



COVID-19 Impact: Building Vaccine Confidence

This meeting will be recorded and will be available at www.fmda.org/journalclub.php



FMDA Journal Club

December 16, 2020

Leslie Beth Eber, MD CMD – Special Guest; President of CMDA – The Colorado Society for Post – Acute & Long - Term Care Medicine

Diane Sanders-Cepeda, DO, CMD – Host

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Agenda

- Opening & Introduction
- Building Vaccine Confidence
 - Presentation with Q&A
- Open Discussion

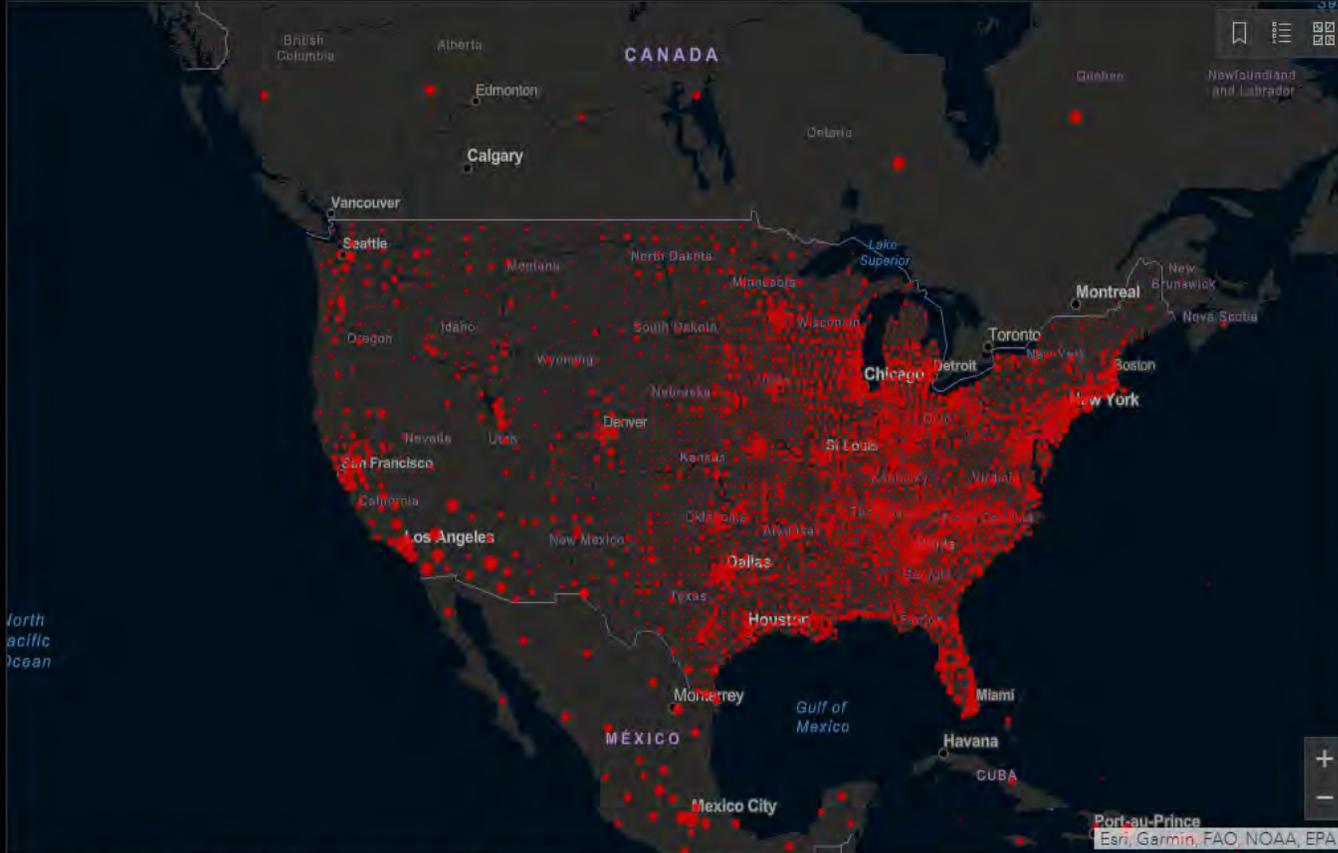
COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

Global Cases

16,725,039

Cases by Country/Region/Sovereignty

16,725,039 US
9,932,547 India
6,970,034 Brazil
2,708,940 Russia
2,447,458 France
1,898,447 Turkey
1,893,436 United Kingdom
1,870,576 Italy
1,762,212 Spain
1,510,203 Argentina
1,444,646 Colombia
1,391,086 Germany
1,267,202 Mexico
1,159,901 Poland
1,131,077 Iran



Cumulative Cases Active Cases Incidence Rate Case-Fatality Ratio Testing Rate

191

countries/regions

Lancet Inf Dis Article: Here. Mobile Version: Here. Data sources: Full list. Downloadable database: GitHub, Feature Layer. Lead by JHU CSSE. Technical Support: Esri Living Atlas team and JHU APL. Financial Support: JHU, NSF, Bloomberg Philanthropies and Stavros Niarchos Foundation. Resource support: Slack, Github and AWS. Click here to donate to the CSSE dashboard team, and other JHU COVID-19 Research Efforts. FAQ. Read more in this blog. Contact US.

Last Updated at (M/D/YYYY) 12/16/2020, 8:26 AM

Global Deaths

1,638,842

303,872 deaths US

US State Level

Deaths, Recovered

35,831 deaths, 92,136 recovered New York US

24,648 deaths, 1,203,398 recovered Texas US

21,501 deaths, recovered California US

20,082 deaths, recovered Florida US

17,872 deaths, 49,245 recovered New Jersey US

15,587 deaths, recovered Illinois US

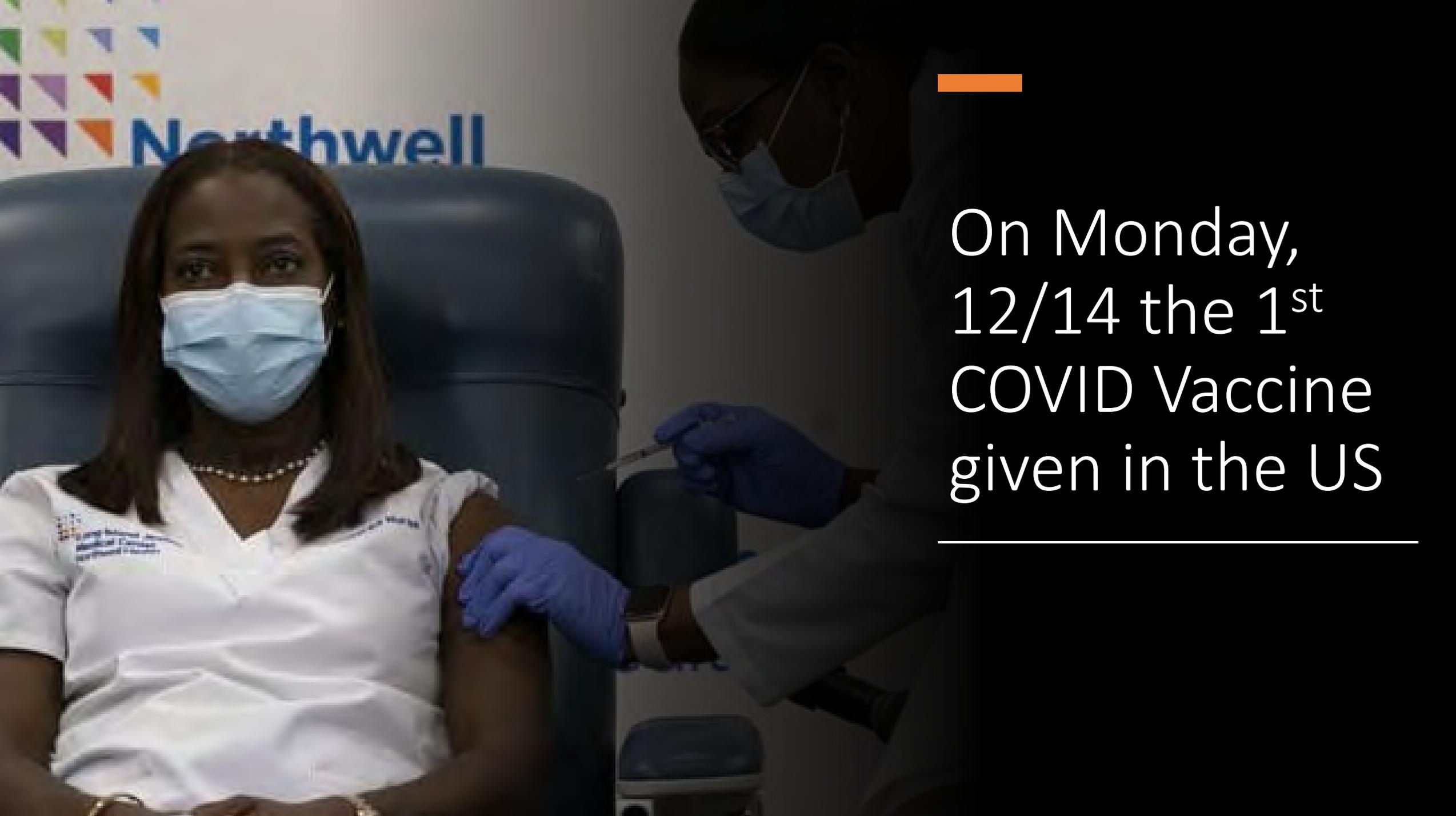
12,796 deaths, 295,405 recovered

Global Deaths Global Recovered

US Deaths, Recovered



Daily Cases



On Monday,
12/14 the 1st
COVID Vaccine
given in the US



Building Vaccine Confidence

Leslie Eber, MD CMD

President of CMDA – The Colorado Society for Post – Acute & Long - Term Care Medicine

Governor’s COVID Residential Care Settings Strike Team Advisor

COVID-19 VACCINE HESITANCY AND EDUCATION

NOW IS THE TIME

Leslie Eber MD CMD



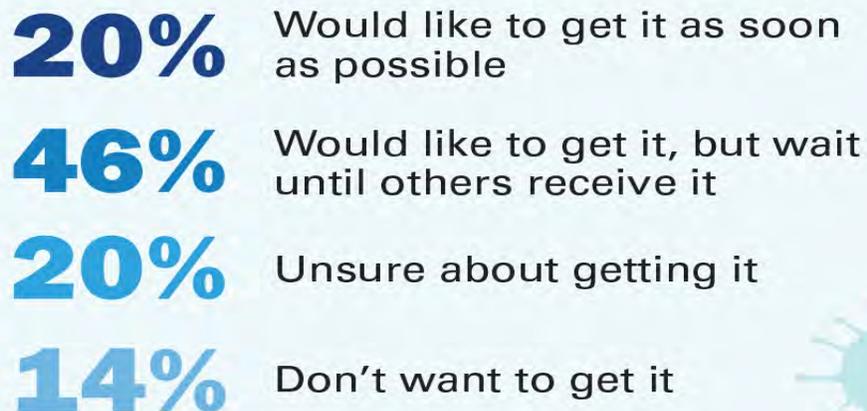
COVID-19 VACCINE HESITATION IS REAL

- Kreps et al found in his survey published in JAMA 10/20/20 that the most important factors for acceptance are efficacy, duration of protection and lower incidence of major side effects
- Other factors: EUA (Emergency Use Authorization) and a vaccine developed outside the United States.
- Specific LTC staff concerns
 - “being first”
 - Safety
 - Not being represented in the vaccine trials

COVID 19 HESITANCY AND OLDER ADULTS

NATIONAL POLL ON HEALTHY AGING REPORT, UNIVERSITY OF MICHIGAN (NOVEMBER, 2020)

Views on Getting a COVID-19 Vaccine AMONG ADULTS AGE 50-80



- Malani P, Singer D, Solway E, Kirch M, Kullgren J. Older Adults' Perspectives on a COVID-19 Vaccine. University of Michigan National Poll on Healthy Aging. November 2020. Available at: <http://hdl.handle.net/2027.42/163523>



HOW TO FRAME THE CONVERSATION

- Most Important: This is what we have been waiting for!
 - This is how we save lives, our own and everyone around us
 - For the first time in the United States, long term care staff are first, we have risked our lives caring for our residents and now we can protect everyone by getting the vaccine
- Meet people where they are
 - Everyone has questions and concerns
 - Listen and respond compassionately
 - Answer questions with respect and honesty

Pfizer (BNT162b2) EUA submitted 11/20/2020

Moderna (mRNA-1273) EUA submitted 11/30/2020

Primary	Trial Size	Primary Efficacy Analysis: 43,661 enrolled, 41,135 received 2nd dose as of 10/18/2020 >50% completed 2 month follow up after 2 nd dose (as of 11/20/2020)	Primary Efficacy Analysis, 30,000 enrolled, 25,654 received 2 nd dose (as of 10/22/20) >50% completed 2 month follow up after 2 nd dose (as of 11/30/2020)
	Efficacy	95% with 170 COVID-19 cases (162 cases placebo group vs 8 cases in vaccine group)	94.1% with 196 COVID-19 cases (185 cases placebo group vs 11 cases vaccine group)
	Immunity	7 days from 2 nd dose	N/A
	Severe cases	9 in placebo group vs 1 in vaccine group	30 in placebo (1 death) vs 0 in vaccine group (0 deaths)
	Side effects	Fatigue 3.8% Headache 2.0% No severe adverse events Older adults fewer side effects	Injection site pain 2.7% Fatigue 9.7% Myalgia 8.9% Arthralgia 5.2% Headache 4.5% Pain 4.1% Erythema/redness 2.0% No severe adverse events
Sub-groups	Older adults	45% age 56-85 (40.9% internationally) 94% efficacy for those ≥65 years in subgroup analysis	>7,000 (23%) age ≥65 No difference in efficacy or side effects in subgroup analysis Of 196 COVID-19 cases, 33 occurred in adults ≥65 years
	Minorities	30% racially/ethnically diverse backgrounds in US, 42% internationally -10.1% black (10.0% internationally) -13.1% Hispanic (26.1% internationally) No difference in efficacy or side effects in subgroup analysis	>11,000 from communities of color (>6,000 (>20%) self-identify as Hispanic/LatinX, >3,000 (>10%) self-identify as Black) No difference in efficacy or side effects in subgroup analysis Of 196 COVID-19 cases, 42 occurred in minority populations (29 Hispanic/LatinX, 6 Black, 4 Asian Americans, 3 multiracial)
	High Risk Conditions	N/A	17% age 18-65 with high risk -36% with DM among high risk group -25% with severe obesity among high risk group No difference in efficacy or side effects in subgroup analysis
Storage	Storage	Ultra low cold (-80 deg) 2-8 deg C for 5 days 30 min – 3 hour defrost time 6 hour post-dilution stability at room temperature	Cold storage (-4 deg) 30 day shelf life in freezer 12 hour room temperature stability

Courtesy of Dr. Anuj Metha, Notes: More information is constantly becoming available. Sub-group comparisons (e.g. comparisons about efficacy between races or age groups) may be less accurate due to smaller numbers. Sub-group numbers for the Pfizer vaccine are given for US participants with international percentages in parentheses.

<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine> , <https://www.pfizer.com/science/coronavirus/vaccine>

<https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy>, https://www.modernatx.com/sites/default/files/content_documents/2020-COVID-19-Study-Enrollment-Completion-10.22.20.pdf



A STRATEGY FOR COVID-19 EDUCATION

- Is it Safe
- Why should we trust the Vaccine
- Is there new technology being used and is that dangerous to me
- What is an EUA and what does that mean for me
- When and how long will I be protected
- Will I Still need to wear a Mask
- Expectations: Important to warn people about possible side effects
- Special circumstances: What if I had COVID 19 or if I have antibodies
- **REVIEW: WHERE ARE YOU GETTING YOUR INFORMATION ?**



ARE THE COVID 19 VACCINES SAFE

- Safety is the most important priority in vaccine approval
- Most adverse side effects occur within 6 weeks of vaccine administration, and the FDA has required 8 weeks of safety monitoring
- FDA advises a minimum of 3,000 participants to assess safety. The current phase 3 trials have 30,000 to 50,000 participants. This really demonstrates how safety is a top priority for the FDA and the medical community.

WHY SHOULD WE TRUST THE COVID 19 VACCINE

- The FDA is using the same standards that it has for decades
- There are no steps being “skipped”
- 2 advisory committees:
 - 1) The Vaccine and Related Biological Products Advisory Committee (VRBPAC) that advises the FDA
 - 2) The Advisory Committee on Immunization Practices (ACIP) that advises the CDC.

NEW TECHNOLOGY FOR THE COVID 19 VACCINE

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- mRNA Vaccines
 - Viral Vectors
 - Can these new technologies give me COVID 19? NO
 - Can these new technologies change my DNA? No
-

WHAT IS AN EUA AND WHAT DOES THAT MEAN FOR ME

- An Emergency Use Authorization (EUA) for a vaccine is based on the need to use a vaccine quickly to save lives during a public health emergency.
- EUA is a shorter process **but no steps are skipped in the safety evaluation process.**
- The FDA will assess if the vaccine's known and potential benefits outweigh the known and potential risks.
- Both advisory boards (VRBPAC and ACIP) will also review all the data and make recommendations
- An EUA does Not imply that the authorization was done too quickly or that the vaccine is not safe

- Be Transparent and Honest
- We will most likely not know how long the vaccine will be protective when we receive it
 - More research needed
- Most of the vaccines are 2 doses, 3-4 weeks apart
- Protection 1-2 weeks after the second dose
- May need to have vaccine shots for COVID-19 on a regular basis (like the flu shot)

WHEN AND HOW LONG WILL I BE PROTECTED BY THE COVID 19 VACCINE



WILL I STILL NEED TO WEAR A MASK

YES !

IMPORTANT:
WARN ABOUT
POSSIBLE SIDE
EFFECTS
WILL THE
VACCINE MAKE
ME SICK?

-
- short-term discomfort : headache, muscle pains, fatigue, chills, fever and pain at injection site
 - 1-2 days
 - Some of the same symptoms as COVID 19 – Emphasize that the vaccine cannot give you COVID-19
 - More pronounced with second dose
 - Normal and common
 - It means your body is doing its job and making antibodies (IT IS A GOOD THING)
 - MUST COME BACK FOR SECOND DOSE, must be the same vaccine as the first dose

SPECIAL
CIRCUMSTANCES:
PAST COVID 19
INFECTION OR
TESTED FOR
ANTIBODIES

-
- It is safe to get the COVID 19 vaccine even if you have had COVID 19 - Yes
 - If + Antibodies PLEASE get the COVID 19 Vaccine
 - Monoclonal antibody treatment trial – wait 90 days
 - If you have food allergies – You can get the vaccine
 - If you have had severe anaphylactic reactions to previous vaccines - CDC recommends you should not get the Pfizer vaccine at this time

WHERE ARE YOU GETTING YOUR INFORMATION!

- It is important to get information from reliable sources (CDC, medical directors, providers)
Social media is **full of misinformation** and opinions based on that misinformation
- CDC: <https://www.cdc.gov/vaccines/hcp/covid-conversations/answering-questions.html>
- CDC: About COVID-19 vaccines: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines.html>
- CDC: Provider Resources for COVID-19 Vaccine Conversations with Patients and Answering Patients' Questions: <https://www.cdc.gov/vaccines/hcp/covid-conversations/>



YOU WILL BE THE LEADER AND ROLE MODEL

- Tell your own vaccine story: talk about how will you make your decision
- Lead by doing: Discuss with staff/family your decision to get the vaccine and talk about your experience after you get immunized

STRATEGIES FOR FACILITIES TO PREPARE FOR THE COVID-19 VACCINE

-
- American Health Care Association (AHCA) Vaccine Clinic Checklist for facilities
 - Consents
 - Residents who do not have capacity
 - Logistics
 - Large Room for social distancing
 - Everyone wears a mask
 - 3 Areas: check-in, vaccination, observation
 - Plan for residents who will be vaccinated in their rooms

QUESTIONS





COVID Hesitancy



Pre-clinical

190+ vaccines

are being tested in animals and lab experiments



Phase 1

15 vaccines

are being tested in a small number of healthy, young people to assess safety and correct dose



Phase 2

14 vaccines

are broadened to a larger group of people, including people at higher risk of illness



Phase 3

10 vaccines

are being tested in thousands of people to check their effectiveness and safety

Pfizer

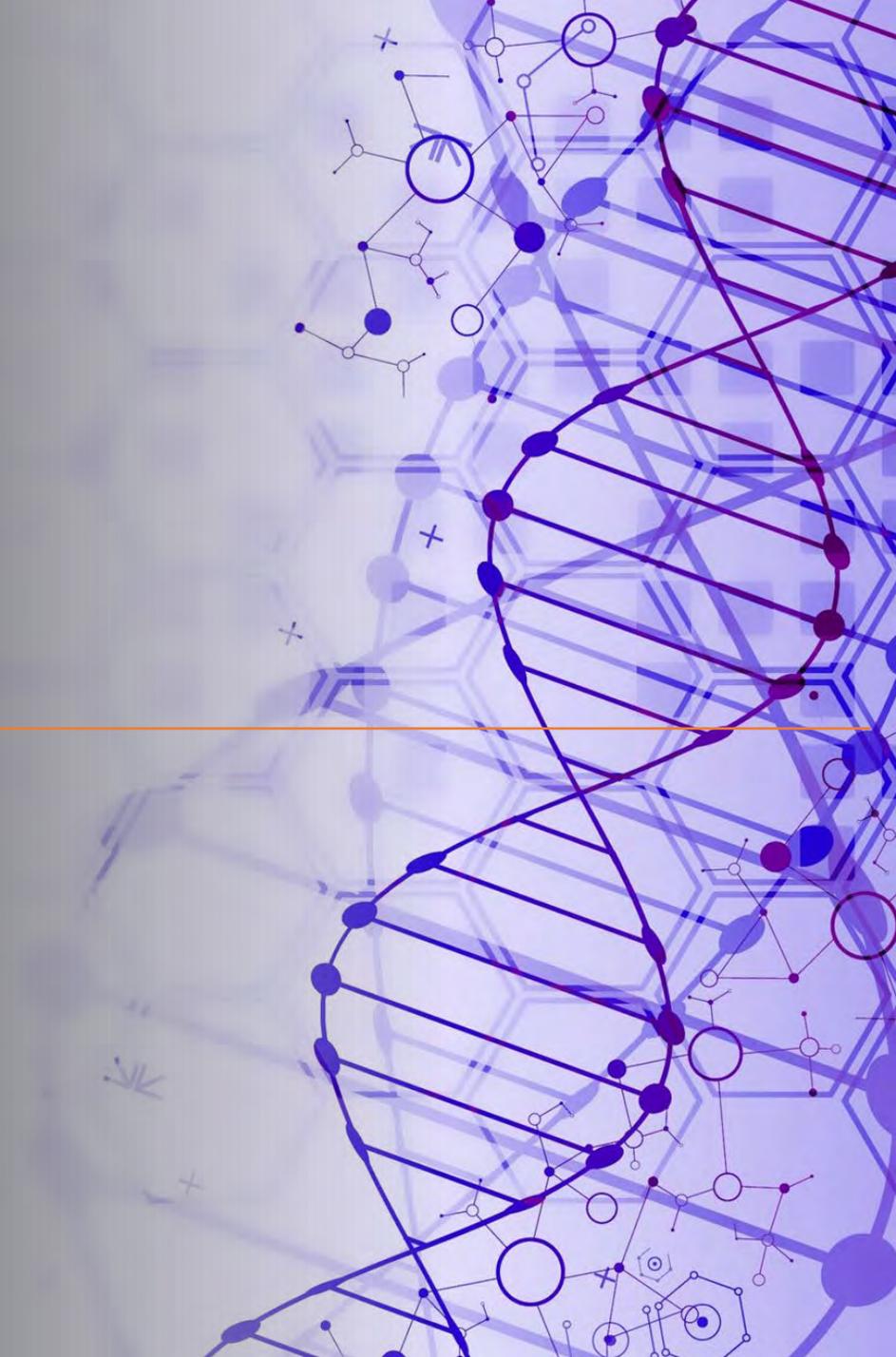


Authorized

1 vaccine

have been determined to provide benefits that outweigh known and potential risks

Vaccine Facts & Administration





Reactogenicity
& Side Effects



Open Discussion



THE FLORIDA SOCIETY
FOR POST-ACUTE AND
LONG-TERM
CARE MEDICINE

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