

# Background on COVID-19 Vaccine Prioritization Frameworks and Considerations for Subprioritizing Vaccine Among Healthcare Personnel (HCP) in Idaho

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# Agenda

- Overview of vaccine program assumptions and vaccines in development and storage/handling challenges
- Overview of Vaccine Prioritization Frameworks
  - CDC current statements on vaccine prioritization
  - World Health Organization
  - Johns Hopkins Framework for Vaccine prioritization
  - National Academy of Medicine prioritization framework
- DRAFT IDAHO healthcare personnel (HCP) vaccine subprioritization
- Discussion regarding goals and principles for Idaho COVID-19 Vaccination Program
- Discussion of HCP subprioritization

# COVID-19 Vaccine Planning Assumptions

- Vaccine supply in 2020 will be limited
  - Prioritization will be recommended by CDC and USG
  - Sub-prioritization of groups in vaccine phases likely needed
- For 2-dose vaccines, both doses must be same COVID-19 vaccine brand

# Process for Evaluating Safety and Effectiveness of COVID-19 Vaccines

Multiple layers of safety and effectiveness evaluation for new vaccines

- Study protocols first reviewed by FDA and ethics committees (IRBs)
  - Rules set in advance about potential triggers to halt a study
- Each study has Data Safety Monitoring Board (DSMB) that includes a statistician and other experts – can view unblinded data during study, if needed
- Review by FDA and FDA’s outside advisory group “Vaccines and Related Biological Products Advisory Committee”
- Review by CDC and CDC’s Advisory Committee on Immunization Practices (ACIP)

# How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

## PHASE 1



**20-100  
healthy volunteers**

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

## PHASE 2



**several hundred  
volunteers**

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

## PHASE 3



**hundreds or thousands  
of volunteers**

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

**FDA licenses the vaccine only if:**

- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.



Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.



FOR MORE INFORMATION, VISIT [HTTPS://WWW.FDA.GOV/CBER](https://www.fda.gov/cber)

[www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

## Selected COVID-19 Vaccines Most Likely for U.S. Market

	Univ. of Oxford (Jenner Institute) with AstraZeneca	ModernaTX USA	BioNTech with Pfizer	Johnson & Johnson (Janssen Vaccines)	Novavax	Sanofi Pasteur with GlaxoSmithKline
Vax candidate/ type	ChAdOx1 Adenovirus vector	mRNA-1273	BNT162-b2 mRNA	Ad26.COVS2-S or S.PP Adenovirus vector	NVX-CoV2373 Subunit protein with Matrix-M	Subunit protein with ASO3 adjuvant
Dosing	Single dose or Days 0 + 28-42	Days 0 + 28	Days 0 + 21	Single dose or Days 0 + 56	Days 0 + 21	Not available
Storage	2-8°C <b>US Trial Paused</b>	Ship @ -20°C. 2-8°C 1 week; 6 hours to use one 10-dose vial once first dose removed	Ship w/ dry ice. POC dry ice. 2-8°C 5 days; use 5-dose vial within 6 hours of reconstitution	2-8°C <b>US Trial Paused</b>	2-8°C	2-8°C  Mix antigen w/ adjuvant prior to vaccination.
Clinical Trial Status	Phase 2/3	Phase 3	Phase 3	Phase 3	Phase 3	Phase 1
Ages Studied (y)	18-55, 5-12	18+	12-85	18+	18-84	18+

\*Publicly reported information. Subject to change.

# CDC/ACIP Discussions on Prioritization, September 22, 2020

- Goals

- Minimize death and serious illness
- Preserve functioning of society
- Reduce disproportionate burden due to disparities
- Increase equity of opportunity to enjoy health and well-being

- Ethical principles

- Maximize benefits and minimize harms
- Equity
- Justice
- Fairness
- Transparency

# Likely CDC-Recommended Early Groups for Vaccine Prioritization

- 1a. Healthcare personnel – any paid or unpaid persons working in healthcare serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials
- 1b. Large group including:
  - Essential workers
  - Adults 65 years and older
  - Adults <65 yrs with high risk conditions
- ACIP / CDC meeting Oct 28-30
- CDC ACIP have mentioned states will likely need to subprioritize vaccine



# Healthcare Personnel within COVID-NET

March 1 to July 11, 2020

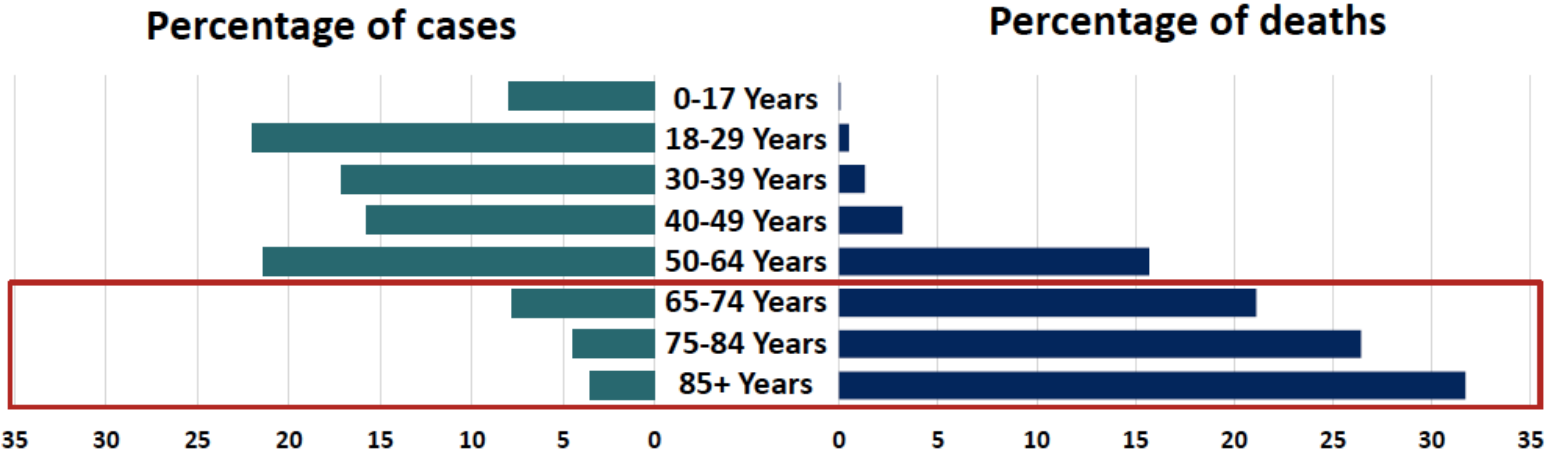
## Healthcare Personnel Type: N=512

- Respiratory Therapist: 3 (<1%)
- Physician: 23 (5%)
- Nurse: 125 (24%)
- Other: 276 (54%)
- Not specified: 85 (17%)

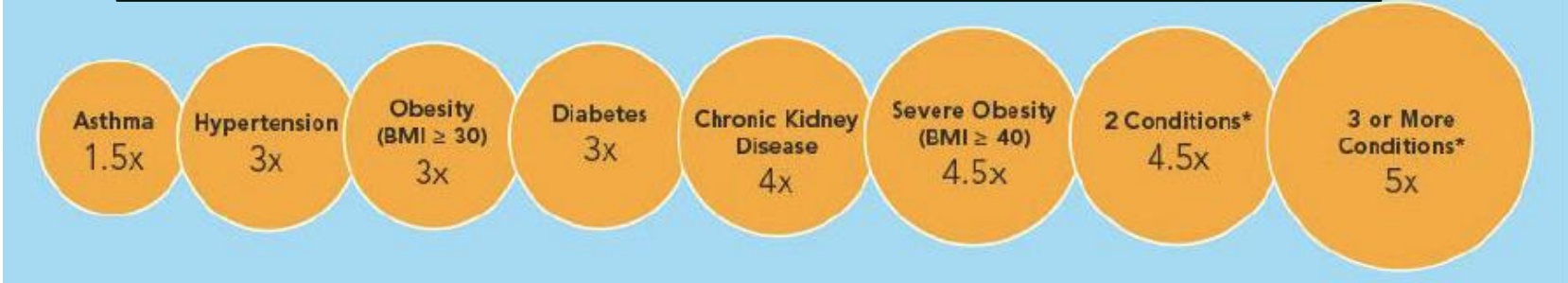


Hospital-based patient care support (e.g. nursing assistant)	73
Other patient care	21
Housekeeping/Environmental Services	20
Other nursing home/LTCF staff	17
Technicians	15
Management	12
Home health worker	12
Emergency medical personnel	10
Social work/counselor	10
Pharmacy	9
Food Services	8
Dentistry	6
Laboratory	6
Other	57

In the United States, adults aged 65 years or older represent 16% of COVID-19 cases, but nearly 80% of COVID-19 deaths



Chronic Conditions Increased risk of being hospitalized with COVID

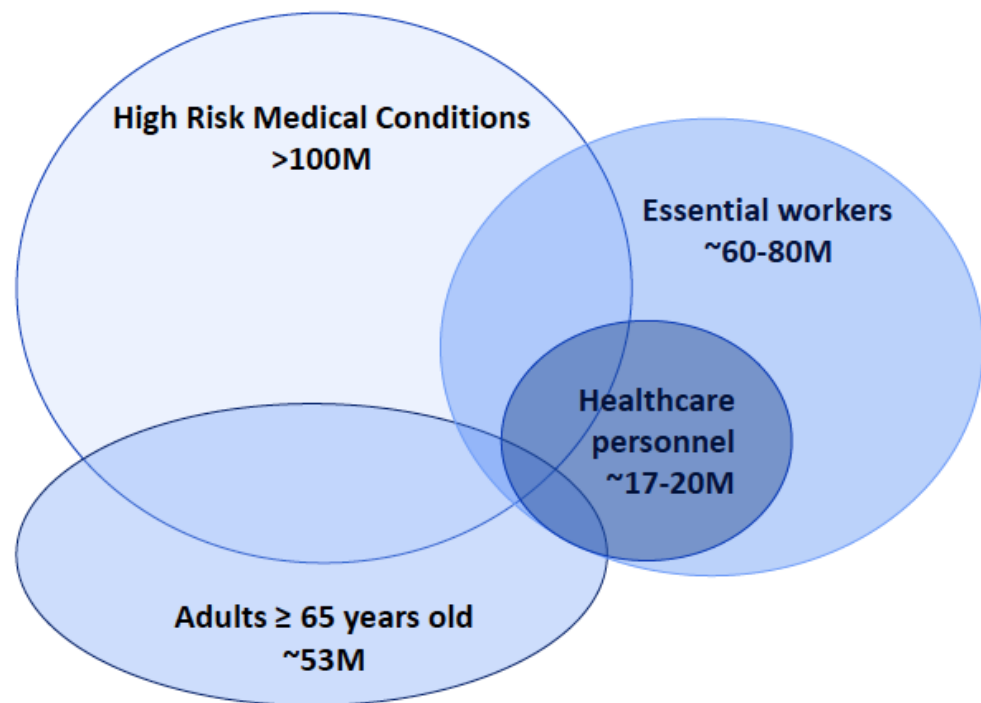


# Critical Infrastructure Sectors

- Non-HCP Critical Infrastructure Personnel Highlighted by ACIP
  - Corrections
  - Food processing
- Other Critical Infrastructure Sectors
  - Education – includes daycare
  - Chemical
  - Commercial facilities
  - Communications
  - Critical Manufacturing
  - Dams
- Other CI, con't
  - Defense industrial base
  - Emergency Services (law enforcement, child protective services, etc.)
  - Energy
  - Financial services
  - Government
  - Information technology
  - Nuclear reactors, materials, and waste
  - Transportation systems
  - Water and wastewater systems

## Summary: Groups for early phase vaccination

- Overlapping
- Significant heterogeneity
- Accounts for > half of U.S. adults
- Need for additional sub-grouping



# WHO SAGE Interim Framework for COVID-19 Vaccine Allocation

- WHO overarching goal: utilitarian: maximize the amount of societal good or benefit
- WHO principle: Reciprocity
  - Honor obligations of reciprocity to those individuals and groups within countries who bear substantial additional risks and burdens of COVID-19 response for the benefit of society
    - Occupation groups judged to be essential differ in the degree of risk their jobs entail and therefore obligations of reciprocity do not apply evenly to all.
  - In addition, “front-line” health and social care workers often in close contact with people who biologically most likely to experience serious COVID-19 if infected and who might be afforded some level of protection if these workers were vaccinated.
- WHO – HCP at high or very high risk – definition yet to be published

# Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States, Johns Hopkins U., August 2020

- Principles:

- Promoting the common good by promoting public health and enabling social and economic activity
- Treating individuals fairly and promoting social equity
  - recognizing the contributions of essential workers who have been overlooked in previous allocation frameworks.
- Promoting legitimacy, trust, and a sense of community ownership over vaccine policy, while respecting the diversity of values and beliefs in our pluralist society.

Note: All authors were from JHU

[https://www.centerforhealthsecurity.org/our-work/pubs\\_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf](https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf)

# Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States, JHU, August 2020

- Goals:
  - Prevent COVID-19-related illness and death
  - Prevent injury, illness, and death from other causes (non-COVID-19)
  - Protect the health system
  - Protect essential services
  - Enable economic activity more broadly
  - Enable children and adult staff to return to school and childcare
  - Among systematically disadvantaged groups and marginalized populations
    - Reduce higher rates of severe COVID-19 illness and mortality
    - Address disproportionate economic and social impact
  - Protect those at highest risk of severe illness and death, especially those with the most years of life left to live
  - Reduce burdens on those with both high health and economic risks

[Note: All authors were from JHU](#)

[https://www.centerforhealthsecurity.org/our-work/pubs\\_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf](https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf)

# JHU Framework – HCP considerations for prioritization with regards to goals and principles

- Close contacts of people at very high risk (eg, nursing home and long-term care facility workers, home health aides, household contacts of those at very high risk)
- Health system workers in contact with COVID-19 patients (eg, nursing home and long-term care facility residents and workers; healthcare workers assigned to care for COVID-19 patients; frontline healthcare workers doing direct patient care; emergency medical services personnel)
- Healthcare workers (including healthcare support staff such as environmental, food, and maintenance services)
- Emergency medical services personnel
- Workers needed for the vaccination effort (eg, vaccinators, vaccine and supply chain workers)
- Workers (essential or nonessential) who cannot work remotely and have higher infection risk or risk of poor outcomes (eg, workers with comorbid conditions)
- Worker groups with a high rate of lower-income workers (eg, home health aides, long-term care facility workers, food retail workers, farmworkers)
- Essential workers with comorbid conditions
- Essential workers with high risk household contacts



# JHU Framework – HCP considered as Vaccination Phase 1 Candidates

- Those most essential in sustaining the ongoing COVID-19 response
  - Frontline health workers providing care for COVID-19 patients
  - Frontline emergency medical services personnel
  - Pandemic vaccine manufacturing and supply chain personnel
  - COVID-19 diagnostic and immunization teams
  - Public health workers carrying out critical, frontline interventions in the community
- Those most essential to maintaining core societal functions
  - Frontline long-term care providers
  - Healthcare workers providing direct care to patients with high-risk conditions
- Those at greatest risk of severe illness and death, and their caregivers

“Frontline” not defined in table of candidate groups for prioritization.

# National Academy of Medicine Framework For Equitable Allocation of COVID-19 Vaccine

- Principles: Maximize benefits \* Equal regard \* Mitigate health inequities \* Fairness \* Evidence-based \* Transparency
- Overarching goal : Maximize societal benefit by reducing morbidity and mortality caused by transmission of SARS-CoV-2
- Allocation criteria are risk based
- Individuals have higher priority to the extent of their:
  - Risk of acquiring infection
  - Risk of severe morbidity and mortality
  - Risk of negative societal impact
  - Risk of transmitting disease

# National Academy of Medicine Framework For Equitable Allocation of COVID-19 Vaccine

- Phase 1a. High-risk health workers (e.g., in hospitals, nursing homes, or providing home care) – those involved in direct patient care.
  - Specifically includes workers who provide transportation, environmental services, and others who risk exposure to bodily fluids or aerosols.
  - Rationale: critical role in maintaining health care system, high risk of being exposed to COVID-19 by patients, and risk of transmitting the virus to others, including family
  - Workers in communities disproportionately impacted by COVID-19
- Phase 1a. First responders

# National Academy of Medicine Framework For Equitable Allocation of COVID-19 Vaccine

- Phase 1b.
  - Older adults living in congregate settings—such as nursing homes or skilled nursing facilities—and other similar settings.
  - Individuals with select high-risk comorbid and underlying conditions
- Phase 2
  - K-12 teachers and school staff
  - Other workers in essential industries
  - Older adults
  - Adults with high risk conditions
  - Persons living in congregate settings and staff (corrections, group homes, homeless shelters)

# National Academy of Medicine Framework For Equitable Allocation of COVID-19 Vaccine

- Phase 3 – broad immunization of other workers, young adults and children (if vaccines tested in children)
- Phase 4 – persons interested in vaccination for their personal protection

# Idaho DRAFT COVID-19 Vaccine Program Goals

- Reduce transmission, severe illness and death
- Preserve functioning of healthcare system
- Recover functioning of society
- Protect persons at risk who have access and functional needs
- Ensure equitable distribution and the equity of opportunity to enjoy health and well-being

# Principles and Factors Considered

- Ethical frameworks published by others described above
- Risk of severe disease or death (e.g., because of age, medical conditions, race or ethnicity)
- Risk of exposure to COVID-19-infected persons based on occupation, the ability to physically distance, access to personal protective equipment (PPE), and living circumstances (e.g., congregate or crowded living conditions).
- Risk of exposing others who are at increased risk of severe disease or death (e.g., live with or caregiver for those at increased risk)
- Impact of occupation on resuming community functioning
- Maintenance of community safety, including law and order

Feasibility of implementation for specific vaccine products

# Discussion

- Goals
  - Any that should be added or changed?
- Principles and factors considered
  - Any that should be added or changed?



# Healthcare Personnel Sub-prioritization Groups – Population Estimates in Development

Hospital and clinic staff essential for care of COVID-19 patients and maintaining hospital capacity. ^	~32,117 = hospital staff per ID Division of Licensing and Certification (IDLC)
<ul style="list-style-type: none"> <li>LTCF staff</li> <li>Home care providers for adults age 65 years and other adults and children with high risk medical conditions.</li> </ul>	~12,500– 14,500 per IDLC
Emergency Medical Services (EMS)*	~4,128 – per <a href="https://www.nremt.org/rwd/public/data/maps/">https://www.nremt.org/rwd/public/data/maps/</a> .
Outpatient and inpatient medical staff not already included in earlier groups who are unable to telework	~42,600 outpatient (Bureau of Labor Statistics) and home healthcare plus ~5,500 outside agency/contract staff – estimates pending
<ul style="list-style-type: none"> <li>Pharmacists, pharmacy technicians, and pharmacy aides not already included in earlier groups</li> <li>Dentists and dental hygienists.</li> </ul>	~3,860 pharmacists and 2,864 dentists and hygienists – Bureau of Labor Statistics - estimate of dental staff pending
Public health and emergency management response workers who are unable to telework	~1,800 <sup>¶</sup>

^May also consider subprioritizing persons at higher risk of severe illness, if necessary within a group of HCP

\*Rural areas may include other first responders as well in initial priority with EMS since many 1<sup>st</sup> responders may play multiple roles.

¶ Assumes 50% able to telework

# Discussion Questions

- What are thoughts about subprioritizing HCP for vaccine in the order described?
- Would the committee prefer more specific categories?

# Future Discussions on Healthcare Personnel Vaccination

- Discussions will include how to achieve equity in COVID-19 vaccine distribution to
  - Rural settings
  - Nursing home and assisted living facility staff
  - Home healthcare
  - Private providers and staff not affiliated with hospitals
    - Part time, full time, contracted, private practice, smaller practices

# Thank you!

- The public are invited to submit written comments on health care provider prioritization through designated email address [covid19vaccinepubliccomment@dhw.idaho.gov](mailto:covid19vaccinepubliccomment@dhw.idaho.gov)
- Based on today's discussion and written comments that we receive through Wednesday, October 28, 2020, we will send revised goals and principles and factors considered in subprioritizing vaccine for HCP voting by committee members on November 2, 2020.