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
Agenda

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

- 20% Would like to get it as soon as possible
- 46% Would like to get it, but wait until others receive it
- 20% Unsure about getting it
- 14% Don’t want to get it

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
<table>
<thead>
<tr>
<th><strong>Primary</strong></th>
<th><strong>Pfizer (BNT162b2) EUA submitted 11/20/2020</strong></th>
<th><strong>Moderna (mRNA-1273) EUA submitted 11/30/2020</strong></th>
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<tbody>
<tr>
<td><strong>Trial Size</strong></td>
<td>Primary Efficacy Analysis: 43,661 enrolled, 41,135 received 2nd dose as of 10/18/2020 &gt;50% completed 2 month follow up after 2nd dose (as of 11/20/2020)</td>
<td>Primary Efficacy Analysis, 30,000 enrolled, 25,654 received 2nd dose (as of 10/22/20) &gt;50% completed 2 month follow up after 2nd dose (as of 11/30/2020)</td>
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<td><strong>Efficacy</strong></td>
<td>95% with 170 COVID-19 cases (162 cases placebo group vs 8 cases in vaccine group)</td>
<td>94.1% with 196 COVID-19 cases (185 cases placebo group vs 11 cases vaccine group)</td>
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<tr>
<td><strong>Immunity</strong></td>
<td>7 days from 2nd dose</td>
<td>N/A</td>
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<tr>
<td><strong>Severe cases</strong></td>
<td>9 in placebo group vs 1 in vaccine group</td>
<td>30 in placebo (1 death) vs 0 in vaccine group (0 deaths)</td>
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| **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%  
Injection site pain 2.7%  
Fatigue 4.5%  
Headache 4.5%  
Pain 4.1%  
Myalgia 8.9%  
Erythema/redness 2.0%  
No severe adverse events |
| **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** | 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 |

**Courtest 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/science/coronavirus/vaccine  
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?
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
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)
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](https://www.cdc.gov/vaccines/hcp/covid-conversations/answering-questions.html)
- CDC: Provider Resources for COVID-19 Vaccine Conversations with Patients and Answering Patients’ Questions: [https://www.cdc.gov/vaccines/hcp/covid-conversations/](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
COVID Hesitancy
190+ vaccines are being tested in animals and lab experiments

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

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

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

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

Vaccine Facts & Administration
Reactogenicity & Side Effects
Open Discussion
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