COVID-19 VACCINE HESITANCY AND EDUCATION

NOW IS THE TIME

Leslie Eber MD CMD

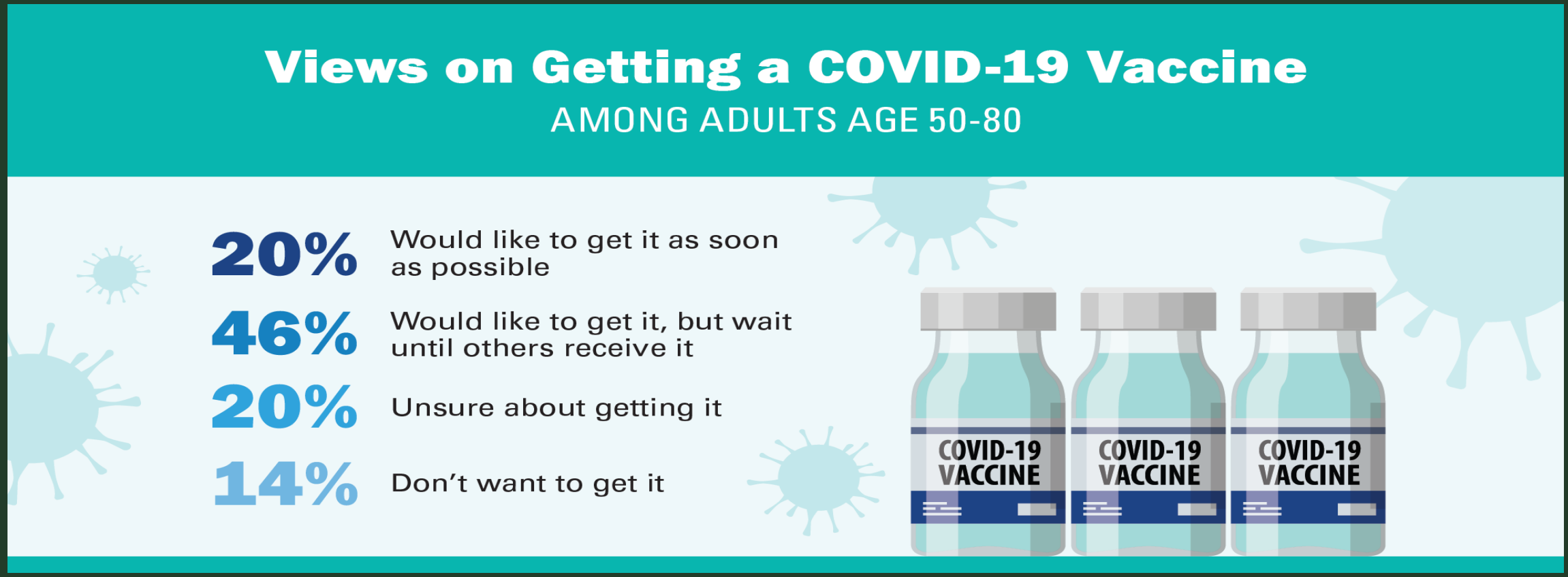
COVID-19 VACCINE HESITATION IS REAL

- 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

JAMA Network Open. 2020;3(10):e2025594. doi:10.1001/jamanetworkopen.2020.25594

COVID 19 HESITANCY AND OLDER ADULTS

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



- 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

		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 2nd dose (as of 11/20/2020)	Primary Efficacy Analaysis, 30,000 enrolled, 25,654 received 2nd dose (as of 10/22/20) >50% completed 2 month follow up after 2nd 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 2nd 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-COVE-Study-Enrollment-Completion-10.22.20.pdf

ASTRAZENECA (AZD1222)

- Inactivated adenovirus vector with spike protein expression
- Cheaper and easier to manufacture. Easier storage. 6 month shelf life.
- Interim analysis 11,636 participants pooled 70% efficacy (131 cases)
  - 2,741 participants half dose/full dose vs placebo arm (~90% effective) almost no participants >55 years
  - 8,895 participants full dose/full dose vs placebo arm (~60% effective)
- “No serious adverse events”
- Target 23,000 COV002 (Phase II/III in UK) and COV003 (Phase III in Brazil) – trials had different protocols but press release results are pooled analysis
- Goal to enroll 60,000 more

Courtesy of Dr. Anuj Mehta, 11/30/20

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

- 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.**
- FDA approval can still take weeks
- 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

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

- 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)

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
- 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
- If + Antibodies PLEASE get the COVID 19 Vaccine
- Monoclonal antibody treatment trial

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/

MOST IMPORTANT

- Tell your own Vaccine Story: 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.

QUESTIONS