

# **Interim Information on COVID-19 mRNA Vaccines Effectiveness and Safety**

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Information provided is derived from public presentations from the companies, their websites, and peer-reviewed publications. All information is subject to change. Only Pfizer/BioNTech vaccine has emergency use authorization (EUA); neither is currently licensed. CDC website should be regularly visited for updates regarding vaccine recommendations including recommended groups, storage, handling, and administration.



IDAHO DEPARTMENT OF  
HEALTH & WELFARE

	BioNTech with Pfizer	ModernaTX USA
Vaccine / type	BNT162-b2 mRNA	mRNA-1273
Dosing	Days 0 + 21	Days 0 + 28
Storage	Ship and store -60 to -80C 5 days (120 hours) at 2-8C	Ship at -20C 30 days at 2-8C
Time at room temp.	2 hours	12 hours
Time after puncture vial	6 hours	6 hours
EUA approved ages	16 yrs. and older	18+ yrs. (EUA pending)
Diluent/reconstitute	Yes	No
Preservative	No	No
Dose size	0.3mL	0.5mL
Doses per vial	5-6	10
Estimated Vaccine effectiveness*	95%	94%

# FDA Review of Pfizer/BioNTech EUA Application – Safety

## Solicited adverse reactions

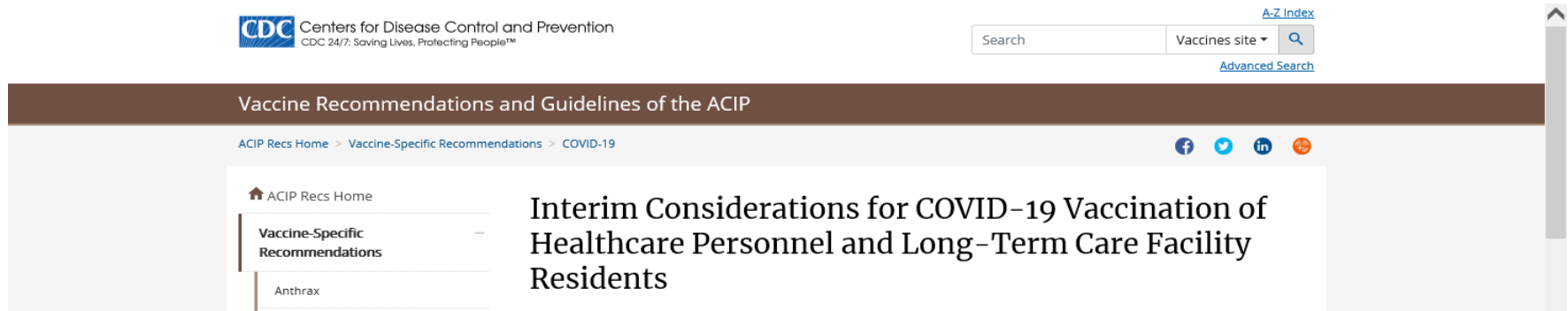
- Injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%)
- Severe adverse reactions: 0.0% to 4.6% for Dose 1 vs Dose 2
  - ≥55 years of age (≤2.8%) as compared to <55 years (≤4.6%).
- Serious adverse events low (<0.5%) and did not differ by vaccine vs placebo

## Unsolicited adverse events

- Lymphadenopathy: 64 cases in vaccine group vs. 6 in placebo group
- 4 cases Bell's palsy among vaccine recipients (3, 9, 37, and 48 days after vaccination) vs none in placebo group

# Adverse Events Reported - Fever

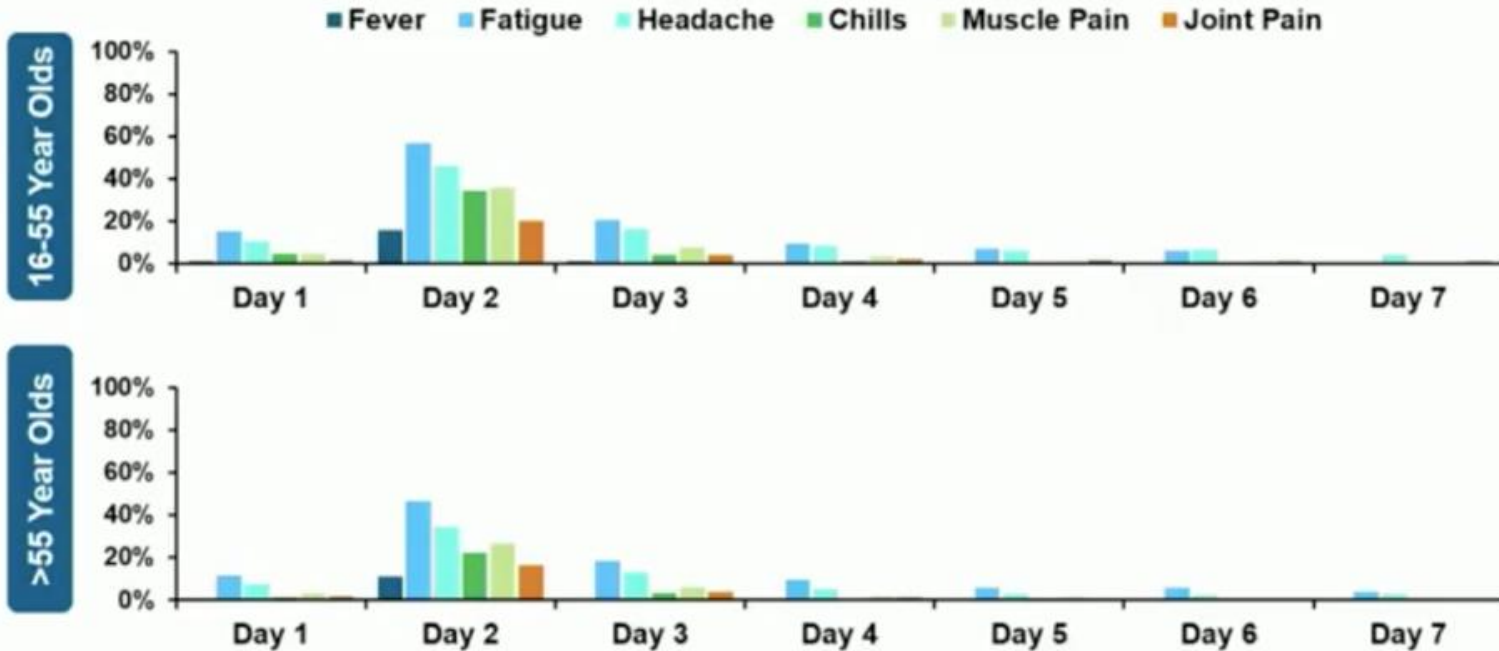
- Fever 38.0 or greater after vaccination
  - 16-55 yo
    - Dose 1 vs dose 2: 4% vs 16%
  - 55 yo+
    - Dose 1 vs dose 2: 1% vs 11%



The screenshot shows the CDC website interface. At the top left is the CDC logo with the text "Centers for Disease Control and Prevention" and "CDC 24/7: Saving Lives, Protecting People™". To the right is a search bar with "Vaccines site" and a magnifying glass icon, and a link for "Advanced Search". Below the search bar is a dark brown navigation bar with the text "Vaccine Recommendations and Guidelines of the ACIP". Underneath is a breadcrumb trail: "ACIP Recs Home > Vaccine-Specific Recommendations > COVID-19". On the right side of the breadcrumb trail are social media icons for Facebook, Twitter, LinkedIn, and YouTube. On the left side, there is a sidebar menu with "ACIP Recs Home" (selected), "Vaccine-Specific Recommendations", and "Anthrax". The main content area displays the title "Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents".

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html>.

# eDiary: Systemic Events Each Day From Dose 2 in 16-55 and >55 Year Olds (N=8,183) BNT162b2



From Pfizer Presentation to ACIP Dec. 12, 2020

# Risk of Severe Allergic Reactions – Pfizer/BioNTech

- Two persons in UK had anaphylaxis after vaccination; 2 in Alaska with allergic reactions (one anaphylaxis) – cases under investigation
- Contraindication: history of a severe reaction to a component of the vaccine
- Precaution: Report of severe allergic reaction to injectable medication
  - Observe 30 minutes after vaccination
- Monitor all other persons for 15 minutes after vaccination

**More information is available on considerations specific to residents in long-term care facilities (LTCF) and HCP who may have vaccine-related side effects at [www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination](https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination).**

# **Safety Monitoring and Reporting**

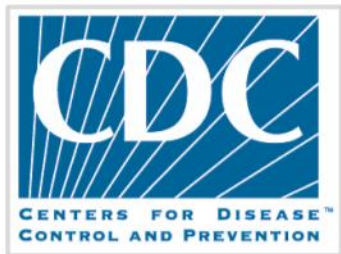


# Adverse Event (AE) Reporting

- EUA anticipated to require the following AEs to be reported to VAERS:
  - Vaccine administration errors (whether associated with an AE or not)
  - Serious AEs\* (irrespective of attribution to vaccination)
  - Multisystem inflammatory syndrome (MIS)
  - Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
- Any clinically significant AEs that occur after vaccine administration should also be reported to VAERS
- Follow any revised EUA safety reporting requirements throughout the duration of the EUA
- Provide a CDC information sheet to recipients on **v-safe**, a smartphone-based tool to help monitor for AEs



\*Definition of serious adverse events: [www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event](https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event)  
Safety monitoring systems for COVID-19 vaccines: [www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html)



1. Text message check-ins from CDC (daily 1<sup>st</sup> week; weekly thru 6 weeks; then 3, 6, and 12 mo.)  
vaccine recipient completes web survey



Vaccine recipient



2. Clinically important health impact reported

- ✓ missed work
- ✓ unable to do normal daily activities
- ✓ received medical care



Call center



3. A CDC representative conducts active telephone follow-up on a clinically important health impact event and takes a report if appropriate



# **Moderna Vaccine Safety and Efficacy**

**Preliminary Information – Not EUA or Licensed Product**

# ModernaTX Vaccine

- EUA application proposes approval for
  - 18 years of age and older.
  - 2 doses, 100 µg each, 0.5mL/dose, administered 1 month apart
- Among ~30,000 study participants without evidence of SARS-CoV-2 infection before the first dose of vaccine AND 14 days after dose 2:
  - 94.5.0% (95% CI 86.5%, 97.8%) efficacy with 5 COVID-19 cases in the vaccine group and 90 COVID-19 cases in the placebo group.
  - similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities

# Moderna – Safety Results

- Most common solicited adverse reactions [AEs]: injection site pain (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%), chills (43.4%)
- Severe adverse reactions in 0.2% - 9.7% of participants,
  - more frequent after dose 2 than after dose 1
  - more frequent among <65 years
- Pregnant women excluded from study – limited data

<b>Solicited AEs Among &lt;65 years</b>	<b>Vaccine Dose 1 (%)</b>	<b>Placebo Dose 1 (%)</b>	<b>Vaccine Dose 2 (%)</b>	<b>Placebo Dose 2 (%)</b>
Fever – any	0.9	0.3	17.4	0.4
Fever –Grade 3/4	1.2	0.02	1.7	0.03
Headache – any	35.4	29.0	62.8	25.4
Headache – Grade 3	1.9	1.4	5.0	1.2
Fatigue – any	38.5	28.8	67.6	24.5
Fatigue – Grade 3/4	1.1	0.7	10.6	0.8
Myalgia – any	23.7	14.3	61.3	12.7
Myalgia – Grade 3	0.6	0.3	10.0	0.4
Arthralgia – any	16.6	11.6	45.2	10.5
Arthralgia – Grade 3/4	0.4	0.3	5.8	0.3
Chills – any	9.2	6.4	48.3	5.9
Chills – Grade 3	0.1	0.07	1.5	0.1

# Moderna – Safety Results

- Compared with placebo (saline), vaccine recipients reported more often:
  - axillary swelling and tenderness of the vaccination arm
    - 21.4% of vaccine recipients <65 years of age vs 7.7% placebo
    - 12.4% of vaccine recipients ≥65 years of age vs 5.8% placebo
  - hypersensitivity adverse events
    - 1.5% of vaccine recipients and 1.1% of placebo recipients
    - No anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine.
  - Bell’s palsy – three in vaccine group and one in placebo.

**Resources**



# COVID-19 Vaccination

## Clinical Resources for Each COVID-19 Vaccine

Find information for COVID-19 vaccination administration, storage and handling, reporting, and patient education for each specific vaccine

Pfizer-BioNTech Vaccine Information



General Vaccine Administration



Storage and Handling Toolkit



ACIP Recommendations



COVID-19 Vaccine EUAs

[https://www.cdc.gov/vaccines/covid-19/index.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F covid-19%2Fvaccination-resources.html](https://www.cdc.gov/vaccines/covid-19/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F covid-19%2Fvaccination-resources.html)