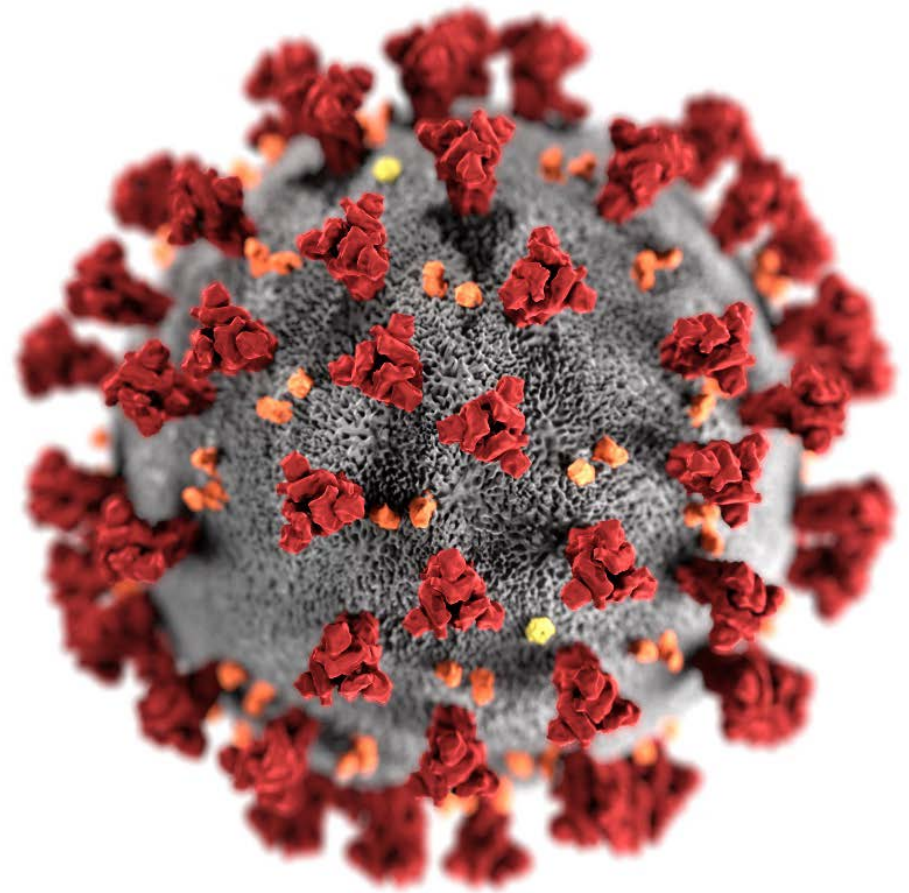


Clinical Considerations for Populations Included in Phase 1a



Sara Oliver MD, MSPH
ACIP Meeting
December 1, 2020



Clinical Considerations

- Health Care Personnel
 - Sub-prioritization
 - Reactogenicity
 - Considerations for implementation
- Long-Term Care Facility Residents
 - Sub-prioritization
 - Reactogenicity
 - Considerations for implementation

Need for Sub-prioritization

- One or more COVID-19 vaccines may be authorized by FDA for use in December
- Initial doses of any COVID-19 vaccine will be limited. We expect a constrained supply environment for some months and need to make the best use of available vaccine.
- By the end of December, the number of doses available will be about **40 million**, enough to vaccinate **20 million** people
 - Anticipate **5-10** million doses per week post-authorization

Clinical Considerations: Health Care Personnel



Health Care Personnel: Sub-prioritization Considerations

- Where sub-prioritization of health care personnel is needed, consider:
 - Individuals with **direct patient contact**¹ and unable to telework:
 - Personnel who provide **services** to patients or patients' family members
 - Personnel who handle **infectious** materials
 - Can include inpatient or outpatient settings
 - Personnel working in residential care or long-term care facilities
 - Personnel without known infection in prior **90 days**
 - Reinfection appears uncommon during the initial 90 days after symptom onset of preceding infection²
 - Serologic testing **not recommended** prior to vaccination

¹Within 6 feet

²[Duration of Isolation and Precautions for Adults with COVID-19 | CDC](#)

Health Care Personnel:

Clinical Considerations: Pregnancy or Breastfeeding

- **75%** of health care workforce are women
 - Approximately **330,000** health care personnel could be pregnant or recently postpartum at the time of vaccine implementation
- Data demonstrate potentially increased risks of severe maternal illness and preterm birth due to COVID-19 disease
- **No data** on use of mRNA vaccines in pregnant/breastfeeding women
- Await Phase III data, FDA assessment, EUA Conditions of Use
 - Once reviewed, anticipate further guidance around use of COVID-19 vaccines in pregnant/breastfeeding Phase 1a populations

Reactogenicity

Data from published Phase I/II trials Adults 18–55 years of age

Moderna¹

100µg	Post-dose 1			Post-dose 2		
N=15	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	5 (33%)	1 (7%)	—
Headache	4 (27%)	—	—	5 (33%)	4 (27%)	—
Myalgia	1 (7%)	—	—	2 (13%)	6 (40%)	—

Pfizer²

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	1 (8%)	1 (8%)	—	—	2 (17%)	—
Headache	3 (25%)	1 (8%)	2 (17%)	6 (50%)	2 (17%)	—
Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

¹Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.

Reactogenicity

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Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

Systemic symptoms more common after second dose

¹Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.

Health Care Personnel: Considerations for Implementation

- Health care systems and public health should work together to ensure vaccine **access** to health care personnel who are not affiliated with hospitals
- Consider **staggering** vaccination of personnel from similar units or positions
- Planning for personnel to have **time away** from clinical care if HCP experience systemic symptoms post-vaccination
- Additional CDC guidance forthcoming:
 - Approach to systemic symptoms in HCP after COVID-19 vaccination

Clinical Considerations: Long-Term Care Facility Residents



Long-Term Care Facility Residents: Sub-prioritization Considerations

- **Long-term care facilities**: Provide a spectrum of medical and non-medical services to frail or older adults unable to reside independently in the community¹
 - Skilled nursing facilities: Facility engaged primarily in providing **skilled nursing care** and rehabilitation services for residents who require care because of injury, disability or illness
 - Assisted living facilities: Facility providing help with activities of daily living; residents often live in their own room or apartment within building/group of buildings
- As of Nov 26, ~730,000 COVID-19 cases and 100,240 deaths among LTCF residents/staff²
 - As of Nov 15, skilled nursing facilities reported nearly 500,000 cases, and 70,000 deaths³
 - Through Oct 15, assisted living facilities from 23 states reported 27,965 cases and 20 states reported 5,469 deaths⁴

¹[2020 LTCF Key Terms and Acronyms \(cdc.gov\)](https://www.cdc.gov/ncidod/dlqp/long-term-care-facilities/)

²[The Long-Term Care COVID Tracker | The COVID Tracking Project](https://www.cdc.gov/mmwr/preview/mmwrhtml/6010a1.htm)

³[COVID19 Nursing Home Data | Data.CMS.gov](https://www.cms.gov/medicare/quality-improvement/quality-improvement-data-reports-and-indicators/quality-improvement-data-reports-and-indicators-reports/2020-nursing-home-covid-19-data)

⁴Yi et al. MMWR Nov 20, 2020 [Characterization of COVID-19 in Assisted Living Facilities— 39 States, October 2020 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/6010a1.htm)

Long-Term Care Facility Residents: Sub-prioritization Considerations

- Where sub-prioritization of long-term care facilities needed, consider:
 - **Skilled nursing facilities** care for most medically vulnerable residents
 - After skilled nursing facilities, consider **broadening** to other facilities, including:
 - Assisted living facilities
 - Residential care communities
 - Intermediate care facilities for individuals with developmental disabilities
 - State Veterans Homes

Reactogenicity

Data from published Phase I/II trials Community-dwelling older adults

Moderna¹

≥71 years of age

100µg	Post-dose 1			Post-dose 2		
N=10	Mild	Moderate	Severe	Mild	Moderate	Severe
Any systemic symptom	3 (30%)	—	—	3 (30%)	3 (30%)	1 (10%)*

*Grade 3 fatigue

Pfizer²

65-85 years of age

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	1 (8%)	—	—
Headache	—	—	—	2 (17%)	1 (8%)	—
Myalgia	—	—	—	2 (17%)	1 (8%)	—

¹Anderson et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. NEJM 2020; online publication Sept 29

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14

Reactogenicity

Systemic symptoms
lower
among
older adult
population

Data from published Phase I/II trials

Moderna¹ ≥71 years of age Community-dwelling older adults

100µg	Post-dose 1			Post-dose 2		
N=10	Mild	Moderate	Severe	Mild	Moderate	Severe
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Long-Term Care Facility Residents: Considerations for Implementation

- Federal pharmacy partners supporting the LTCF program will be required to adhere to all EUA Conditions of Use
 - Must provide **fact sheets** to recipients in accordance with the conditions of use
 - EUA fact sheets will be provided directly to staff and residents getting vaccinated, as well as families/medical proxies as applicable
 - Language clarifying available data in adults ≥ 65 years of age, and lack of data specific to individuals in LTCF will be included in information on CDC's website

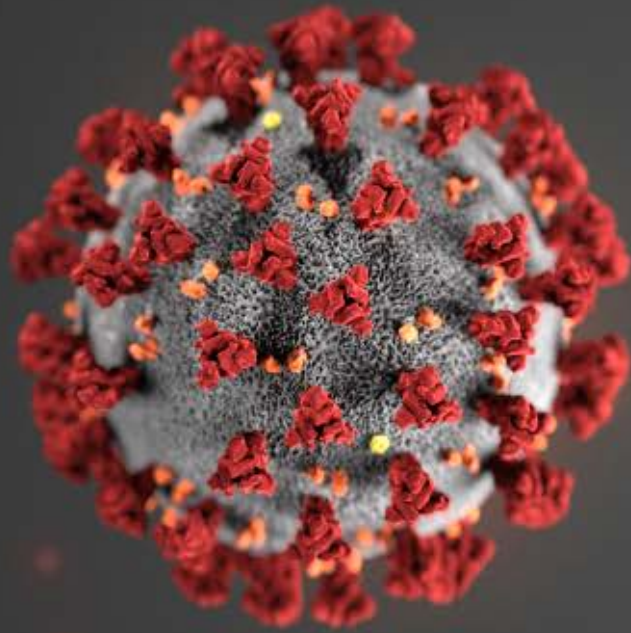
Consent/assent will be obtained from residents or families/medical proxies and documented in the patients' charts as is standard practice for other vaccines

Summary



Summary:

- **Sub-prioritization** may be required with initial limited supply
- Implementation of vaccination programs for health care personnel will need to consider **reactogenicity** post-vaccination
 - Additional post-vaccination guidance forthcoming from CDC
- Reactogenicity appears **lower** in older adult population for mRNA vaccines
 - No reactogenicity data in LTCF residents
 - **Safety monitoring** of all populations in Phase 1a, especially LTCF residents, will be critical post-authorization



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

