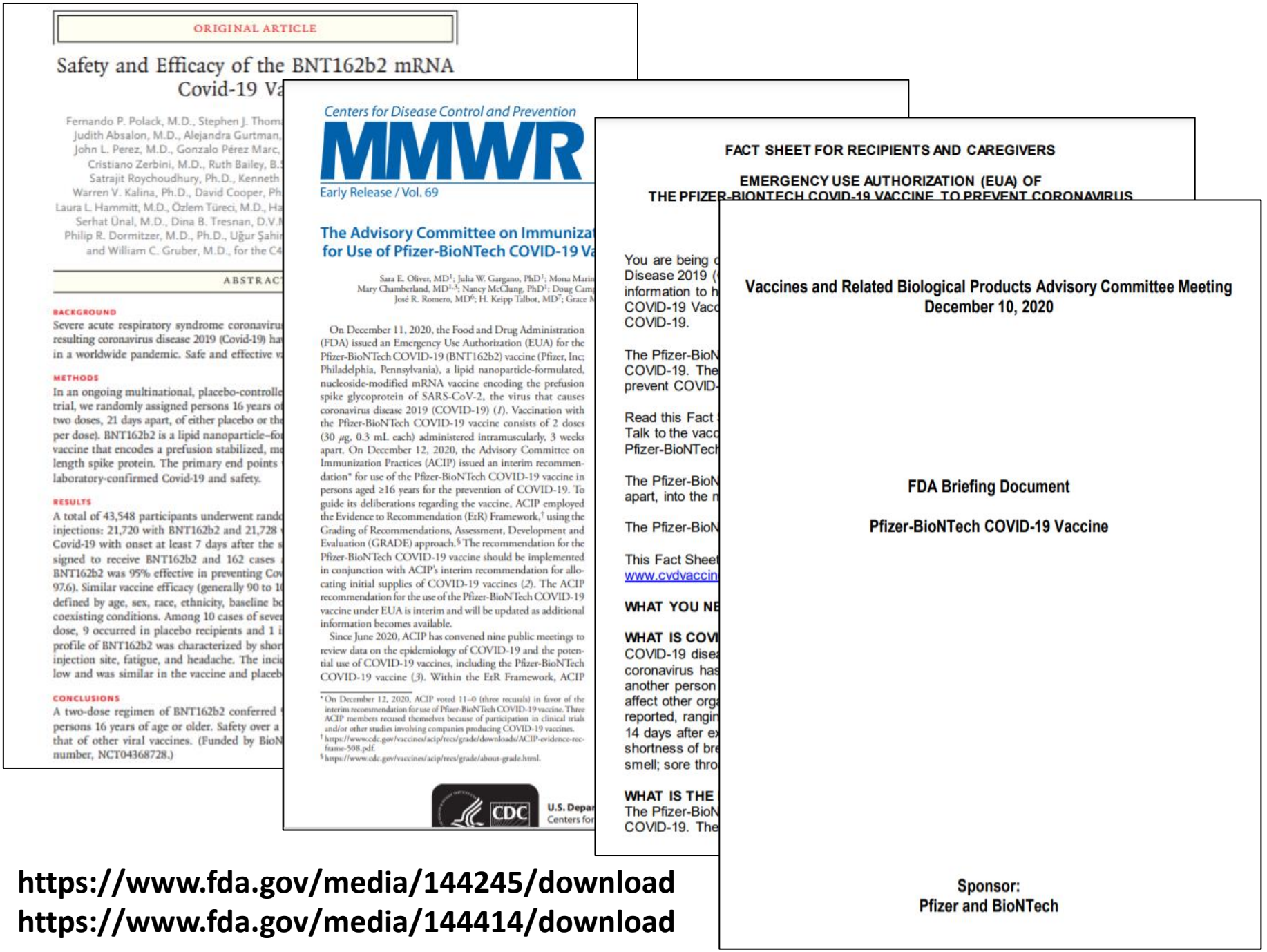


Who should get the flu vaccine?

- Everyone age 6 months and older
- Including pregnant women
- Nasal spray ages 2-49
- Special higher dose vaccine for age 65 and over

Phased COVID-19 vaccine allocation





ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Va

Fernando P. Polack, M.D., Stephen J. Thom
Judith Absalon, M.D., Alejandra Gurtman,
John L. Perez, M.D., Gonzalo Pérez Marc,
Cristiano Zerbini, M.D., Ruth Bailey, B.
Satrajit Roychoudhury, Ph.D., Kenneth
Warren V. Kalina, Ph.D., David Cooper, Ph
Laura L. Hammitt, M.D., Özlem Türeci, M.D., Ha
Serhat Ünal, M.D., Dina B. Tresnan, D.V.
Philip R. Dormitzer, M.D., Ph.D., Uğur Şahi
and William C. Gruber, M.D., for the C4

ABSTRAC

BACKGROUND

Severe acute respiratory syndrome coronaviru
resulting coronavirus disease 2019 (Covid-19) ha
in a worldwide pandemic. Safe and effective v

METHODS

In an ongoing multinational, placebo-controlle
trial, we randomly assigned persons 16 years o
two doses, 21 days apart, of either placebo or th
per dose). BNT162b2 is a lipid nanoparticle–fo
vaccine that encodes a prefusion stabilized, m
length spike protein. The primary end points
laboratory-confirmed Covid-19 and safety.

RESULTS

A total of 43,548 participants underwent rando
injections: 21,720 with BNT162b2 and 21,728
Covid-19 with onset at least 7 days after the s
signed to receive BNT162b2 and 162 cases
BNT162b2 was 95% effective in preventing Co
97.6). Similar vaccine efficacy (generally 90 to 1
defined by age, sex, race, ethnicity, baseline b
coexisting conditions. Among 10 cases of seve
dose, 9 occurred in placebo recipients and 1 i
profile of BNT162b2 was characterized by shor
injection site, fatigue, and headache. The inci
low and was similar in the vaccine and placeb

CONCLUSIONS

A two-dose regimen of BNT162b2 conferred
persons 16 years of age or older. Safety over a
that of other viral vaccines. (Funded by BioN
number, NCT04368728.)

Centers for Disease Control and Prevention

MMWR

Early Release / Vol. 69

The Advisory Committee on Immunizat
for Use of Pfizer-BioNTech COVID-19 Va

Sara E. Oliver, MD[1]; Julia W. Gargano, PhD[1]; Mona Marin
Mary Chamberland, MD[1,3]; Nancy McClung, PhD[1]; Doug Cam
José R. Romero, MD[6]; H. Keipp Talbot, MD[7]; Grace M

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 (BNT162b2) vaccine (Pfizer, Inc; Philadelphia, Pennsylvania), a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (*1*). Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 doses (30 μg, 0.3 mL each) administered intramuscularly, 3 weeks apart. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation* for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19. To guide its deliberations regarding the vaccine, ACIP employed the Evidence to Recommendation (EtR) Framework,† using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.§ The recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's interim recommendation for allocating initial supplies of COVID-19 vaccines (*2*). The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine under EUA is interim and will be updated as additional information becomes available.

Since June 2020, ACIP has convened nine public meetings to review data on the epidemiology of COVID-19 and the potential use of COVID-19 vaccines, including the Pfizer-BioNTech COVID-19 vaccine (*3*). Within the EtR Framework, ACIP

*On December 12, 2020, ACIP voted 11–0 (three recusals) in favor of the interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine. Three ACIP members recused themselves because of participation in clinical trials and/or other studies involving companies producing COVID-19 vaccines.
†https://www.cdc.gov/vaccines/acip/recs/grade/downloads/ACIP-evidence-rec-frame-508.pdf.
§https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html.

CDC

U.S. Depar
Centers for

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF
THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS

You are being c
Disease 2019 (
information to h
COVID-19 Vacc
COVID-19.

The Pfizer-BioN
COVID-19. The
prevent COVID-

Read this Fact
Talk to the vacc
Pfizer-BioNTech

The Pfizer-BioN
apart, into the n

The Pfizer-BioN

This Fact Sheet
www.cvdvaccin

WHAT YOU NE

WHAT IS COVI
COVID-19 disea
coronavirus has
another person
affect other orga
reported, rangin
14 days after ex
shortness of bre
smell; sore thro

WHAT IS THE
The Pfizer-BioN
COVID-19. The

Vaccines and Related Biological Products Advisory Committee Meeting
December 10, 2020

FDA Briefing Document

Pfizer-BioNTech COVID-19 Vaccine

Sponsor:
Pfizer and BioNTech

https://www.fda.gov/media/144245/download
https://www.fda.gov/media/144414/download

Phase 1a

- **COVID-19 Vaccine Frequently Asked Questions**

We will continue to update this information as often as possible to provide the most factual and current information possible for South Carolinians. Click below to view frequently asked questions. A downloadable and printable version of the most common FAQs are available here for public use.

COVID-19 Vaccine FAQs

NEW: Phase 1A Guidance for COVID-19 Allocation and a Letter to Mission Critical Workers (Dec. 10)

NEW: Click here to view a vaccine outline presentation accurate as of Dec. 8, 2020.

https://scdhec.gov/covid19/covid-19-vaccination

Phase 1 will be divided into two sub-phases: Phase 1a and 1b.

In Phase 1a, vaccine allocation will be prioritized to subsets outlined by the Centers for Disease Control and Prevention (CDC) to include staff and residents of nursing homes and long-term care facilities and people serving in healthcare settings. The purpose is to maximize vaccinations for those serving in roles that reduce COVID-19 morbidity and mortality and to reduce the burden on strained healthcare capacity and facilities. Phase 1a will likely continue for many weeks, if not months.

Hospitals will receive vaccinations in the first weeks of Phase 1a, followed by other enrolled and approved providers. The purpose of this document is to provide guidance to those facilities that will vaccinate people eligible in Phase 1a.

DO NOT CONTACT HOSPITALS TO BE VACCINATED. People included in the groups identified below as eligible for Phase 1a vaccinations should not contact any hospital or healthcare provider. Instead, contact the South Carolina Department of Health and Environmental Control (DHEC) as provided below for additional information. If you work for an enrolled and approved COVID-19 provider, your employer will contact you about being vaccinated. For all others in Phase 1a, DHEC will publish and communicate information in the coming weeks regarding how those who are eligible can be vaccinated.

PHASE 1A

The overarching principle in Phase 1a is averting deaths. For this initial phase DHEC

Phase 1a mission-critical workers include:

- Persons performing direct medical care to suspected and/or confirmed COVID-19 patients: medical house staff (i.e., interns, residents, fellows), nurses, nurse's aides, physical therapists (PT), physicians, physician assistants, respiratory therapists (RT), speech pathologists providing swallowing assessments during a patient's infectious period, students (medical, nursing, PT, RT)
- Ancillary staff directly interacting with suspected and/or confirmed COVID-19 patients: laboratory personnel handing potentially infectious specimens, phlebotomists, and radiology technicians
- Emergency room staff in the above categories who provide direct patient care who are at high risk of exposure to undiagnosed, suspected and/or confirmed COVID-19 patients
- Paid and volunteer medical first responders (EMS, fire department, and law enforcement personnel who provide emergency medical services) and hospital transport personnel in direct contact with suspected and/or confirmed COVID-19 patients
- Persons providing direct medical care in correctional facilities
- Persons providing direct medical care in dialysis and infusion centers
- Workers in outpatient medical settings frequently treating persons with suspected or confirmed COVID-19 infection
- Workers in settings where monoclonal antibodies for COVID-19 infusions are given
- Home health and Hospice workers
- Public health nurses/personnel visiting facilities w/possible COVID-19 cases
- Autopsy room staff, coroners, embalmers, and funeral home staff at risk of exposure to bodily fluids

These critical workers in high-risk settings will vary in different settings depending in part on the resources within each facility and the communities they serve.

DHEC recommends facilities apply higher vaccination status priority for the following factors during these limited vaccine supply circumstances:

- Personnel with the highest exposure because of longest duration of hands-on patient care or involvement in aerosol-generating procedures
- Co-morbid conditions, including age ≥65 that place workers at higher risk of severe COVID-19 illness and death
- "Bench depth" or the number of workers available for a given skilled task

COVID-19 among healthcare workers

US and UK Frontline HCWs: Impact of Setting

Participant Setting	Age-Adjusted Risk of SARS-CoV-2+ HR (95% CI)	Multivariate-Adjusted Risk of SARS-CoV-2+ HR (95% CI)	HCWs Reporting Reused PPE, %	HCWs Reporting Inadequate PPE, %
General community	1 (reference)	1 (reference)	—	—
Front-line HCW				
▪ Inpatient	23.6 (21.2-26.3)	24.3 (21.8-27.1)	23.7	11.9
▪ Nursing homes	16.5 (13.6-20.0)	16.24 (13.4-19.7)	15.4	16.9
▪ Outpatient hospital clinics	10.6 (8.1-14.3)	11.2 (8.4-14.9)	16.3	12.2
▪ Home health sites	7.79 (5.6-10.9)	7.9 (5.6-11.0)	14.7	15.9
▪ Ambulatory clinics	6.9 (4.9-9.0)	6.9 (5.1-9.4)	19.3	11.8
▪ Other	9.42 (7.4-12.0)	9.5 (7.5-12.1)	12.0	13.8

- **In post hoc analysis, Black, Asian, and minority ethnic HCWs more likely to work in inpatient settings or nursing homes (adjusted OR: 1.13; 95% CI: 1.03-1.23)**

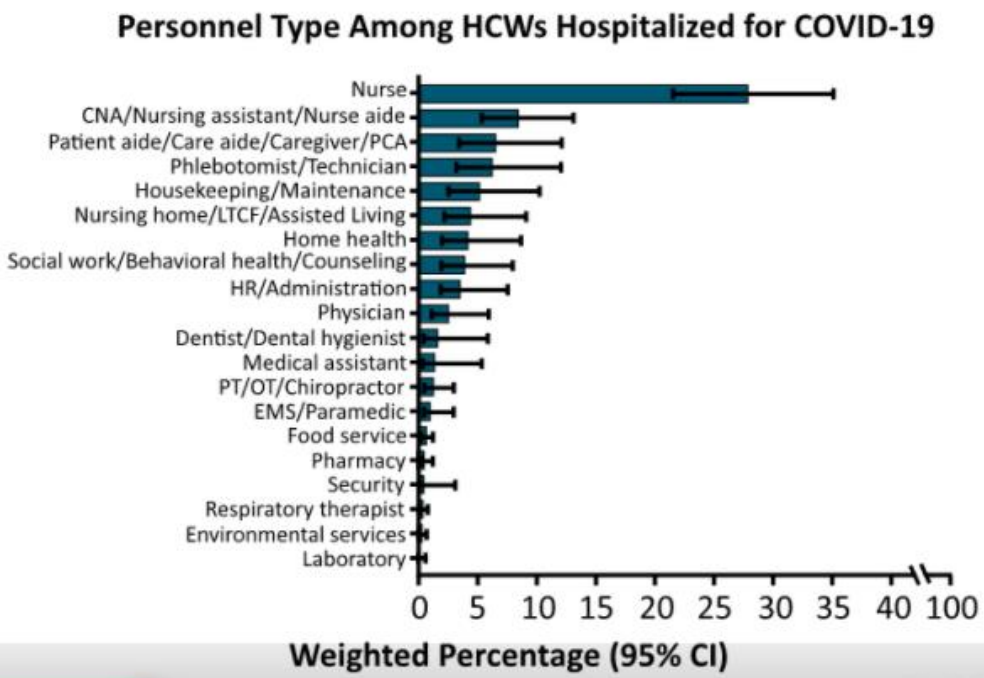
Nguyen. Lancet. 2020;5:E475.

Slide credit: clinicaloptions.com

Severe COVID-19 among HCW

COVID-NET: Hospitalizations of HCW by Personnel Type

- 438 HCWs hospitalized with COVID-19
  - 67.4% in direct patient contact roles
  - 36.3% nurses or nursing aides
- Although HCWs with direct patient contact had higher rates of hospitalization, it remains unknown if exposed in the workplace or community

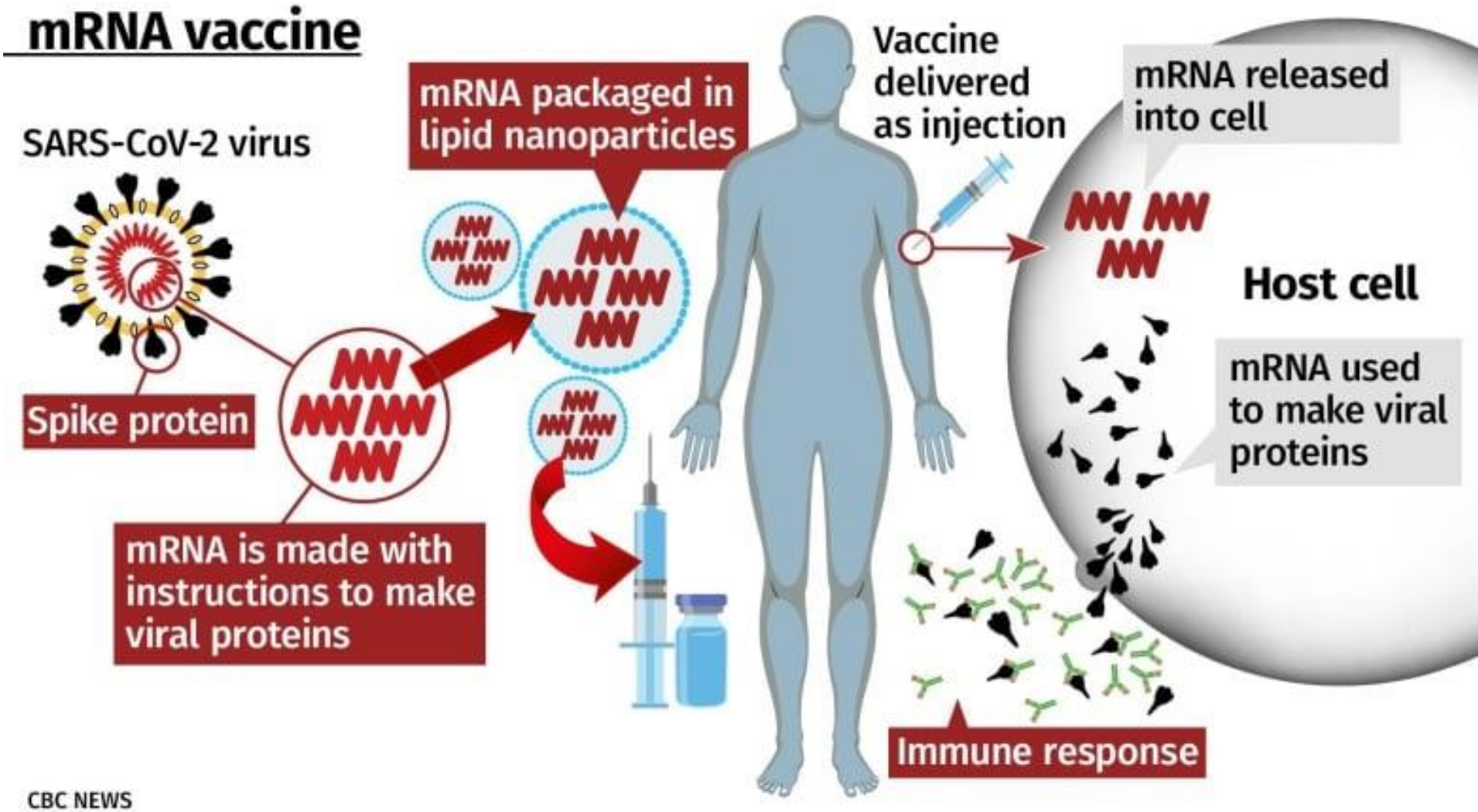


6:56 12:35

MMWR. 2020;69:1576.

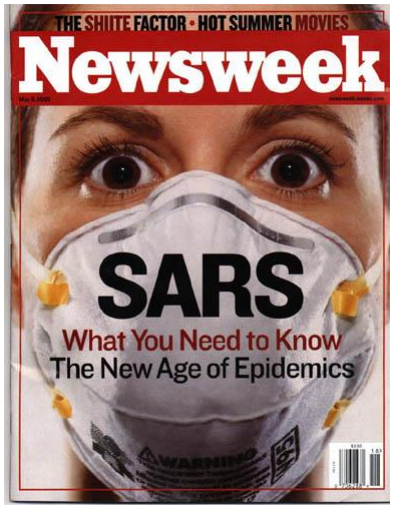
Slide credit: clinicaloptions.com

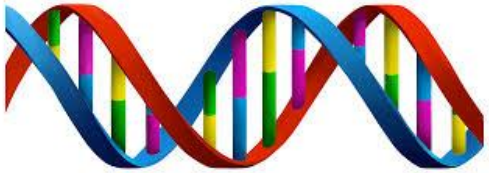
New vaccine technology



Build on past, work in parallel

- Multiple vaccine approaches
- Concurrent testing
- Rapid data sharing
- New approaches to funding and research collaboration
- Early manufacturing scale-up

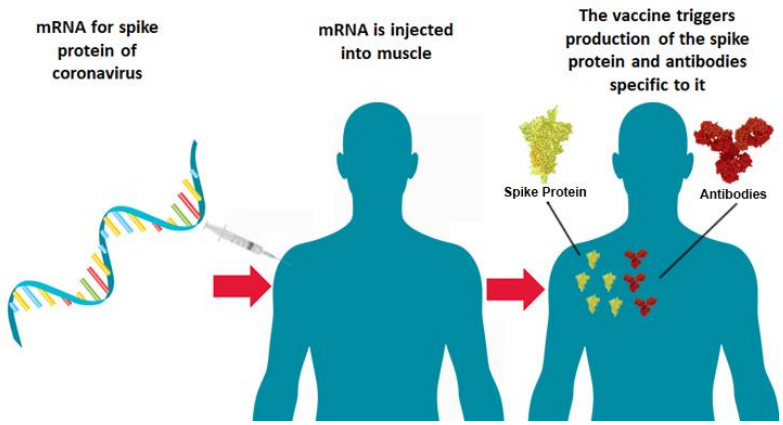




“Rational design”

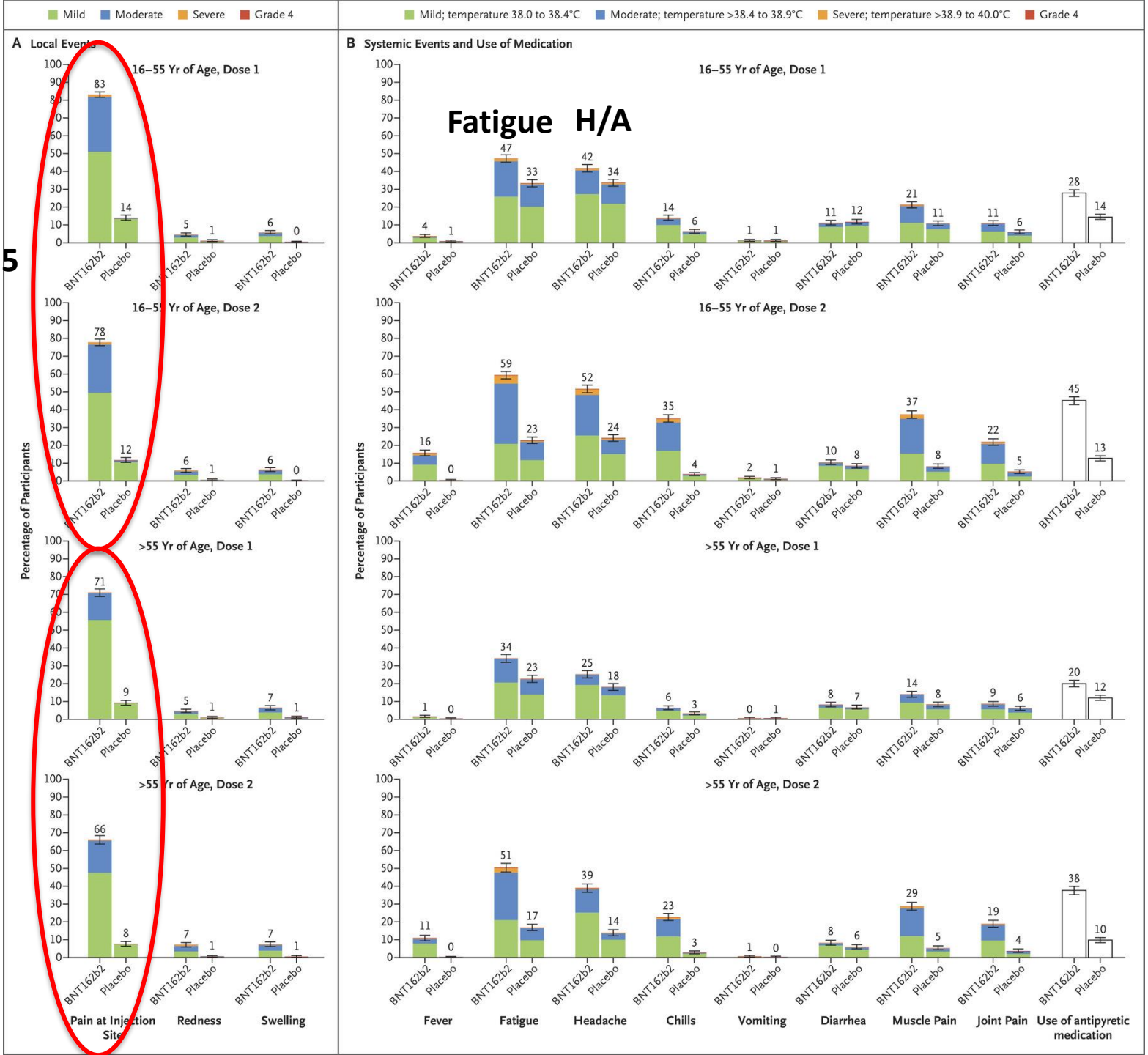
- **Sequence released 1/10/2020**
- **Gene for spike protein identified 42 days later**
- **Phase 1 begins for mRNA vaccines 20 days later**

Pfizer



- New technology, store at -70°C
- 2 injections 21 days apart
- Phase 3 study in 42,000 people
  - 95% efficacious: 170 w/symptoms & tested positive for COVID
  - 162 placebo (9 severe disease), 8 vaccine (1 severe)
  - Immunity 7 days after 2nd dose (28 days after initiate vaccine)
- No serious adverse events, but more than half had fatigue, chills, headache, muscle aches after 2nd dose
- Mild-moderate pain at the injection site in almost all
- Likely authorized for emergency use after FDA and ACIP reviews 12/11/2020
- Special requirements to maintain cold chain

https://www.nejm.org/doi/full/10.1056/NEJMoa2027906?query=featured_coronavirus


Mild
Moderate
Severe
Grade 4
Mild; temperature 38.0 to 38.4°C
Moderate; temperature >38.4 to 38.9°C
Severe; temperature >38.9 to 40.0°C
Grade 4
A Local Events
B Systemic Events and Use of Medication
Fatigue H/A
Age 16-55
Age >55
16–55 Yr of Age, Dose 1
16–55 Yr of Age, Dose 2
>55 Yr of Age, Dose 1
>55 Yr of Age, Dose 2
Percentage of Participants
BNT162b2
Placebo
Pain at Injection Site
Redness
Swelling
Fever
Fatigue
Headache
Chills
Vomiting
Diarrhea
Muscle Pain
Joint Pain
Use of antipyretic medication

Pfizer vaccine logisitics

- Vaccine sent via a thermal shipper
- Three options for storage:
  - Ultra-low-temperature freezers
  - Pfizer thermal shippers can be used as temporary storage units by refilling with dry ice every five days for up to 30 days of storage.
  - Refrigeration units that are commonly available in hospitals
  - Once thawed, vaccine can be stored for five days at refrigerated 2-8°C conditions

Emergency Use Authorization (EUA)

- EUA issued only after safety and efficacy standards are met
- Determination that the known and potential benefits of the investigational product outweigh its known and potential risks
- Use of an investigational vaccine under an EUA is not subject to informed consent requirements; rather a Fact Sheet is provided

EUA Fact Sheet

Fact Sheet for Vaccine Recipients and Caregivers

- Similar to Vaccine Information Statement (VIS) for licensed vaccines
- Will provide specific information about each COVID-19 vaccine, including:
  - Basic information on COVID-19, symptoms, and what to discuss with a healthcare professional before vaccination
  - Who should and should not receive the vaccine
  - That recipients have the choice to receive the vaccine
  - Vaccine series information
  - Risks and benefits of the vaccine, including common side effects
  - Information on reporting side effects to VAERS
  - An explanation of what an EUA is and why it is issued
  - Any approved available alternatives for preventing COVID-19
  - Additional resources
- Written informed consent is not required under EUA
- Translations anticipated to be available


FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE xxxx COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS xx YEARS OF AGE AND OLDER

Discussing the facts around vaccine including side effects

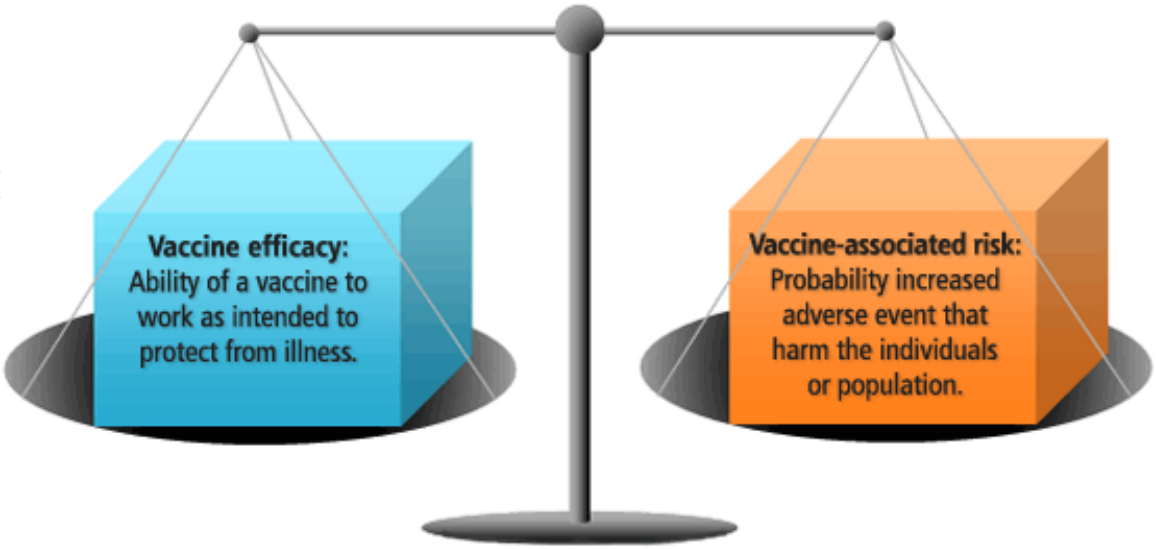
- You, as a health care professional, are a trusted voice
- People need to know ahead of time about **possible local and systemic symptoms** (so they are not surprised!)
- Avoid the term “side effects”
- Use “temporary symptoms”
- Explain the symptoms are a sign that the vaccine is working; the immune system is responding

What should I tell people?

- Severe symptoms are rare, but mild-moderate ones are common, with the COVID-19 vaccines
- Consider the shingles vaccine analogy
  - Which would you prefer: the old shingles vaccine that causes fewer symptoms but only works half the time, or the new one that is 97% efficacious but may give you fever, myalgias, and fatigue for a couple of days?
  - Risks of vaccine vs. risk of COVID-19 disease
  - Don’t forget you can take acetaminophen
- Workers might consider getting vaccinated when they have 1-2 days off following vaccination, especially after the second dose

What about long-term or rare side effects?

- Might not know about rare or long-term side effects until millions are vaccinated



- FDA and CDC will collect safety data from those vaccinated
- Will also have safety data from other countries (e.g., England)
- Each of us must weigh risk/benefit ratio:
  - Benefit of vaccine (with 95% efficacy) protecting from COVID-19 now vs.
  - Symptoms with vaccination and unknown rare or long-term risks

Pfizer phase 2/3 study

Included people with

- Autoimmune disease
- Hypertension, asthma, diabetes
- Infection with HIV, hepatitis B or hepatitis C
- Age 16 (study amendment October 2020)
  - 283 (138 vaccine,145 placebo) age 16-17 years

No evidence for vaccine-enhanced disease

Adverse events

- Bell’s palsy in 4 vaccine group (consistent with general background rate), 0 placebo
- Appendicitis: 8 in vaccine, 4 in placebo group
- Lymphadenopathy in 64 vaccine and 6 placebo
- Six deaths (2 vaccine, 4 placebo)
- No other notable adverse events, including other neurologic, neuro-inflammatory, and thrombotic events, that would suggest a causal relationship to vaccine

Preventing disease vs. Preventing infection

IPV

OPV

Prevent disease vs prevent infection

- Did not evaluate for preventing asymptomatic infection and transmission
- Will study over the next couple of months
- Pfizer stated they will do transmission studies with nasal swabs post vaccination

Pregnancy and CDC recommendations

- mRNA vaccine not a live vaccine
- mRNA degraded quickly, does not enter nucleus
- Considerations for vaccination:
  - Level of COVID-19 community transmission
  - Personal risk (occupation, other activities)
  - Risk of COVID-19 infection to woman & unborn child
  - Efficacy of the vaccine
  - Known side effects of vaccine
  - Lack of data during pregnancy
- If symptoms post vaccination, take acetaminophen as fever associated with adverse pregnancy outcomes
- Routine testing for pregnancy prior to COVID-19 vaccination is not recommended

ACIP recommendations

- Lactating mothers?
  - No risk to breastfeeding infant
- When vaccinate after monoclonal antibodies?
  - Wait 90 days
- Vaccinate during quarantine?
  - No, don’t expose others (except LTCF in quarantine)
- Autoimmune disease flare with vaccine?
  - Benefit outweighs risk
- Immunocompromised, transplant, cancer, steroids?
  - No data but CDC recommends consider benefit > risk
- Window of time for 2nd shot? Need to start over if late?
  - Don’t start over
- Do not give within 2 weeks of other vaccines

I had COVID-19: when can I be vaccinated?

- Vaccine is recommended for people previously infected
- According to data reviewed by CDC, people appear to become susceptible to reinfection after >90 days after initial infection
- To date, reinfection appears to be rare during the initial 90 days after symptom onset of the preceding infection
- DHEC recommends persons eligible for vaccine in Phase 1a who had COVID-19 within the previous 90 days consider delaying vaccination to allow more vulnerable access to scarce resource

Annex: Quarantine of Persons Recovered from Laboratory-diagnosed SARS-CoV-2 Infection with Subsequent Re-Exposure

Anaphylaxis

- In the US, severe allergic reaction in ~ one of every 1.4 million doses of other vaccines
- 2 severe allergic reactions to Pfizer COVID vaccine thus far in the UK
- Both had a history of severe allergic reaction (one to food items, one to a drug)
- ACIP recommendation: severe allergic reaction to another vaccine, or any injectable (SC, IM, IV) should not receive Pfizer vaccine at this time
- Observe patient after vaccination
  - Hx anaphylaxis (e.g., to food, not to vaccine): 30 minutes; Others: 15 minutes
  - Have epinephrine and resuscitation capability available

Contraindications

Allergy to any of the vaccine components:

- mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3- phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

Pfizer COVID-19 vaccine ingredients

- Active Ingredient
  - nucleoside-modified messenger RNA (modRNA) encoding the viral spike protein of SARS-CoV-2
- Four lipids (including polyethylene glycol or PEG)
  - Encase the mRNA, fuse with cell membrane, provide structural integrity
  - PEG most likely to cause symptoms or allergic reaction (used in laxatives, bowel prep
- Four salts (including NaCl) -- pH buffer
- Sugar (sucrose) – Cryoprotectant, keeps nanoparticles from sticking together

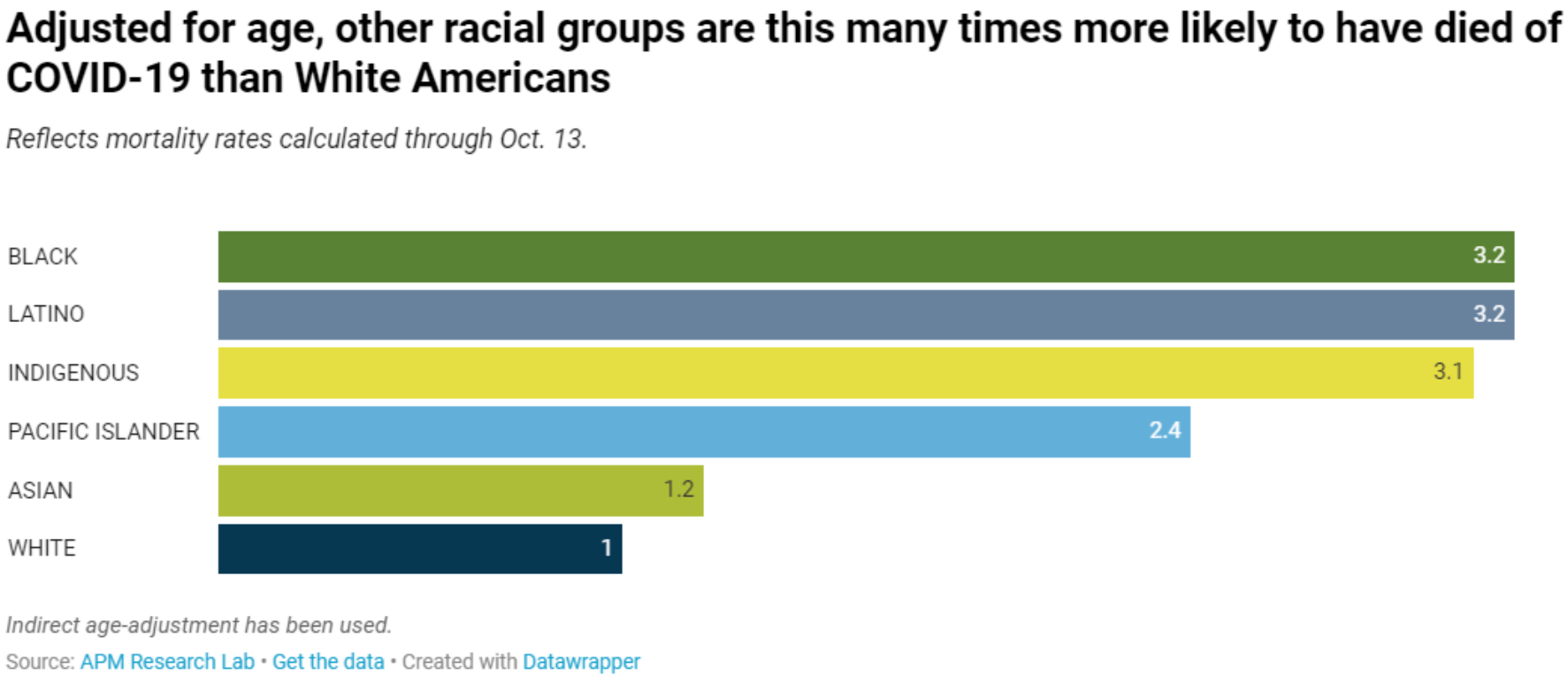
No Thimerosal, mercury, antibiotics, or preservatives

Institute for Health Metrics and Evaluation, SC, 12.06.2020

Table 1. Ranking of COVID-19 among the leading causes of mortality this week, assuming uniform deaths of non-COVID causes throughout the year

Cause name	Weekly deaths	Ranking
COVID-19	173	1
Ischemic heart disease	172	2
Tracheal, bronchus, and lung cancer	75	3
Chronic obstructive pulmonary disease	73	4
Stroke	73	5
Chronic kidney disease	39	6
Alzheimer's disease and other dementias	36	7
Colon and rectum cancer	28	8
Diabetes mellitus	27	9
Lower respiratory infections	25	10

Death rates for COVID-19



Pfizer vaccine

Trial Locations

Approximately **150 clinical trial sites** in **6 countries,** including **39 U.S. states**

Trial Progress

The Phase 2/3 clinical trial **has enrolled 43,661 participants** and **41,135 participants** have received their **second vaccination**

Participant Diversity

Approximately **42%** of overall and **30%** of U.S. participants have diverse backgrounds

Participants	Overall Study	U.S. Only
Asian	4.5%	5.5%
Black	10.0%	10.1%
Hispanic/Latinx	26.1%	13.1%
Native American	0.8%	1.0%
Ages 56 to 85	40.9%	45.4%

Updated as of Monday, November 16, 2020 at 09:00am ET. Updates are made on a weekly basis.

Approximately 42% of overall and 30% of U.S. participants have diverse backgrounds

Participants	Overall Study	U.S. Only
Asian	4.5%	5.5%
Black	10.0%	10.1%
Hispanic/Latinx	26.1%	13.1%
Native American	0.8%	1.0%
Ages 56 to 85	40.9%	45.4%

Questions?

kellyjm1@dhec.sc.gov
scdhec.gov/covid19
cdc.gov/covid19