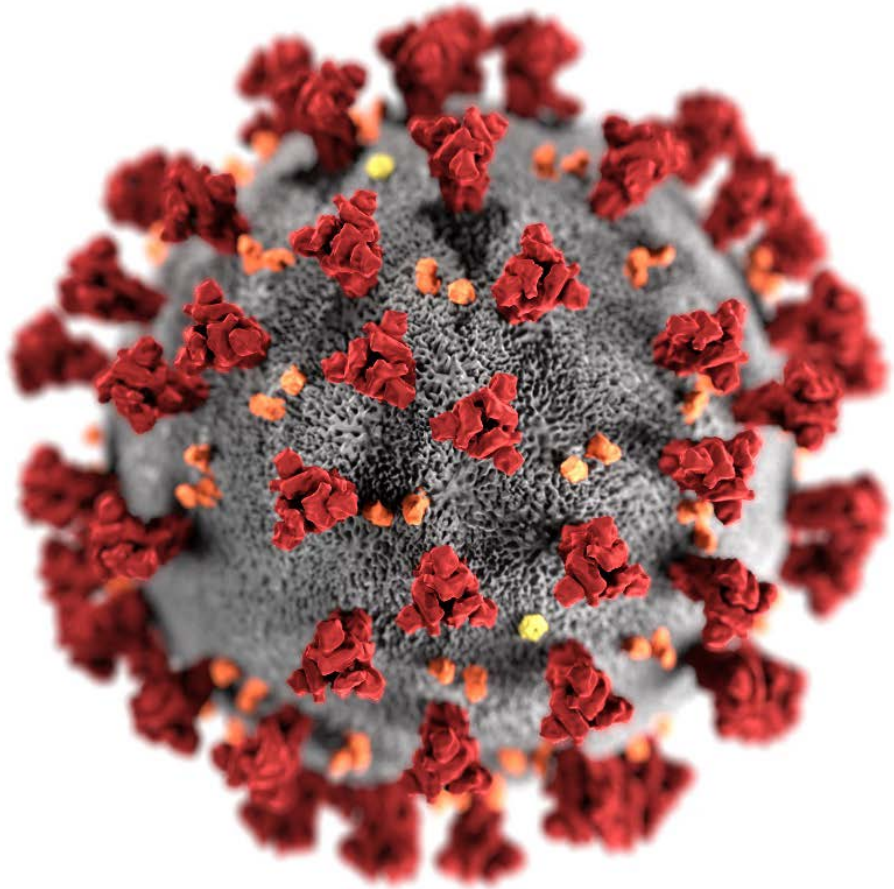
ACIP COVID-19 Vaccines Work Group



Dr. Beth Bell, Work Group Chair

December 1, 2020

Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of additional ACIP meetings

- At the November 23rd meeting, ACIP reviewed:
  - Evidence to Recommendation Framework:
    Public Health Problem, Resource Use and Equity Domains
  - Evidence to Recommendation Framework:
    Values, Acceptability and Feasibility Domains
  - Phased Allocation of COVID-19 Vaccines

COVID-19 Work Group activities – November 2020

- COVID-19 Vaccine Work Group meets weekly

- Topics covered since last ACIP meeting:
  - Additional discussions around Phase 1a populations
  - Clinical considerations for populations included in Phase 1a

Today's agenda

- **Allocation of initial supplies of COVID-19 vaccine: Phase 1a**
  Dr. Kathleen Dooling (CDC)
- **Clinical considerations for populations included in Phase 1a**
  Dr. Sara Oliver (CDC)
- **Post-authorization safety monitoring update**
  Dr. Tom Shimabukuro (CDC)
- **Public Comment**
- **Vote:**
  Allocation of initial supplies of COVID-19 vaccine: Phase 1a

Vaccine Update

- **Two** COVID-19 vaccine manufacturers announced filing with U.S. FDA for Emergency Use Authorization
  - Pfizer/BioNTech announced submission on November 20, 2020[1]
  - Moderna announced submission on November 30, 2020[2]

[1] Pfizer and BioNTech to Submit Emergency Use Authorization Request Today to the U.S. FDA for COVID-19 Vaccine | Pfizer

[2] Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization | Moderna, Inc. (modernatx.com)

Work group members

ACIP members

- Beth Bell (chair)
- Grace Lee
- Jose Romero
- Keipp Talbot

Ex-officio/government members

- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Jillian Doss-Walker
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

CDC Co-leads

- Kathleen Dooling
- Sara Oliver

Liaisons

- AAFP: Jonathan Temte
- AAP: Sean O'Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

Liaisons, cont'd

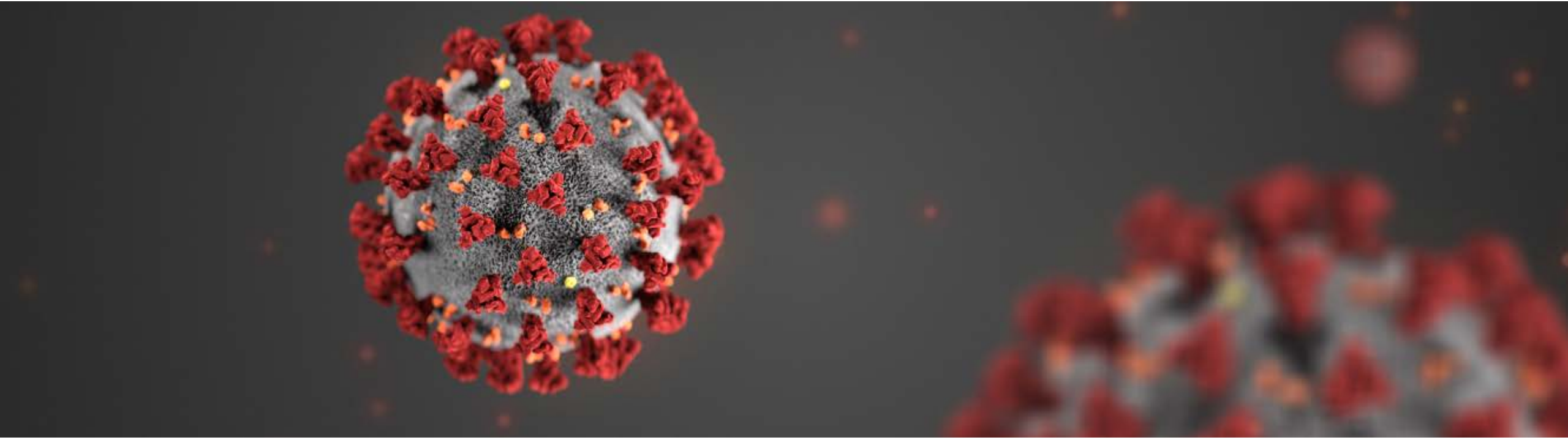
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao(alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

Consultants

- Ed Belongia (safety)
- Matthew Daley (safety)
- Kathy Kinlaw (ethics)
- Dayna Matthew (health equity)
- Kathleen Neuzil (vaccinology)
- Stanley Perlman (microbiology/immunology)

CDC participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Katie Curran
- Jonathan Duffy
- Anthony Fiore
- Mark Freedman
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Julia Gargano
- Rita Helfand
- Terri Hyde
- Tara Jatlaoui
- Cynthia Jorgensen
- Erin Kennedy
- Ram Koppaka
- Jessica MacNeil
- Mona Marin
- Sarah Mbaeyi
- Nancy McClung
- Lucy McNamara
- Rebecca Morgan
- Titilope Oduyebo
- Christina Ottis
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Tom Shimabukuro
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Yon Yu
- Jane Zucker



For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

Thank you!

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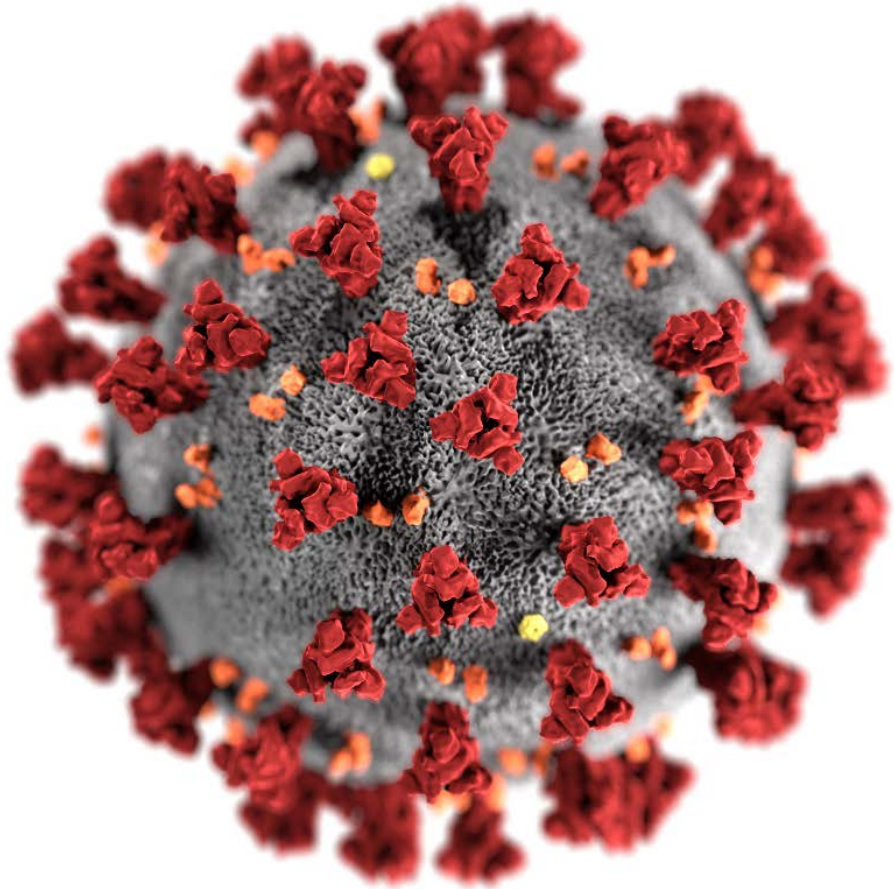
Phased Allocation of COVID-19 Vaccines

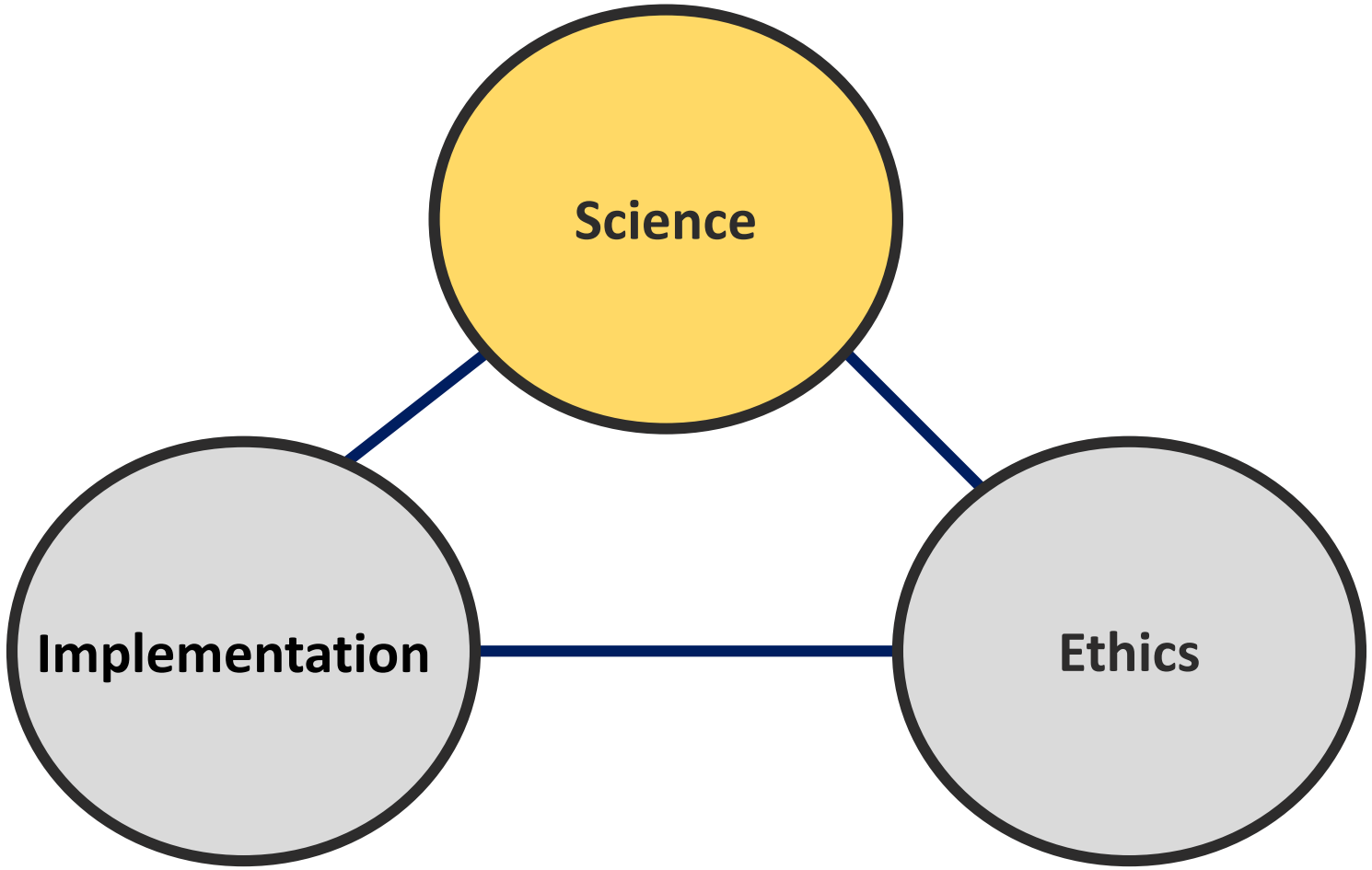


Kathleen Dooling, MD, MPH
ACIP meeting
December 1st, 2020

Policy Question:

- **Should health care personnel and residents of long-term care facilities be offered COVID-19 vaccination in Phase 1a?**

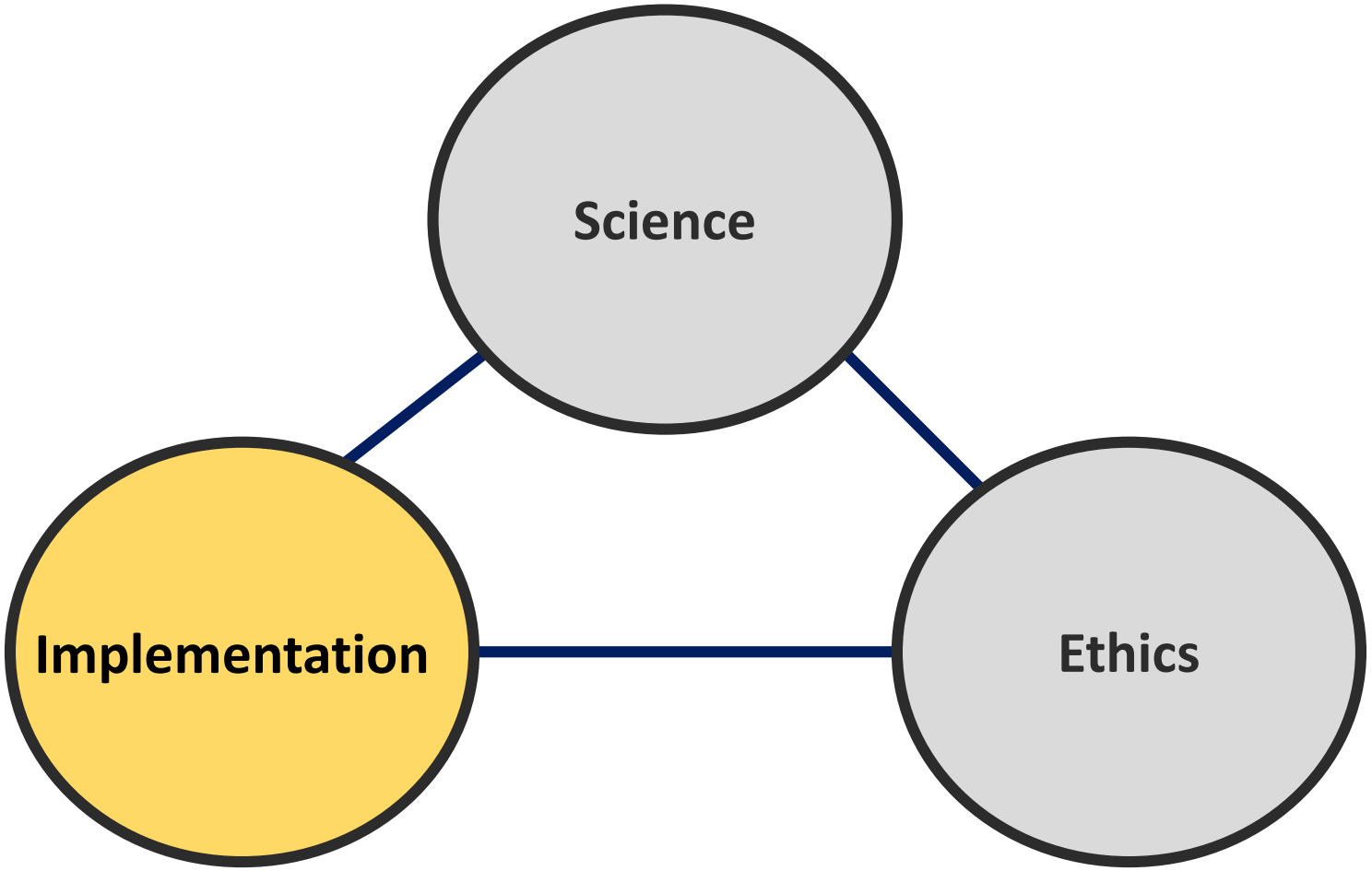
Allocation of initial COVID-19 vaccine: Phase 1a



Science:

- COVID-19 disease burden
- Balance of benefits & harms of vaccine

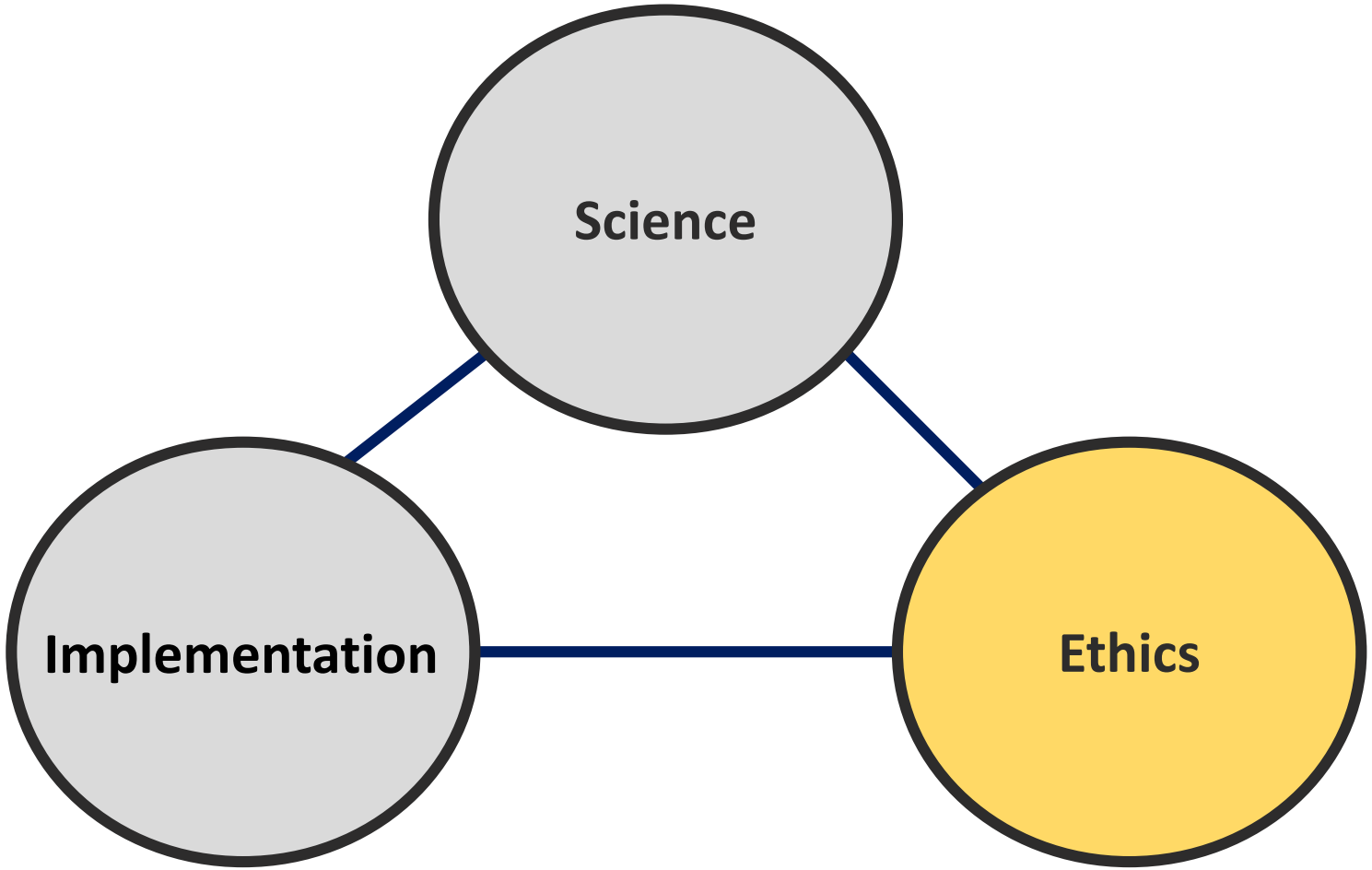
Allocation of initial COVID-19 vaccine: Phase 1a



Implementation:

- Values of target group
- Feasibility

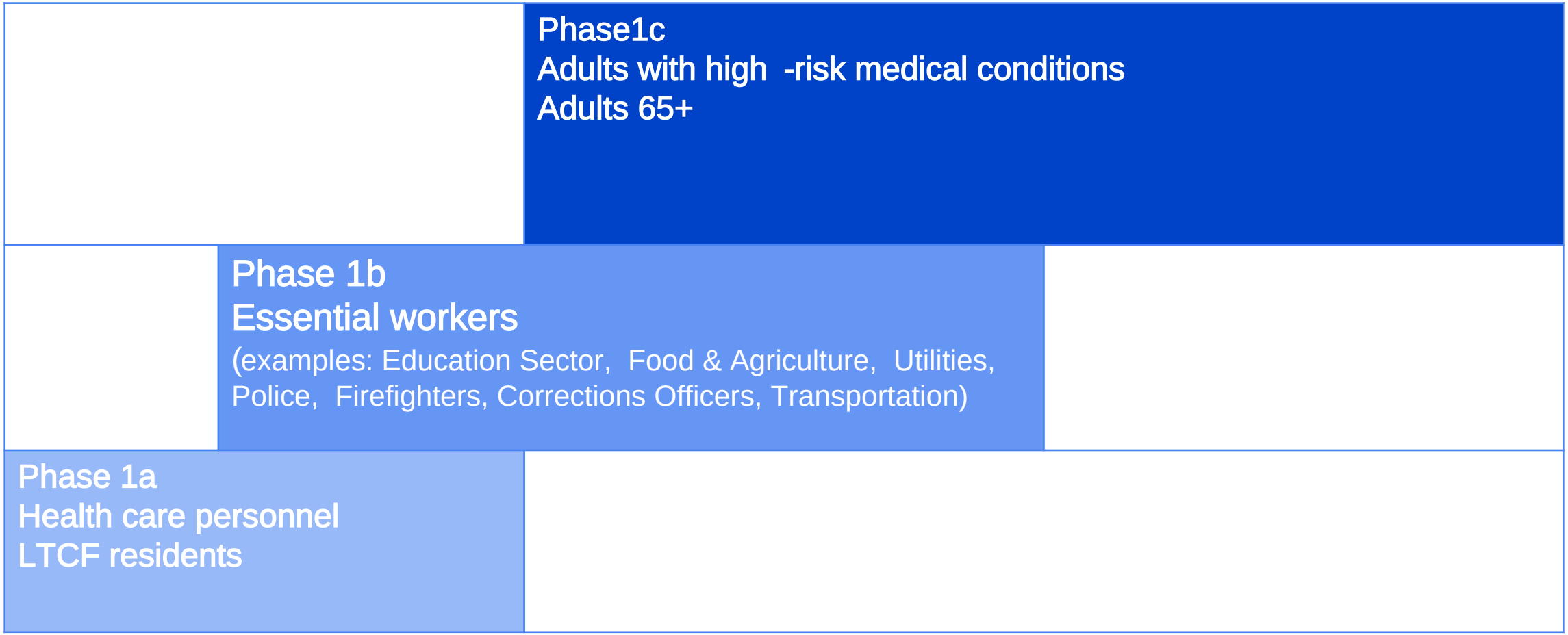
Allocation of initial COVID-19 vaccine: Phase 1a



Ethical Principles:

- Maximize benefits & minimize harms
- Promote justice
- Mitigate health inequities

Work Group Proposed Interim Phase 1 Sequence



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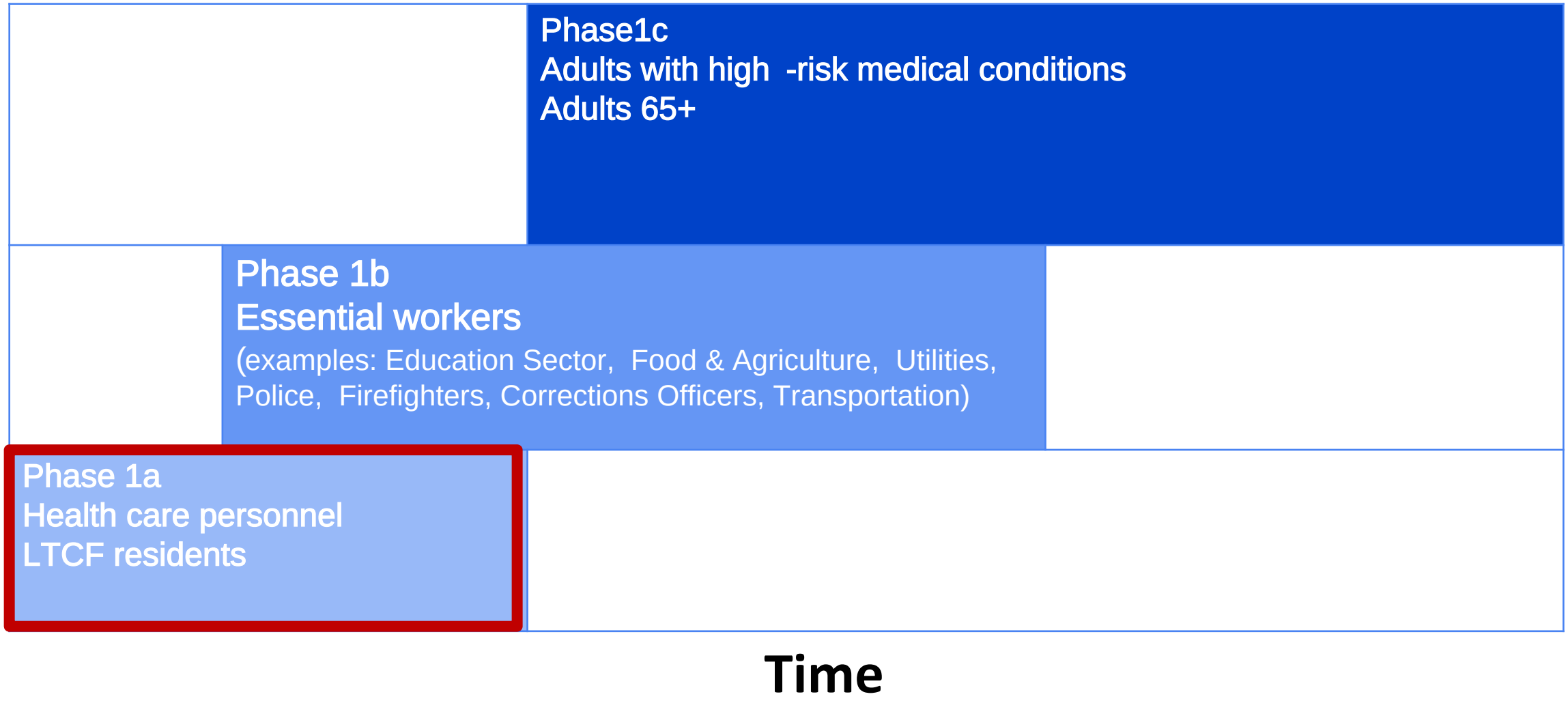
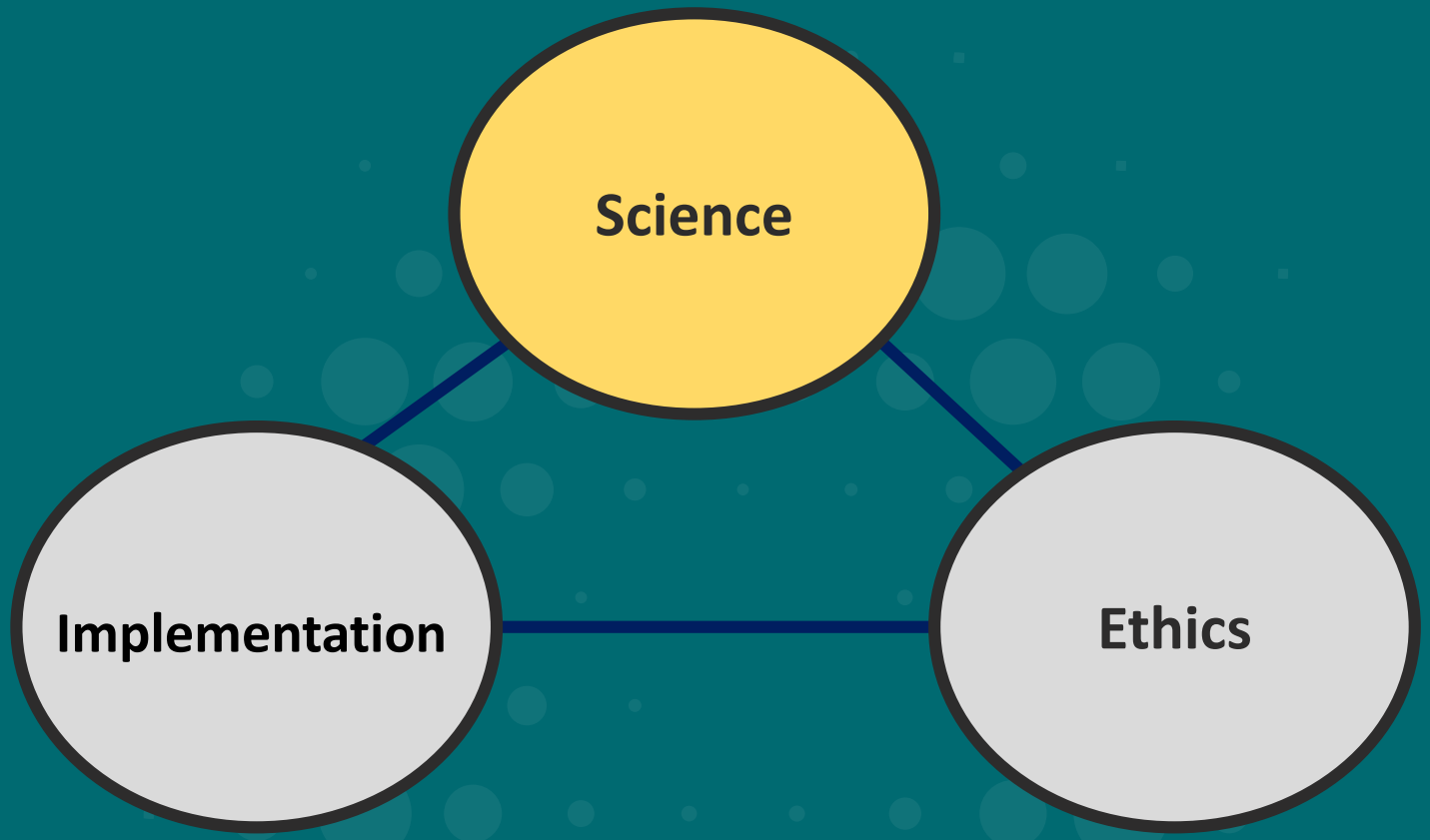


Proposed groups for Phase 1a vaccination

Health care Personnel[1,2] (HCP) (~21million)	Long-Term Care Facility (LTCF) Residents[3] (~3M)
Examples	
• Hospitals • Long-term care facilities • Outpatient clinics • Home health care • Pharmacies • Emergency medical services • Public health	• Skilled nursing facilities (~1.3 M beds) • Assisted living facilities (~0.8 M beds) • Other residential care (~0.9 M beds)

1. https://www.cdc.gov/infectioncontrol/guidelines/healthcare
2. personnel/index.html https://www.cisa.gov/publication/guidance -essential-critical-infrastructure-workforce
3. https://www.cdc.gov/longtermcare/index.html

Science



Summary of Work Group considerations supporting vaccinating health care personnel in Phase 1a

- As of Nov 30, at least 243,000 confirmed COVID-19 cases among HCP, with 858 deaths[1]
- LTCF modeling demonstrates more cases and death averted at the facility by vaccinating staff compared to vaccinating residents[2]
- COVID-19 exposure (inside and outside the healthcare setting) results in absenteeism due to quarantine, infection and illness. Vaccination has the potential to reduce HCP absenteeism

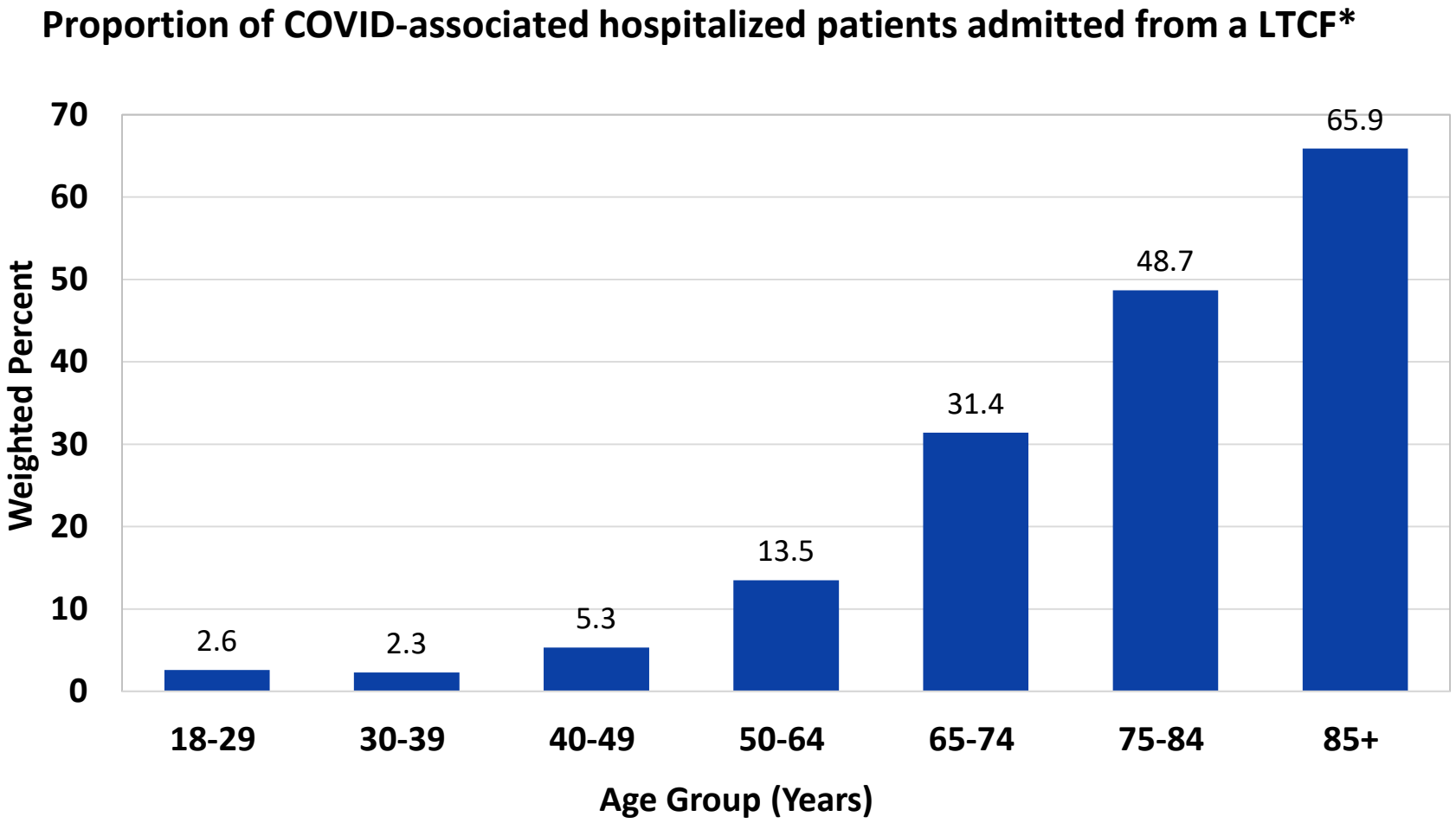
1. https://covid.cdc.gov/covid-data-tracker/#health-care-personnel
2. Slayton, Modeling Allocation Strategies for the initial SARS-CoV-2 Vaccine Supply, ACIP Aug 21, 2020, https://www.cdc.gov/vaccines/acip/meetings/slides-2020-08.html

Older adults in congregate settings are disproportionately affected by COVID-19

- Long-Term Care Facility (LTCF) residents and staff accounted for 6% of cases and 40% of deaths in the U.S.[1] (Nov 24, 2020)
  - Skilled Nursing Facilities (~1.3M)
    - ~496,000 confirmed + probable cases (as of Nov 15, 2020)[2]
    - >69,000 deaths
  - Assisted Living Facilities (~0.8M)
    - 27,965 confirmed + suspected cases (as of Oct 15/2020, based on 23 states[3])
    - 5,469 deaths (as of Oct 15/2020, based on 20 states[3])

1. Kaiser Family Foundation. State data and policy actions to address coronavirus: COVID-19 metrics by state. San Francisco, CA: Kaiser Family Foundation; 2020. https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/#long-term-care-cases-deaths
2. CMS COVID-19 data: https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/
3. Yi SH, See I, Kent AG, et al. Characterization of COVID-19 in Assisted Living Facilities — 39 States, October 2020. MMWR Morb Mortal Wkly Rep 2020;69:1730–1735. DOI: http://dx.doi.org/10.15585/mmwr.mm6946a3

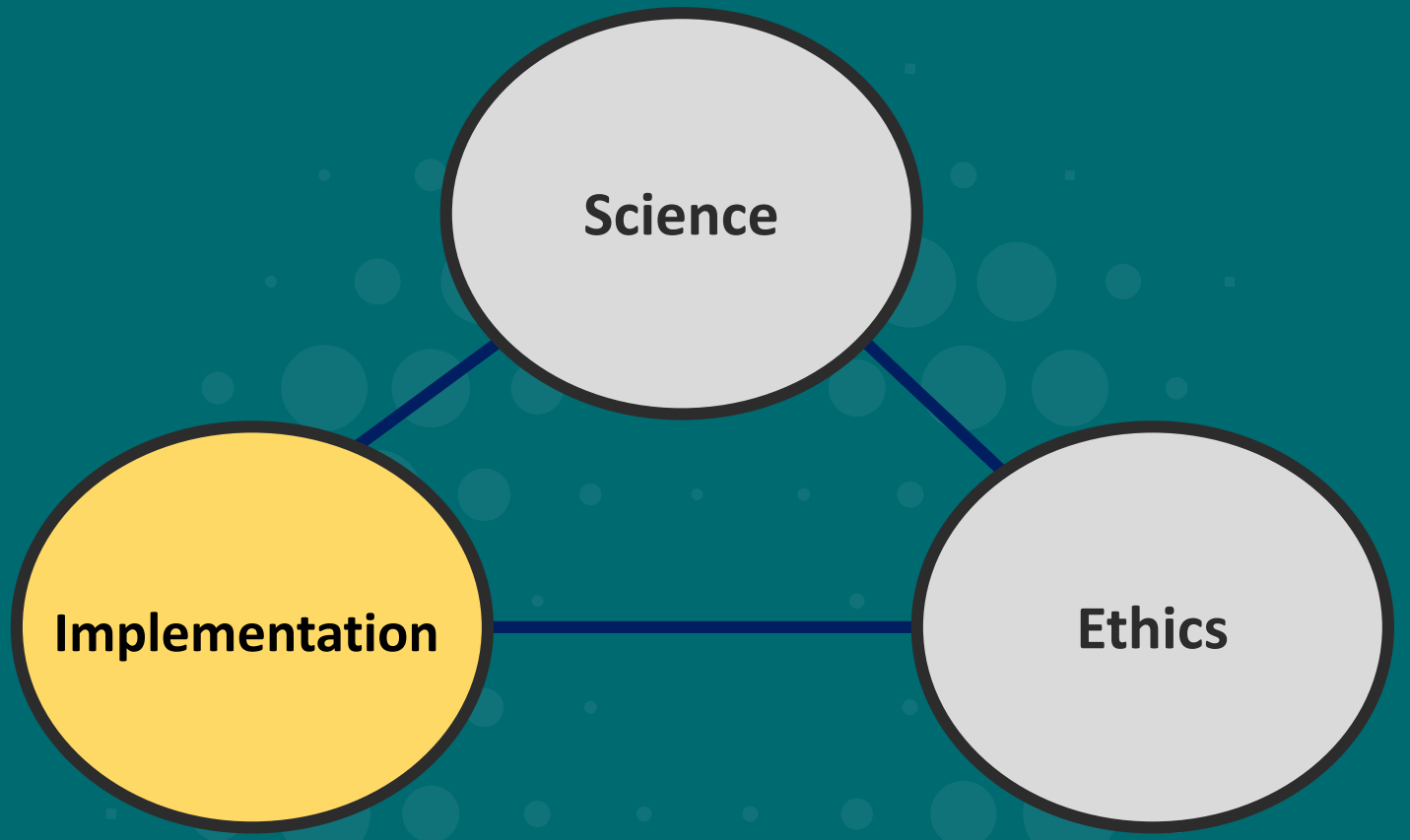
The majority of COVID-associated hospitalized patients older than 75 years, were admitted from a LTCF*



*LTCF= Nursing home/skilled nursing facility, rehabilitation facility, assisted living/residential care, LTACH, group home/retirement, psychiatric facility, or other long-term care facility

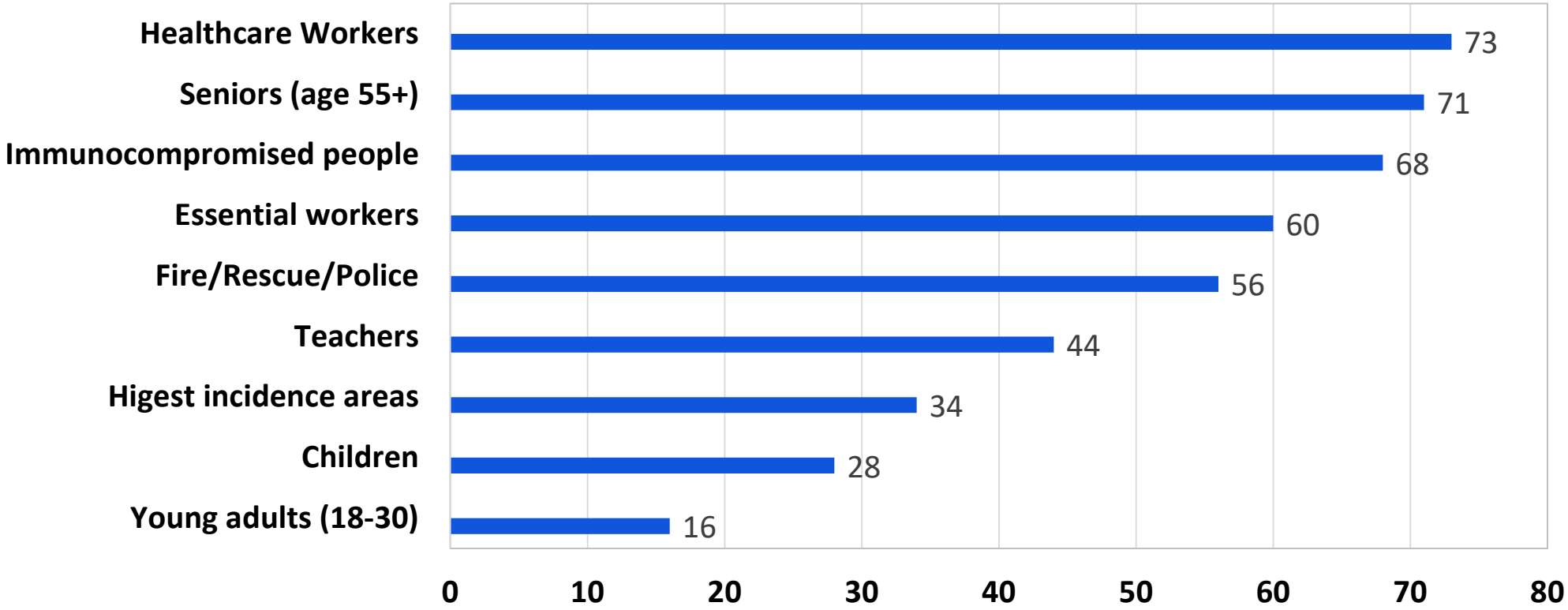
Data Source: COVID-19 associated hospitalizations reported to Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) surveillance system. COVID-NET is a population-based surveillance system that collects data on laboratory-confirmed COVID-19-associated hospitalizations among children and adults through a network of over 250 acute-care hospitals in 14 states.

Implementation



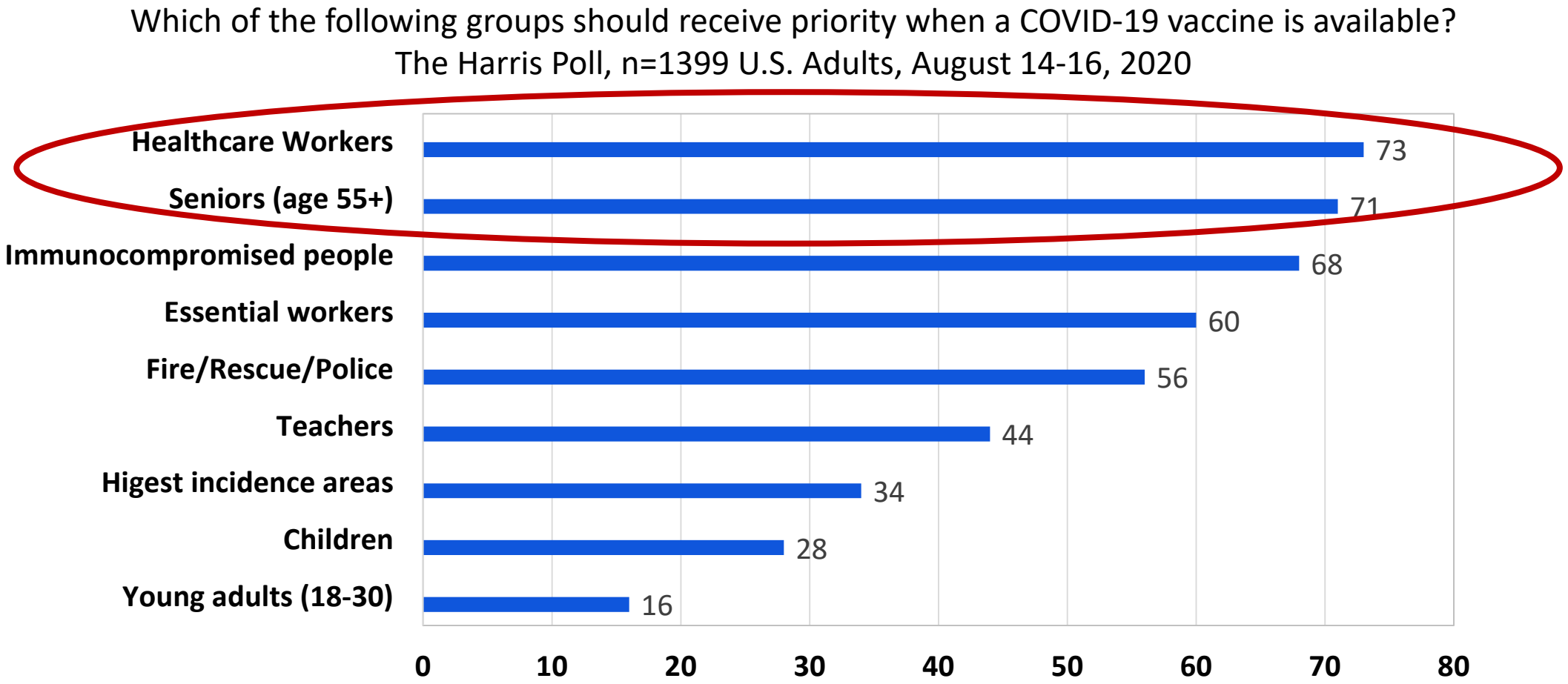
Survey respondents supported early allocation of COVID-19 vaccine to health care personnel and seniors

Which of the following groups should receive priority when a COVID-19 vaccine is available?
The Harris Poll, n=1399 U.S. Adults, August 14-16, 2020



Source: https://theharrispoll.com/americans-want-high-risk-people-to-get-a-coronavirus-vaccine-first/

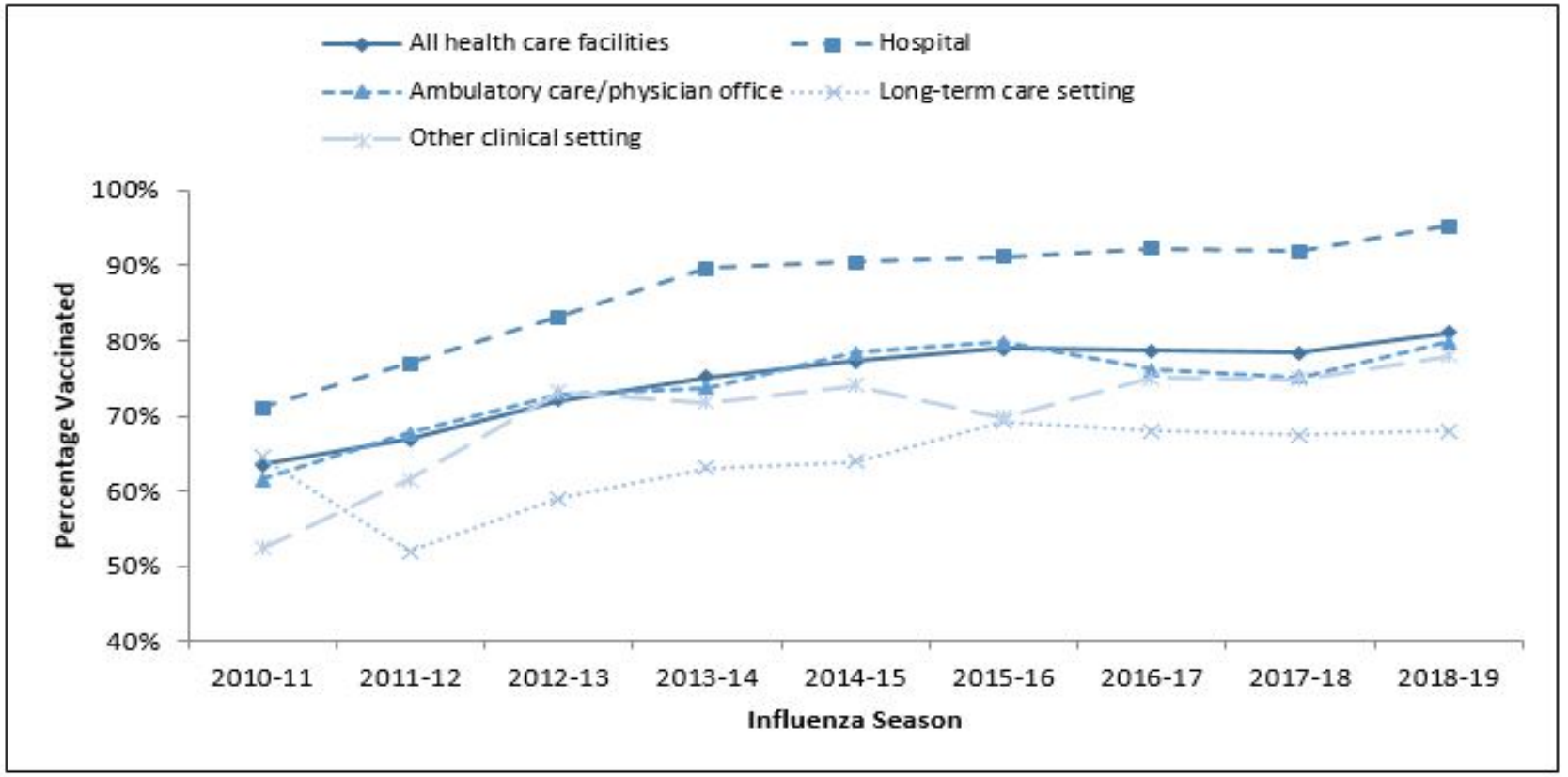
Survey respondents supported early allocation of COVID-19 vaccine to groups proposed for Phase 1



Source: https://theharrispoll.com/americans-want-high-risk-people-to-get-a-coronavirus-vaccine-first/

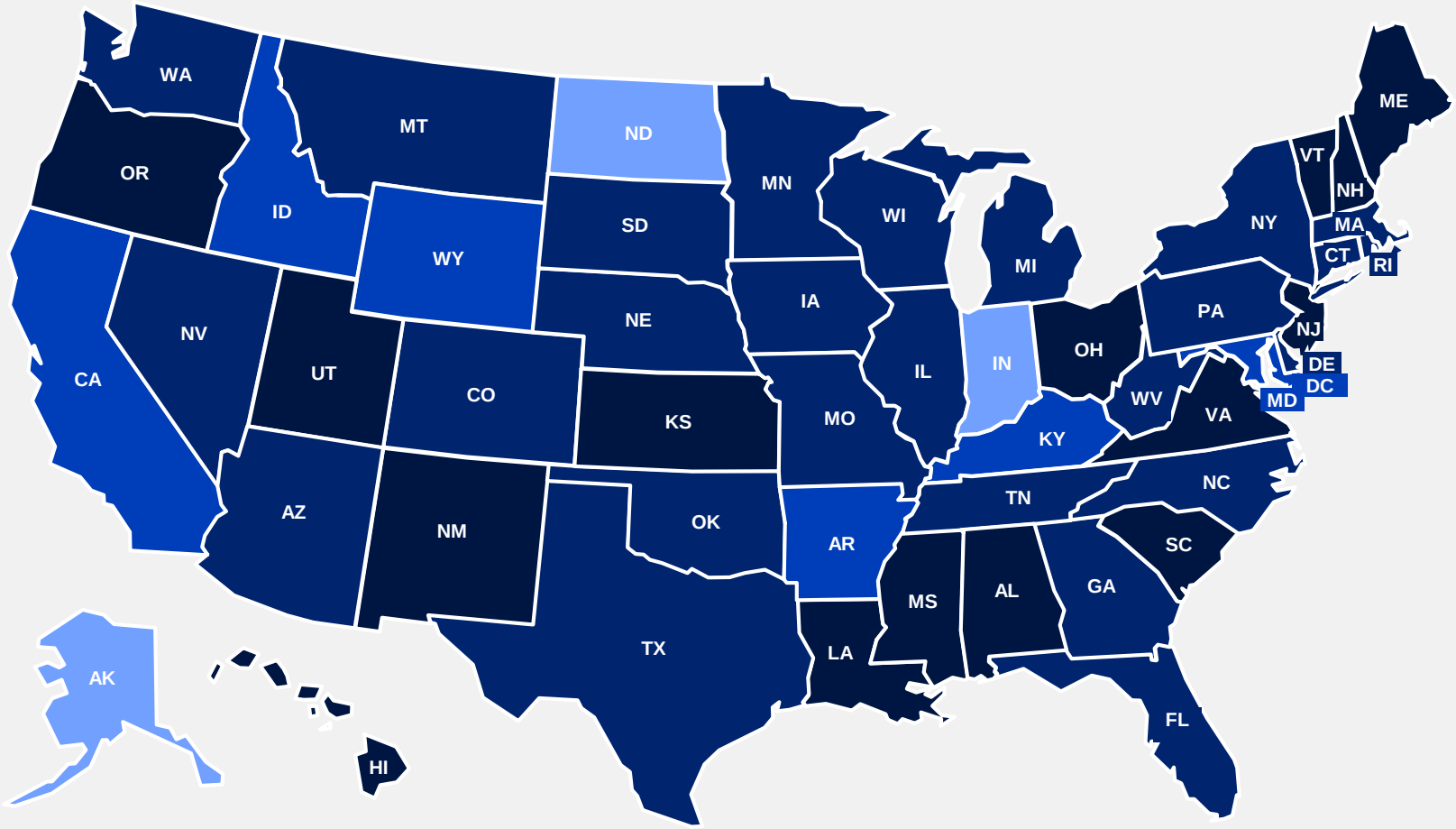
Hospital staff influenza vaccine uptake highest among health care personnel

Percentage of health care personnel who received influenza vaccination, by work setting* — Internet panel surveys, † United States, 2010–11 through 2018 –19 influenza seasons



https://www.cdc.gov/flu/fluvaxview/hcp-coverage_1819estimates.htm

Skilled Nursing Facilities (SNFs) Enrolled in Pharmacy Partnership for Long-Term Care Program

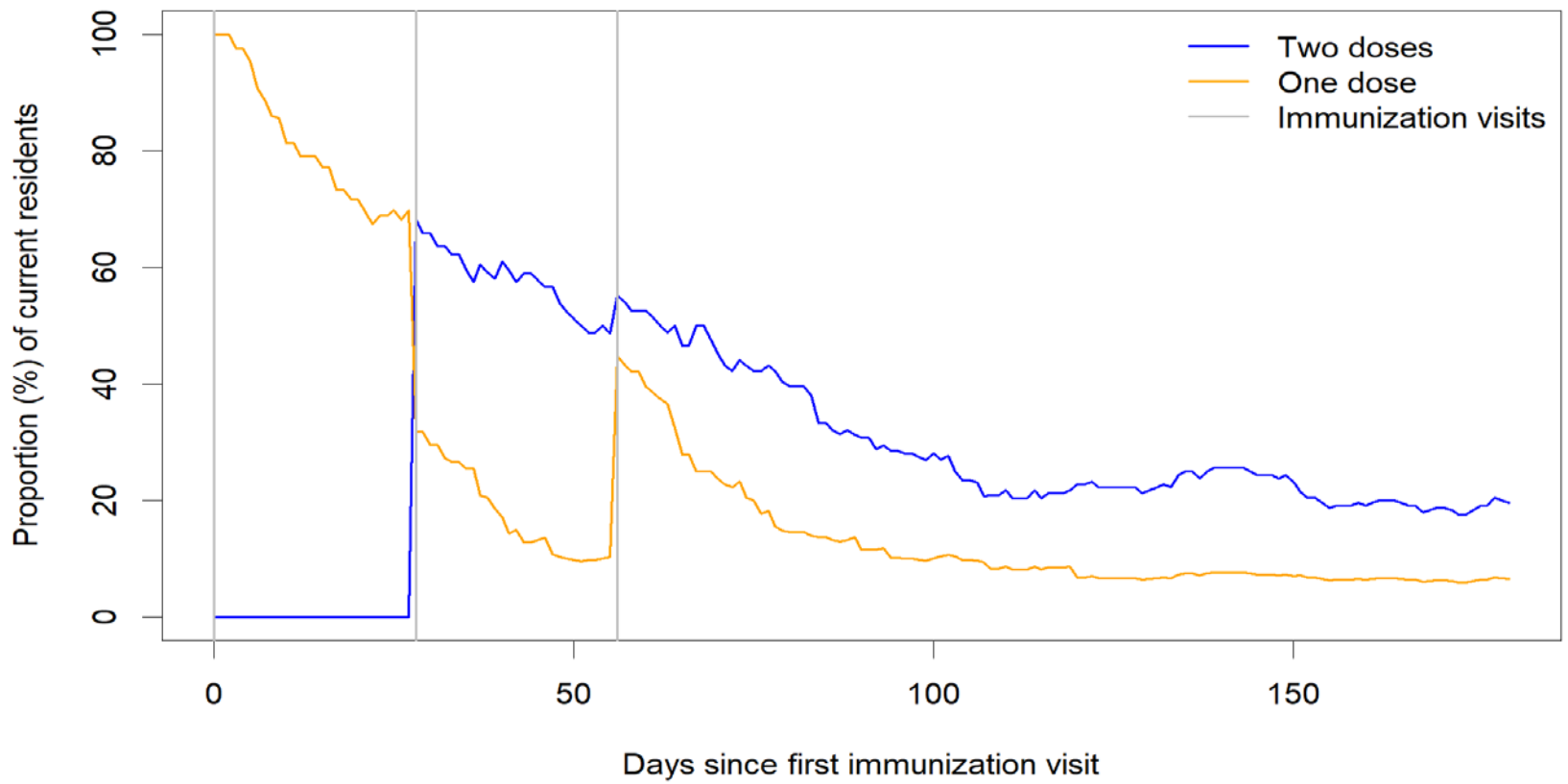


100% of SNFs enrolled
95-99% of SNFs enrolled
90-94% of SNFs enrolled
80-89% of SNFs enrolled
<80% of SNFs enrolled

99% of total SNFs nationwide have enrolled (N=15,353)

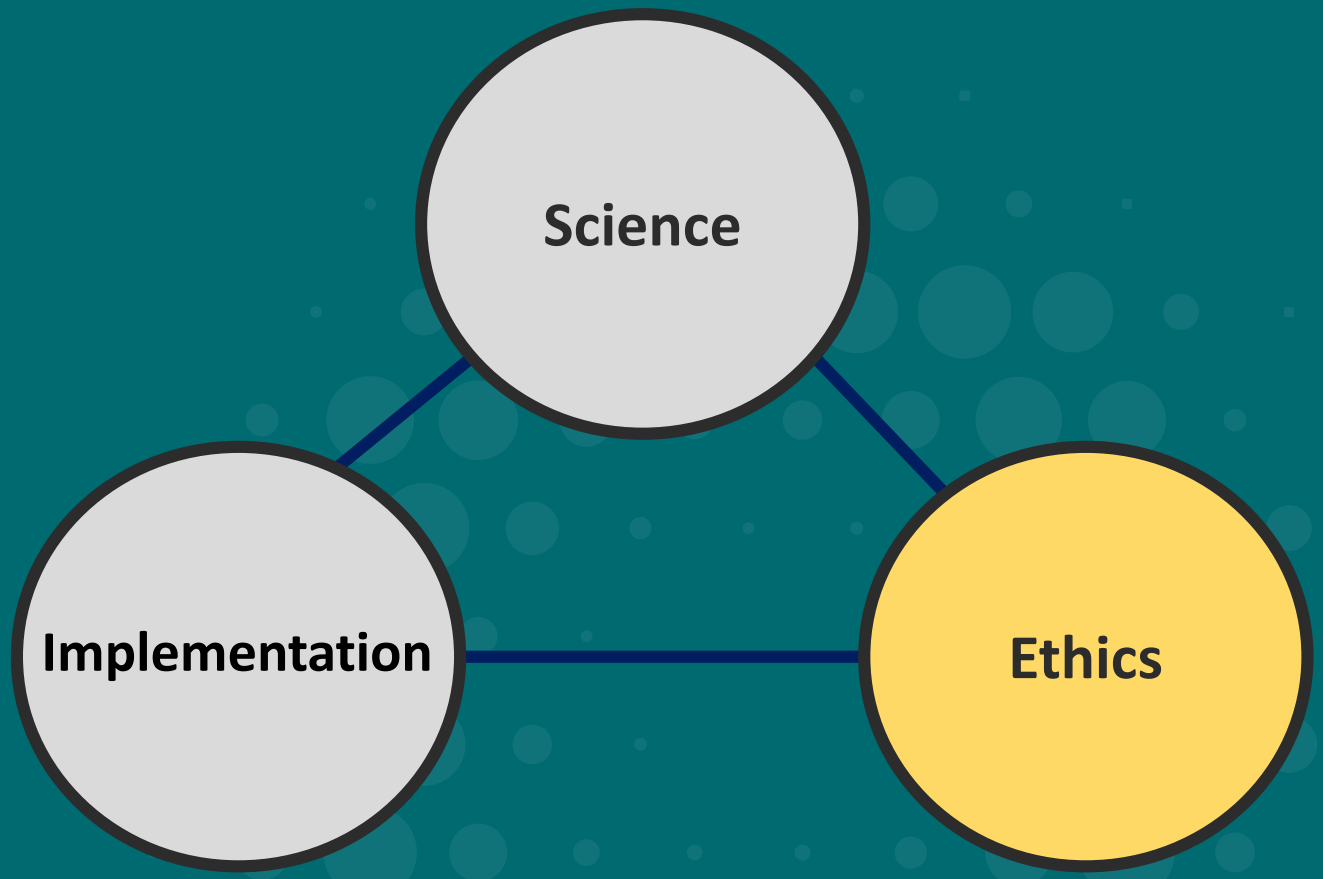
* States >100% enrollment: Numerator may include non-CMS-certified SNFs. Denominator is only CMS-certified.

Example: One-dose and two-dose coverage among Skilled Nursing Facility residents



Note: Results from a simulation run based on SNF lengths of stay, excluding stays longer than a year. Discharge data from MDS Minimum Data Set, 2016

Ethics



Work Group assessment: Ethics

Ethical Principle	Health care personnel (~21 million)	Long-Term Care Facility Residents (~3 Million)
Maximize benefits & minimize harms	Multiplier effect - protection of HCPs and preservation of healthcare capacity	LTCF residents are at high risk for infection severe disease and death from COVID-19. Prevention may reduce hospital utilization
Promote justice	HCP provide care in high-risk settings and will be essential for vaccine distribution	Federal Pharmacy Partnership Program will facilitate equal access to vaccine across most LTCFs
Mitigate health inequities	HCP includes broad range of occupations, inclusive of low-wage earners and racial and minority groups	Federal Pharmacy Partnership Program will reach LTCF across the socioeconomic spectrum

Work Group assessment:

	Health care personnel (~21 million)	Long-Term Care Facility Residents (~3 Million)
Science	+++	+++
Implementation	+++	+++
Ethics	+++	+++

Additional Work Group considerations for Phase 1a

- This represents interim guidance for Phase 1a– allocation policy will need to be dynamic and adapt as new information such as vaccine performance and supply and demand become clear
- Gating criteria will be necessary to move expeditiously from one Phase to the next, as demand saturates
- Following vaccination, measures to stop the possible spread of SARS-CoV-2, such as masks and social distancing, will still be needed
- The U.S. government is committed to making COVID-19 vaccines available to all residents who want them, as soon as possible

Feedback from ACIP meeting, November 23, 2020:

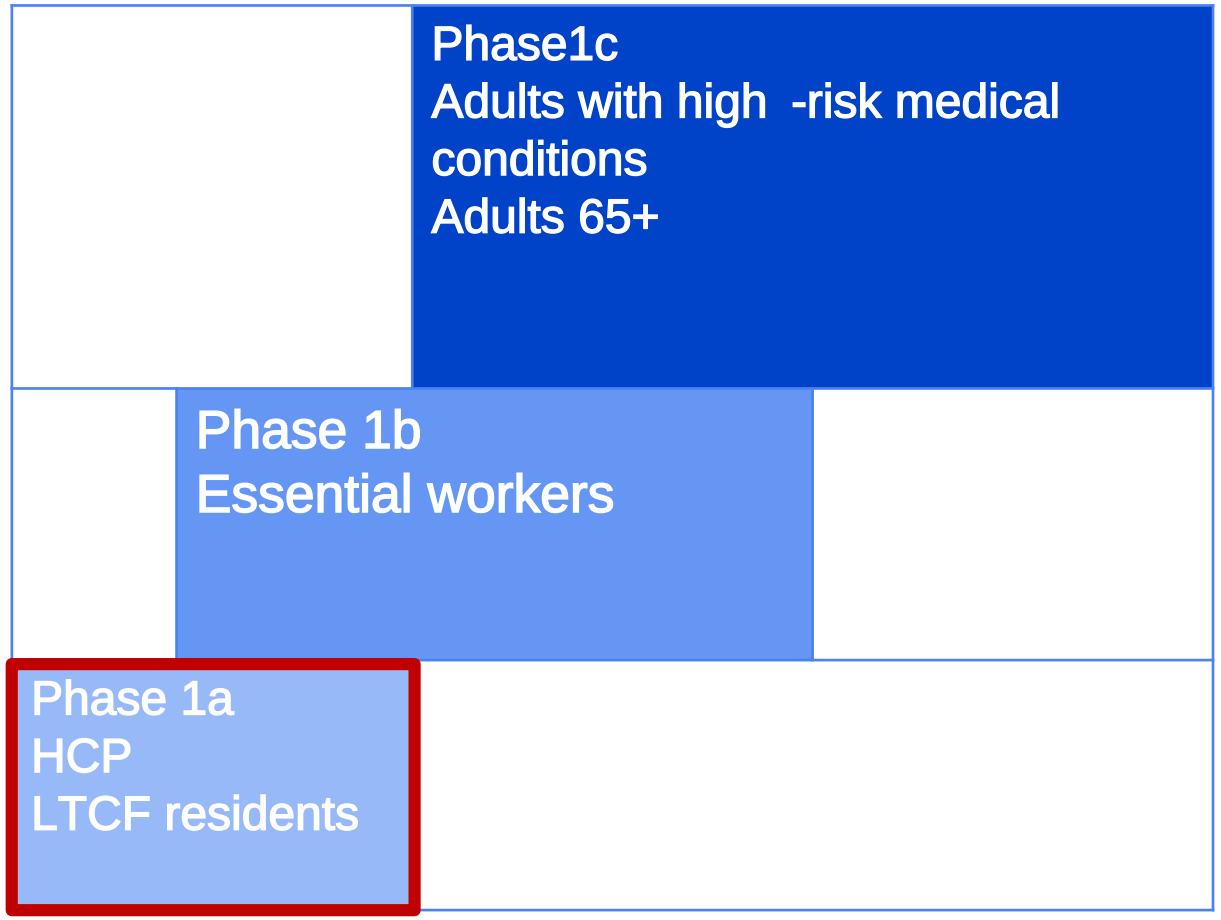
Heath care personnel

- Guidance on sub-prioritization of HCP when vaccine supply is limited
- Address vaccination in pregnant/lactating HCP
- Reactogenicity following vaccination:
  - Guidance on scheduling to avoid potential clustering of worker absenteeism related to systemic reactions
  - Guidance on evaluation of systemic symptoms following vaccination

LTCF Residents

- Understanding of LTCF resident consent/assent for vaccination
- Reactogenicity following vaccination

Proposed Interim Phase 1 Sequence



Policy Question:

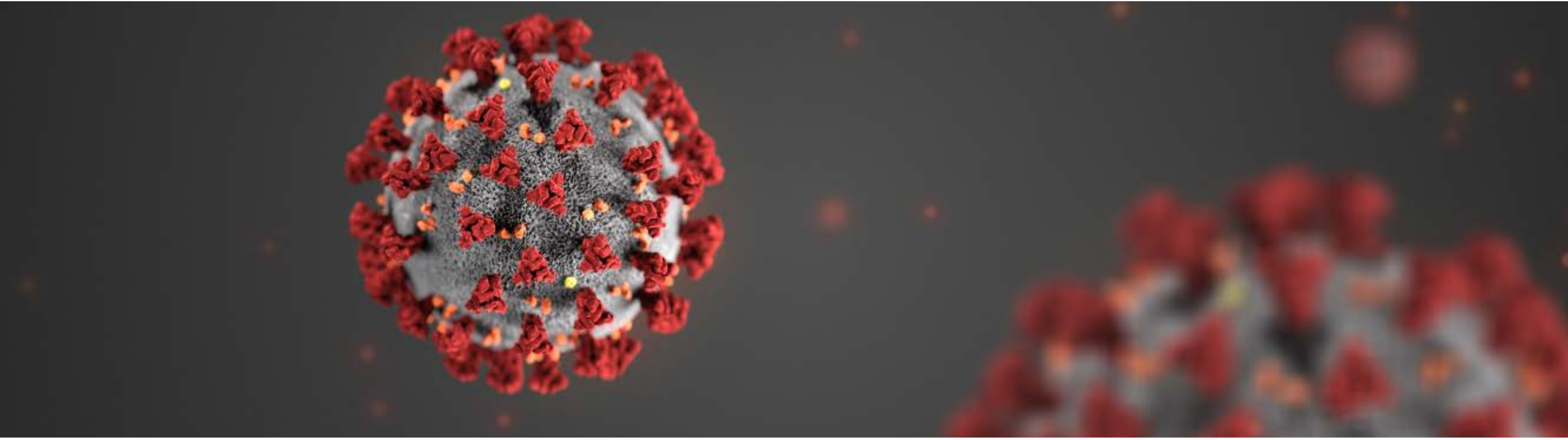
Should health care personnel and residents of long-term care facilities be offered COVID-19 vaccination in Phase 1a?

ACIP Vote – Interim Recommendation

When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, health care personnel[§] and residents of long-term care facilities[¶] should be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a)

[§]Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials

[¶] Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently



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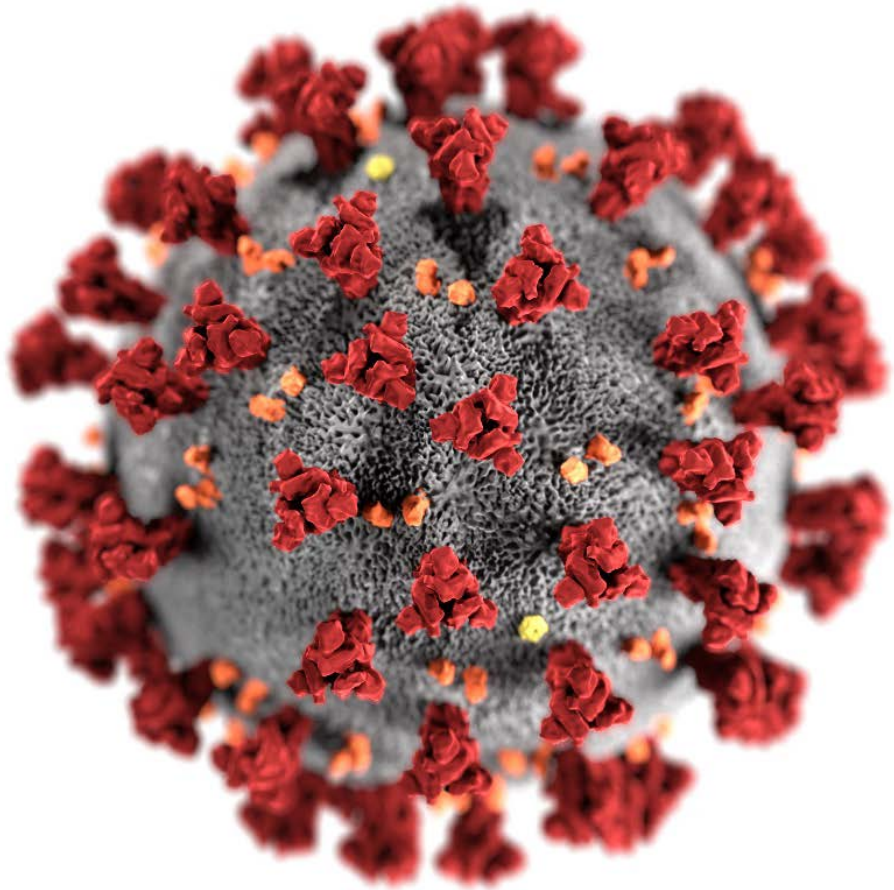
Clinical Considerations for Populations Included in Phase 1a



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 infection[2]
    - Serologic testing **not recommended** prior to vaccination

[1]Within 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

Moderna[1]

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%)	—

Pfizer[2]

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%)	—

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

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

Reactogenicity

Systemic symptoms more common after **second** dose

Data from published Phase I/II trials

Moderna[1]

Adults 18–55 years of age

100µg	Post-dose 1			Post-dose 2		
N=15	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
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[1]Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.

[2]Walsh 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 community[1]
  - 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/staff[2]
  - As of Nov 15, skilled nursing facilities reported nearly 500,000 cases, and 70,000 deaths[3]
  - Through Oct 15, assisted living facilities from 23 states reported 27,965 cases and 20 states reported 5,469 deaths[4]

[1] 2020 LTCF Key Terms and Acronyms (cdc.gov)
[2] The Long-Term Care COVID Tracker | The COVID Tracking Project
[3] COVID-19 Nursing Home Data | Data.CMS.gov
[4] Yi et al. MMWR Nov 20, 2020 Characterization of COVID-19 in Assisted Living Facilities – 39 States, October 2020 | MMWR (cdc.gov)

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

Moderna[1]

≥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

Pfizer[2]

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%)	—

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

[2]Walsh 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

Community-dwelling older adults

Moderna[1] ≥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

Pfizer[2] 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%)	—

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

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

Long-Term Care Facility Residents:
Considerations for Implementation

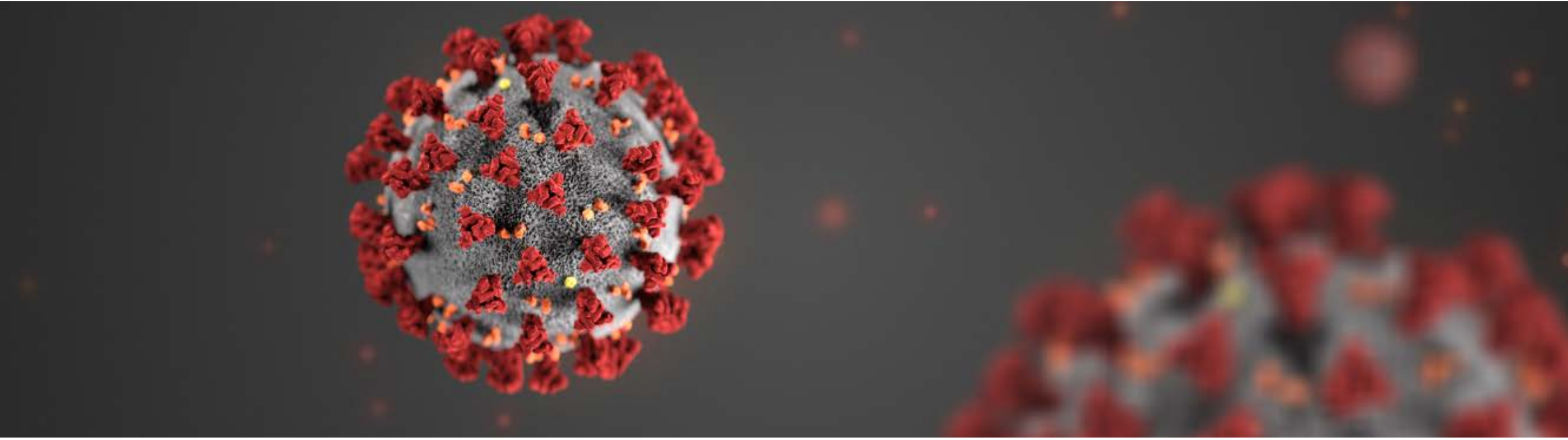
- Federal pharmacy partners supporting the LTCF program will be required to adhere to all EUA Conditions of Use
  - Must provide **fact sheets** to recipients in accordance with the conditions of use
  - EUA fact sheets will be provided directly to staff and residents getting vaccinated, as well as families/medical 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.

COVID-19 vaccine post-authorization safety monitoring update

Tom Shimabukuro, MD, MPH, MBA
U.S. Centers for Disease Control and Prevention
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

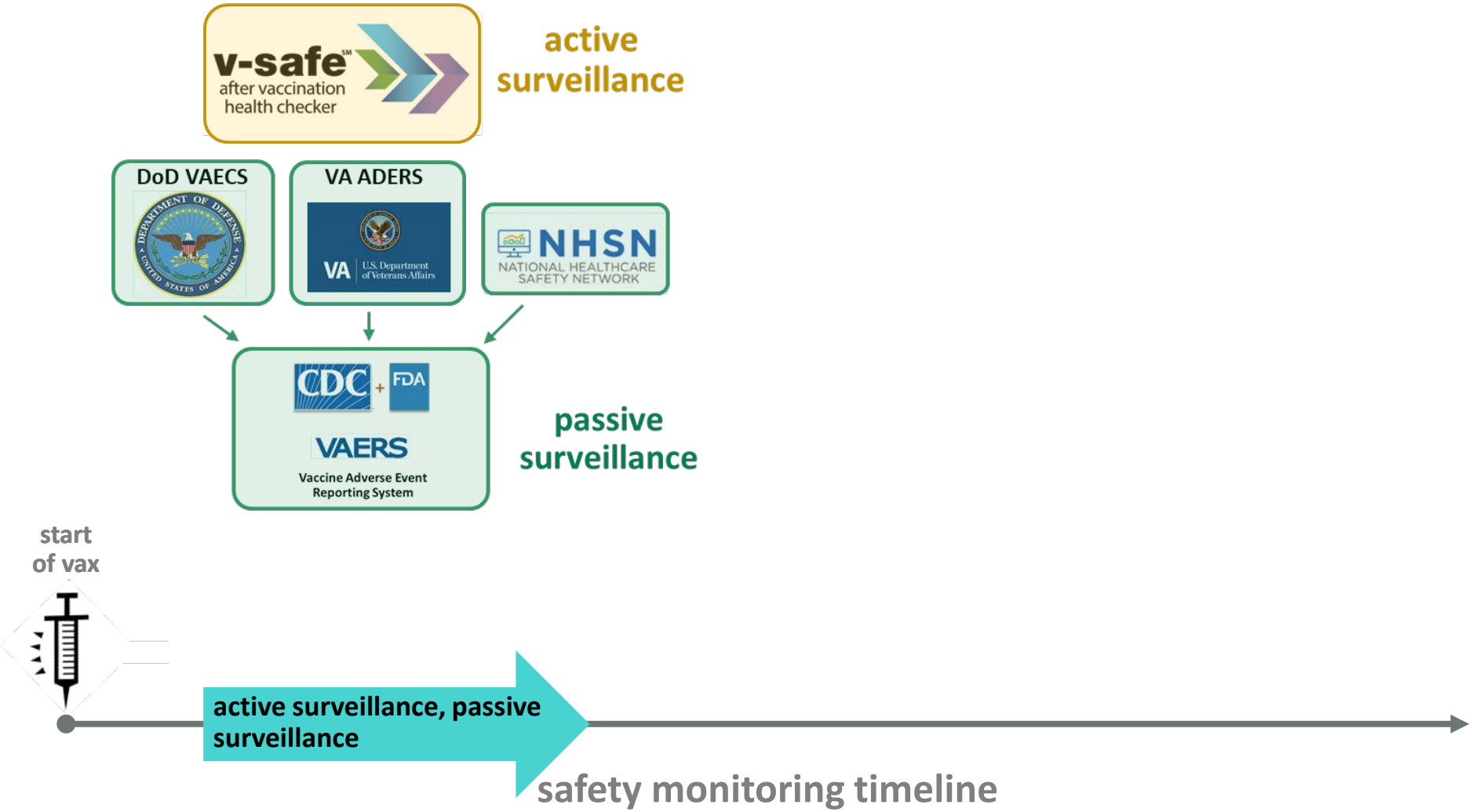
Safety monitoring timeline and covered populations in early vaccination

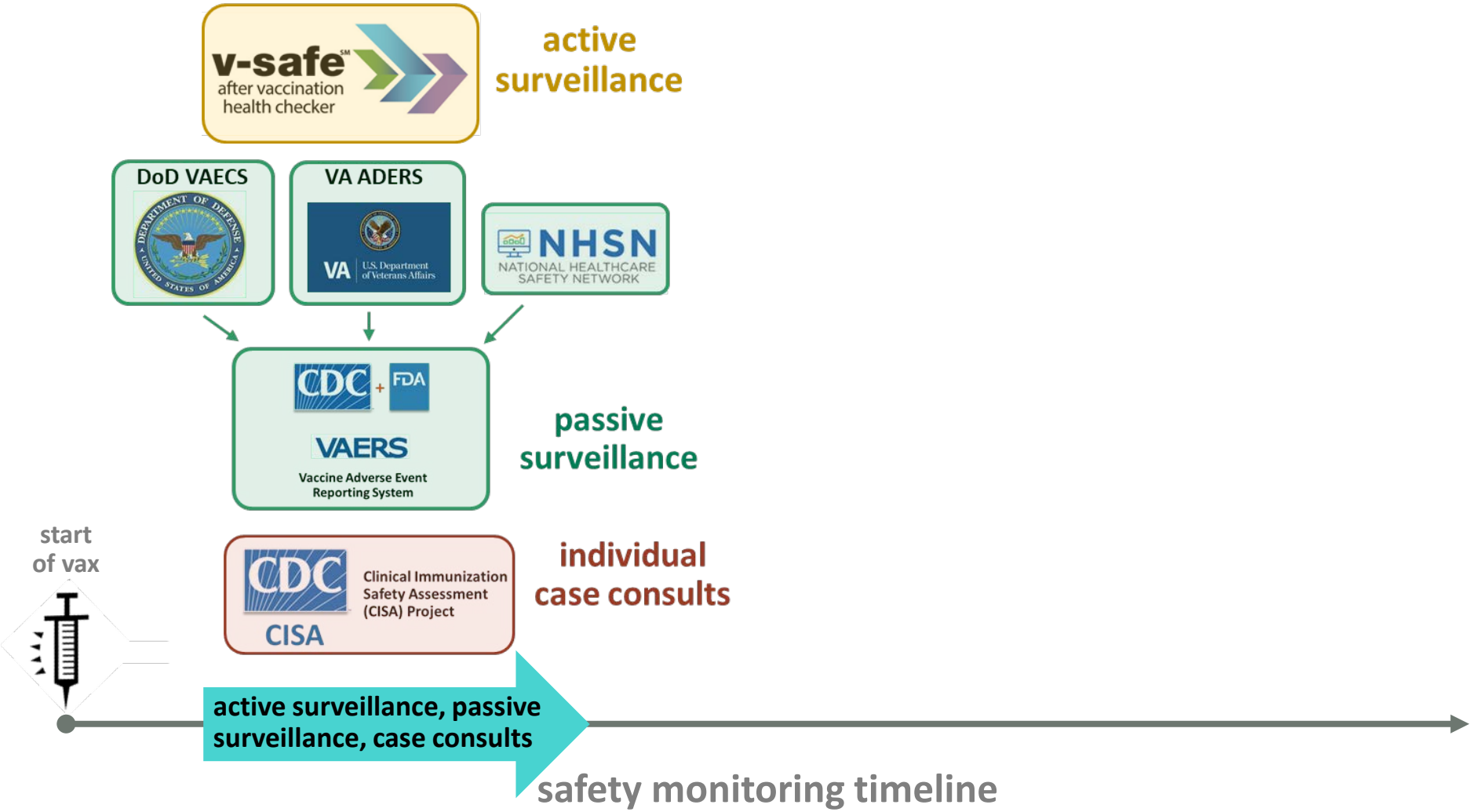
start
of vax

safety monitoring timeline

v-safe℠
after vaccination
health checker

active surveillance


v-safe
after vaccination health checker
active surveillance
DoD VAECS
VA ADERS
VA U.S. Department of Veterans Affairs
NHSN
NATIONAL HEALTHCARE SAFETY NETWORK
CDC + FDA
VAERS
Vaccine Adverse Event Reporting System
passive surveillance
start of vax
active surveillance, passive surveillance
safety monitoring timeline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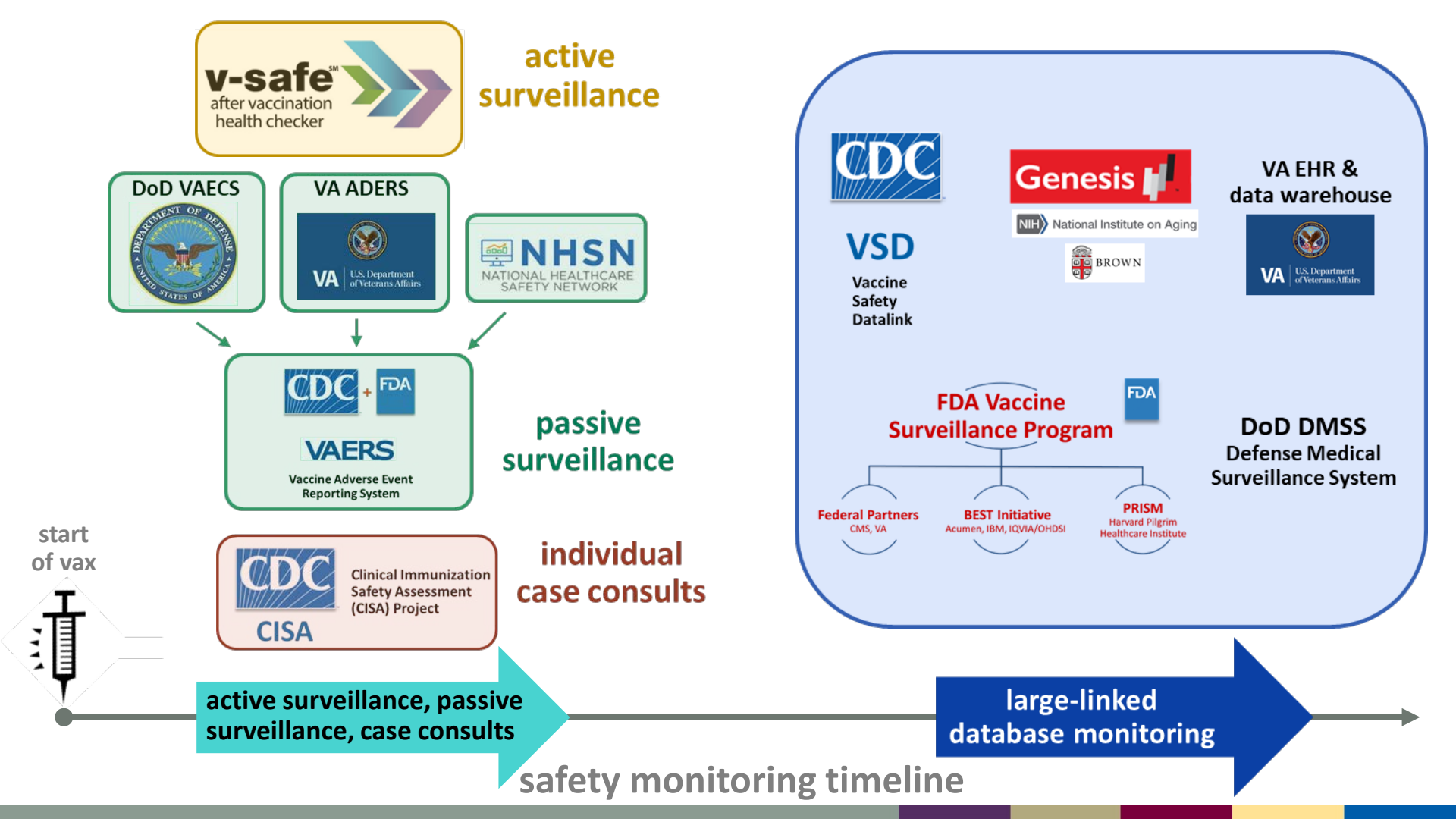
start of vax
CDC
CISA
Clinical Immunization Safety Assessment (CISA) Project
individual case consults
active surveillance, passive surveillance, case consults
safety monitoring timeline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Clinical Immunization Safety Assessment (CISA) Project
CISA
individual case consults
CDC
VSD
Vaccine Safety Datalink
Genesis
NIH National Institute on Aging
BROWN
VA EHR & data warehouse
VA U.S. Department of Veterans Affairs
FDA Vaccine Surveillance Program
FDA
Federal Partners
CMS, VA
BEST Initiative
Acumen, IBM, IQVIA/OHDSI
PRISM
Harvard Pilgrim Healthcare Institute
DoD DMSS
Defense Medical Surveillance System
active surveillance, passive surveillance, case consults
large-linked database monitoring
safety monitoring timeline

Monitoring systems and populations

	Monitoring systems	Population	Healthcare workers	LTCF residents
early	**VAERS** (CDC & FDA) VA ADERS DoD VAECS CDC NHSN	General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities	Yes	Yes
early	**V-safe** (CDC)	All COVID-19 vaccine recipients eligible	Yes	Limited
later	**VSD** (CDC)	Insured patients in VSD sites	Yes	Limited
later	**FDA-CMS**	Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)	Limited	Yes
later	**BEST & PRISM** (FDA)	Insured patients in BEST & PRISM sites	Yes	Limited
later	**VA EHR & data warehouse**	Enrolled VA patients	Limited	Yes
later	**DoD DMSS**	Active duty military (limited info on beneficiaries [i.e., family members, retirees])	Yes	Limited
later	**Genesis HealthCare** (Brown U. & NIH-NIA)	Long-term care facility residents (~35,000 long stay residents)	No	Yes

Routine systems

signal detection

VAERS* (CDC & FDA)

VAECS (DoD)

VA ADERS (VA)

VA EHR & data warehouse

VSD (CDC)

FDA-CMS (FDA & CMS)

DMSS (DoD)

signal assessment

VSD (CDC)

FDA-CMS (FDA & CMS)

VA EHR & data warehouse

CISA (CDC)

DMSS (DoD)

New systems

signal detection

v-safe (CDC)

BEST# (FDA)

Sentinel surveillance (DoD MTFs)

NHSN (CDC)

Genesis LTCF (Brown U. & NIH

signal assessment

BEST# (FDA)

Other EHR and payer partners (FDA)

*DoD and IHS have VAERS data sharing agreements with CDC; #BEST includes most of the major partners from Sentinel PRISM

Safety monitoring in long-term care facility residents

VAERS is the nation's early warning system for vaccine safety

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

VAERS covers the entire U.S. population

- **320 million U.S. residents** as a covered population for safety monitoring
- All ages, races, occupations (**including healthcare workers**) states/jurisdictions, healthy people, those with chronic health problems, **long-term care facility residents**, older adults living in the community, etc.

VAERS

VA Adverse Drug Event Reporting System (ADERS)

- Includes VA healthcare workers
- Includes 8,000 residents per day in VA LTCFs

reports to VAERS

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1070
Transmittal Sheet
May 15, 2020

ADVERSE DRUG EVENT REPORTING AND MONITORING

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes national policy for the reporting, monitoring, and surveillance of adverse drug events (ADEs) entered into VHA's voluntary ADE reporting system for observed adverse drug reactions (ADRs) and new ADEs at Department of Veterans Affairs (VA) medical facilities. ***NOTE***: *This directive also maintains national policy, which is co-managed by the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) on the reporting requirements of ADEs due to vaccines.*

4. POLICY

It is VHA policy that ADEs voluntarily reported to VA ADERS that meet the criteria of serious adverse drug events must be reported to FDA MedWatch. ADEs due to vaccines must be reported to VAERS. The ADEs and observed ADRs in subjects participating in VA clinical trials or research protocols must be reported into VA ADERS, when appropriate, to enhance Veteran safety. ***NOTE:*** *ADRs are the majority of the ADEs reported to the VA ADERS program, but for clarity, both ADE and ADR are noted here.*

5. RESPONSIBILITIES

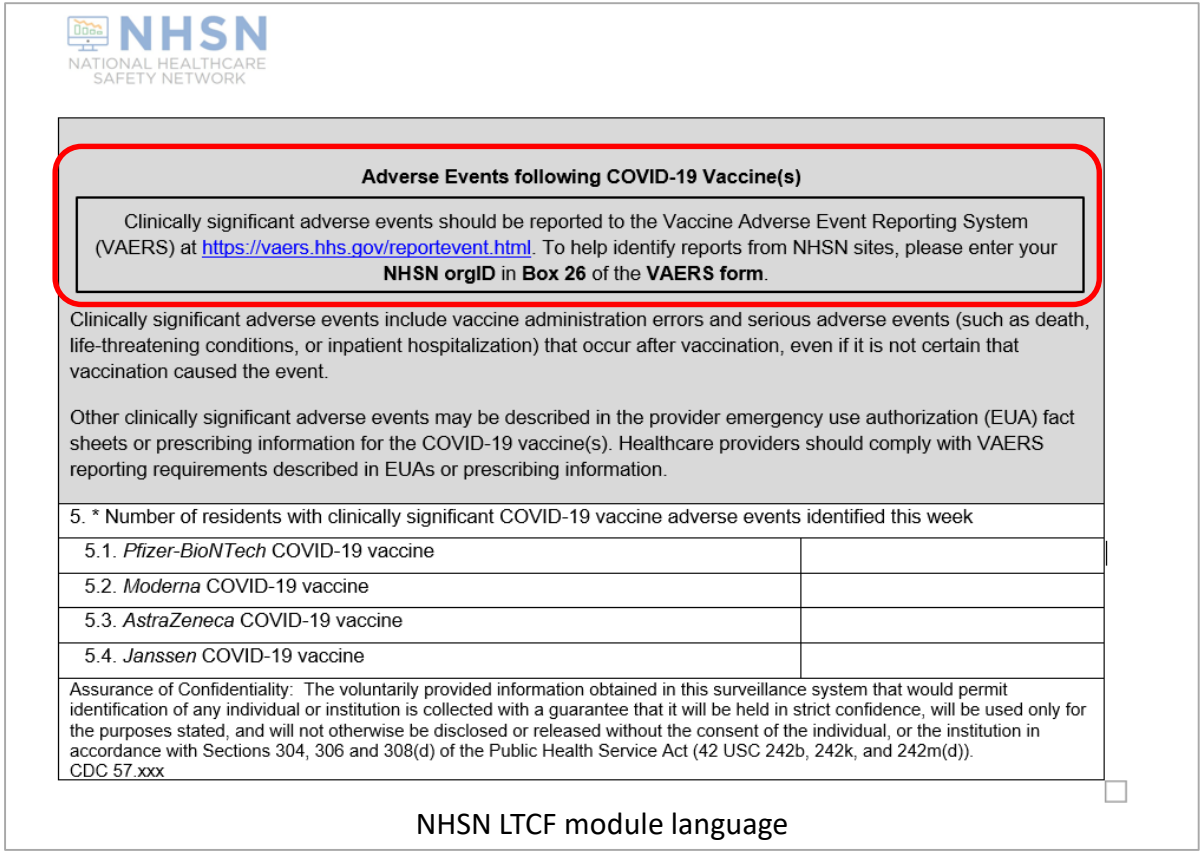
a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

4

https://www.va.gov/vhapublications/publications.cfm?pub=1

National Healthcare Safety Network (NHSN)



NHSN
NATIONAL HEALTHCARE SAFETY NETWORK

Adverse Events following COVID-19 Vaccine(s)

Clinically significant adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html. To help identify reports from NHSN sites, please enter your **NHSN orgID** in **Box 26** of the **VAERS form**.

Clinically significant adverse events include vaccine administration errors and serious adverse events (such as death, life-threatening conditions, or inpatient hospitalization) that occur after vaccination, even if it is not certain that vaccination caused the event.

Other clinically significant adverse events may be described in the provider emergency use authorization (EUA) fact sheets or prescribing information for the COVID-19 vaccine(s). Healthcare providers should comply with VAERS reporting requirements described in EUAs or prescribing information.

5. * Number of residents with clinically significant COVID-19 vaccine adverse events identified this week	
5.1. *Pfizer-BioNTech* COVID-19 vaccine	
5.2. *Moderna* COVID-19 vaccine	
5.3. *AstraZeneca* COVID-19 vaccine	
5.4. *Janssen* COVID-19 vaccine	

Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).
CDC 57.xxx

NHSN LTCF module language

- 17,000 LTC facilities
- Aggregate voluntary reporting of vaccine doses administered and counts of non-specific AEs
- Guidance on reporting AEs to VAERS

Pharmacy partnership program for LTCF vaccination

- Pharmacy partners may vaccinate in 70-80% of LTCFs
  - Can provide early denominator information (COVID-19 vaccine doses administered) in LTCF residents
    - Will improve the accuracy of reporting rate estimates
  - Outreach to pharmacy partners on VAERS reporting planned

Rapid Cycle Analysis (RCA) in 65+ y/o adults

- FDA RCA in CMS data
  - 55-60 million 65+ y/o (92% of the U.S. elderly), including ~650K LTCF residents
  - Data are refreshed weekly with weekly sequential analyses
  - CMS Medicare (FFS) average data lag is around 4 weeks; average data lag can be up to 5-6 weeks for hospitalizations (mostly due to hospital stay)
- VA RCA in VA electronic health record and data warehouse
  - Historically, 60% of VA patients who get flu vaccination are 65+ y/o (~1.56 million 65+ y/o vaccinated for flu annually in recent years)
  - ~8,000 LTCF (VA Community Living Centers) residents per day
  - Data refreshed weekly with weekly sequential analyses
  - Approximate 1-week average data lag; up to around 4 weeks for hospitalization (mostly due to hospital stay)

Rapid Cycle Analysis (RCA) in 65+ y/o adults

- CDC RCA in the Vaccine safety Datalink (VSD)
  - 1.8 million 65+ y/o (9 integrated health systems)
  - Data refreshed weekly with weekly sequential analyses
  - Approximate 1- to 2-week average data lag; up to around 6 weeks for hospitalization (mostly due to hospital stay)

Case evaluations of adverse events

Planned activities

- Rapid processing and review of reports to VAERS classified as serious* and for adverse events of special interest
- Investigation of clusters of clinically serious adverse events by multidisciplinary CDC teams if necessary
- Clinical case reviews by CDC's Clinical Immunization Safety Assessment (CISA) Project

*Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect

Coordination, communication, and implementation

ACIP COVID-19 Vaccine Safety Technical Sub-Group (VaST)

- Built off lessons learned from H1N1 vaccine safety monitoring
- Terms of reference and composition are finalized and VaST is ready to begin reviewing data once implementation commences
  - Co-Chaired by ACIP member and a National Vaccine Advisory Committee (NVAC) member
  - ACIP and NVAC representation
  - 7 independent expert consultants
  - ACIP federal agency ex officio members (NIH, FDA, OIDP, CMS, HRSA, IHS)
  - Veterans Affairs (VA) and Department of Defense (DoD) liaisons

VaST post-implementation objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data
- Serve as the central hub for technical SMEs from federal agencies conducting post-authorization/approval safety monitoring to share vaccine safety surveillance data
- Advise on analyses, interpretation, and data presentation
- Liaise with the ACIP COVID-19 Vaccines WG on issues of safety data presentation to the ACIP and application of safety data to policy decisions

Communication: product dissemination and outreach

- Distribute communications materials to state health officials, healthcare providers, and healthcare systems
- Provide up-to-date information and Q&A on CDC COVID-19 website
- Conduct ongoing partner outreach and engagement to raise awareness of **v-safe** and VAERS reporting requirements
  - Healthcare provider professional organizations
  - Public health partners
  - Healthcare organization and other private sector partners
  - Long-term care partners
  - Pharmacy partners

Summary

- Early data on COVID-19 vaccine safety in **healthcare workers** will be mainly available through v-safe and VAERS and systems that report into VAERS
- Early data on safety in **LTCF residents** will be mainly available through VAERS and systems that report into VAERS
- VAERS is a long-standing established safety monitoring system that is critical to monitoring new vaccines during the early uptake period
- Large-linked database monitoring systems (e.g., CDC's Vaccine Safety Datalink) will provide safety data when vaccines become more widely available in priority groups and in the general population
- Efforts are ongoing to increase awareness and provide information needed to partners for safety monitoring

Your role

COVID-19 vaccine safety gets stronger with your participation

Public health partners

- promote participation in **v-safe** ✓
- promote reporting to **VAERS** ✓
- communicate with your partners on vaccine safety ✓

Healthcare providers

- encourage patient participation in **v-safe** ✓
- report adverse events to **VAERS** ✓
- communicate with patients on vaccine safety ✓

How to report an adverse event to VAERS

- Go to vaers.hhs.gov and submit a report online
- For help: call 1-800-822-7967, email info@VAERS.org
- Video instructions https://www.youtube.com/watch?v=sbCWhcQADFE

How to contact CDC at CDC-INFO

- Go to https://www.cdc.gov/cdc-info/index.html
- Call 1-800-CDC-INFO (800-232-4636)

CDC-INFO
You have questions? We have answers.
CDC's national contact center and publications fulfillment system

Safety information resources

- https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Questions