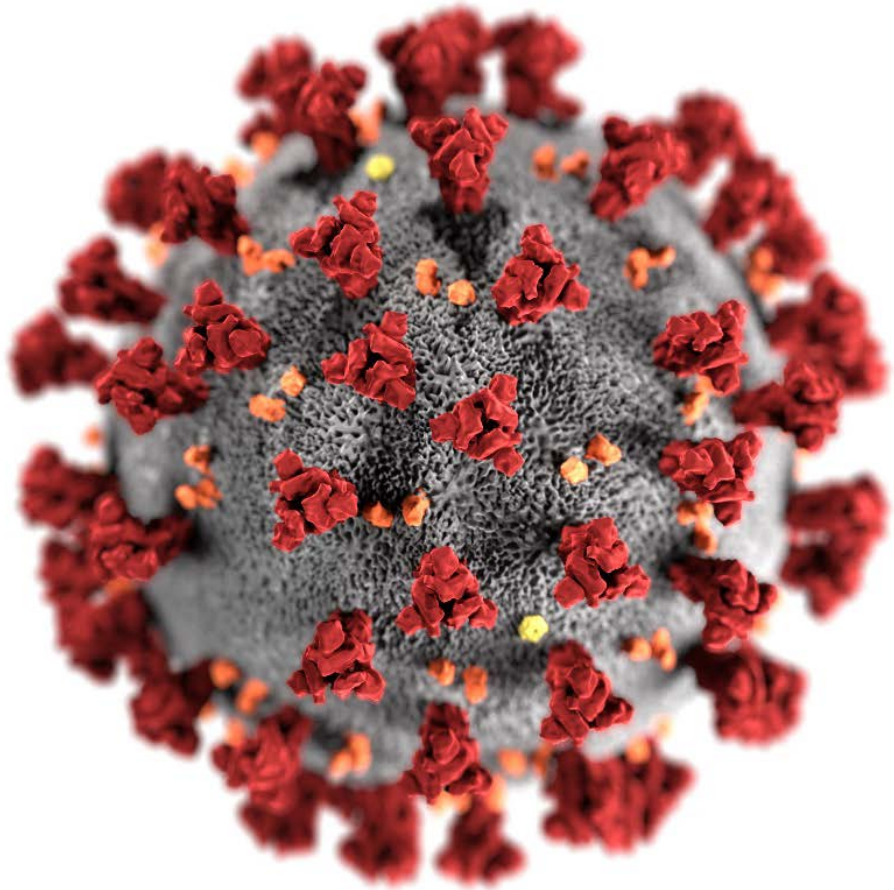
ACIP COVID-19 Vaccines Work Group



COVID-19 vaccine prioritization: Work Group considerations

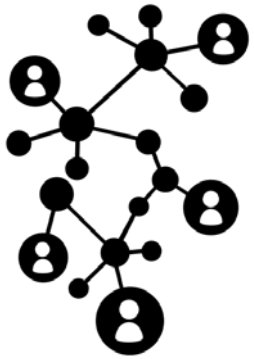
Kathleen Dooling, MD MPH

August 26, 2020

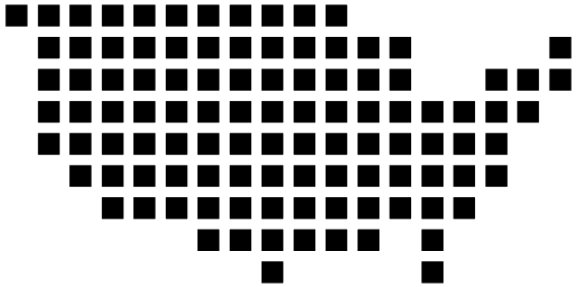
Work Group Considerations:
Goals of the COVID-19 Vaccine Program

- Ensure safety and effectiveness of COVID-19 vaccines
- Reduce transmission, morbidity, mortality of COVID-19 disease
- Help minimize disruption to society and economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution

Identifying groups for allocation of initial doses COVID-19 vaccine: critical for program planning



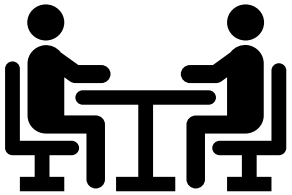
Strengthen vaccine distribution networks to reach target groups



Develop state and local microplans for vaccine implementation

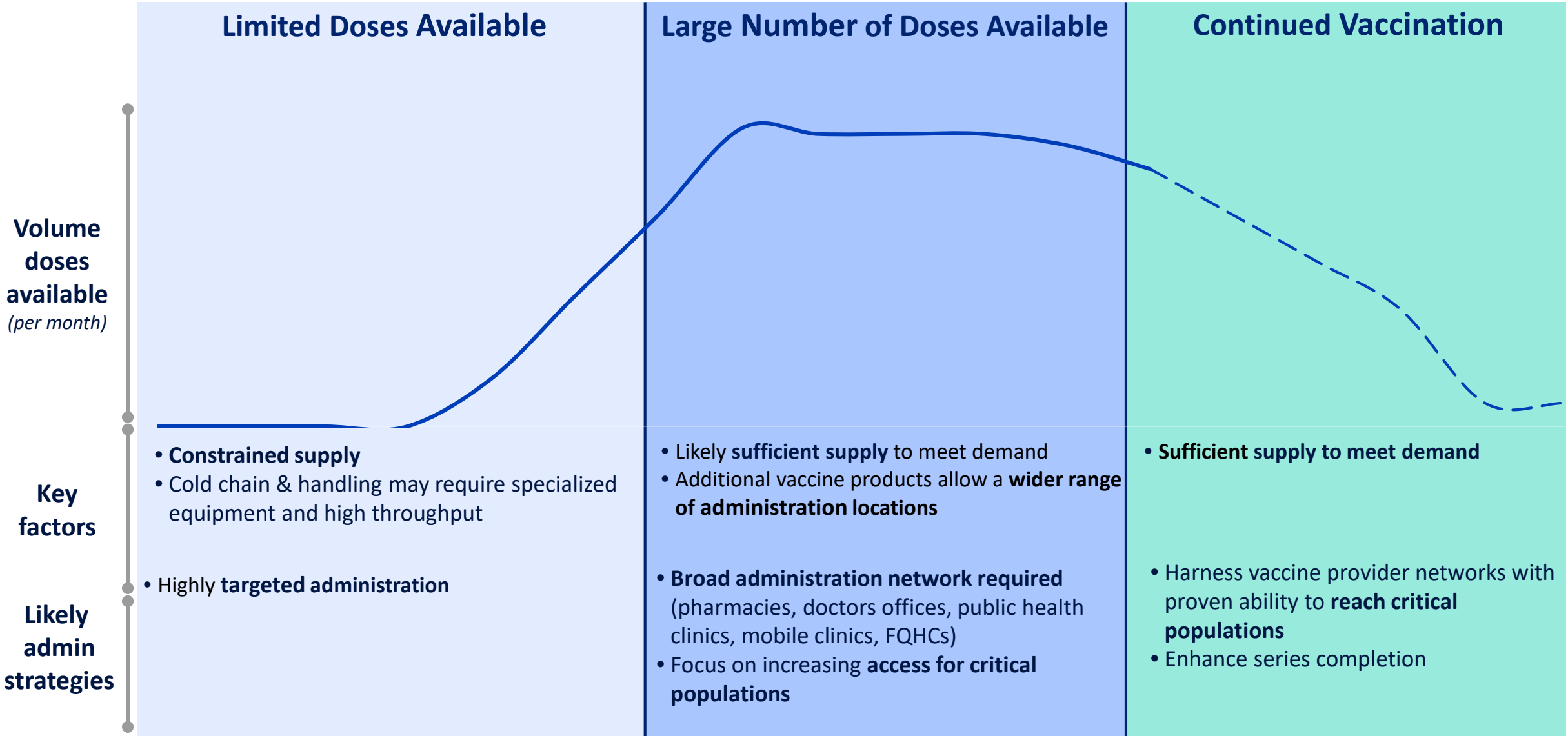
Create communications strategies to promote vaccination in target groups

Plan evaluations to rapidly monitor vaccine safety, effectiveness, and coverage



Engage partners and stakeholders

Administration of COVID-19 vaccine will require a phased approach



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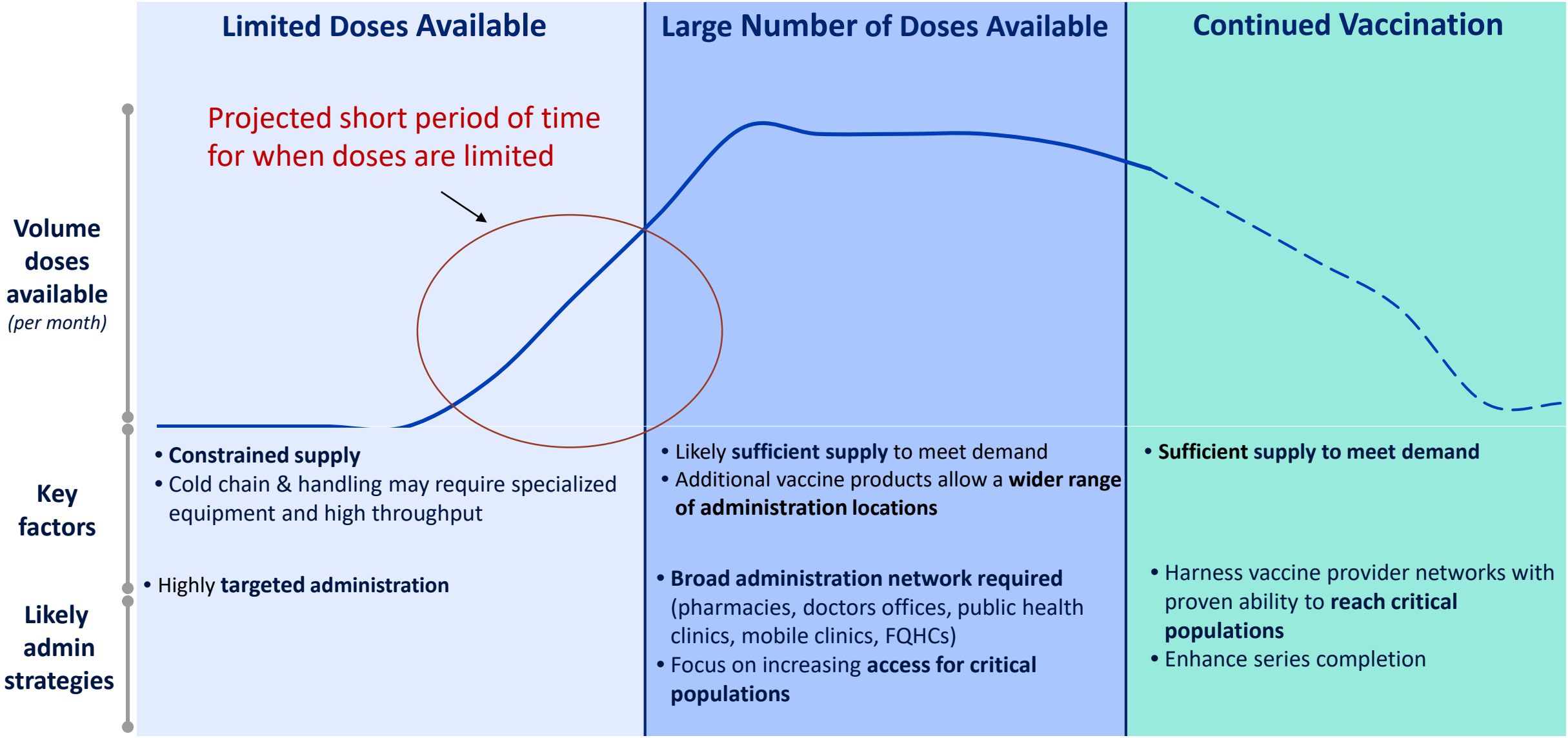
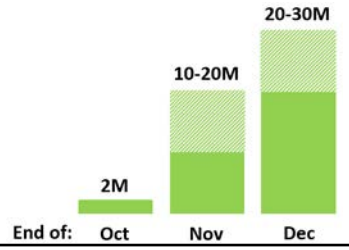
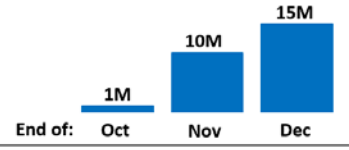
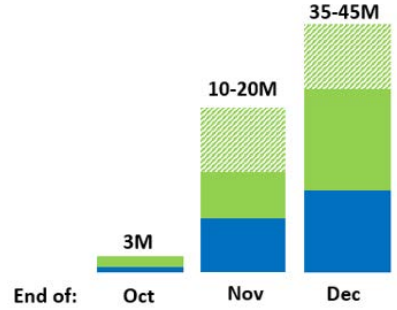


Proposed scenarios for planning for D&A initial phase (Q4 2020)

Does not represent decisions; preliminary scenarios for planning

Scenario	Cumulative Doses available	Distribution requirements	Administration
1. **Vaccine candidate A** is the first to demonstrate safety & efficacy		• **Shipped direct at --70-80°C** on dry ice, to be used within 10 days	• Vaccine can be stored at 2-8°C for 24 hours • 6 hour shelf life at room temperature • Unique diluent / kit requirements • Only shippable to large admin sites
2. **Vaccine candidate B** is the first to demonstrate safety & efficacy		• **Central distro capacity at -20°C,** may be stored for months at -20°C	• Vaccine can be stored at 2-8°C for 7 days • 6 hour shelf life at room temperature
3. Vaccine candidates A and B demonstrate safety & efficacy		• As above	• Administration site considerations as above • Complexity increases significantly if sites are administering 2 products with different requirements and differing dose schedules

CDC Activities to Support Implementation Planning

- Microplanning
- Critical population focus
- Federal entity planning
- Development of IT tools
- Communications and engagement materials

Recap of ACIP discussions early phase COVID-19 vaccination

Meeting	
June	➢ Support for identification of groups for allocation of initial vaccine to aid implementation planning ➢ Recognition of disparity in COVID-19 impact on race/ethnic groups, essential workers, low income families, etc. ➢ Need to build on existing vaccine infrastructure to meet challenges of the COVID-19 vaccination
July	➢ Support for **healthcare personnel and other essential workers** to receive initial vaccine allocation

Objective for today's ACIP discussion:

Focus on the Work Group's proposed groups for early phase vaccination

- Healthcare personnel
- Essential workers
- Persons with high risk medical conditions
- Older adults (≥65 years)

- Describe the group
- Estimate the size
- Consider implementation challenges

ACIP considerations for sequence of groups

September:
Possible vote on interim allocation of initial vaccine doses

Healthcare personnel

- All paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials

- Includes persons not directly involved in patient care but potentially exposed to infectious agents while working in a healthcare setting

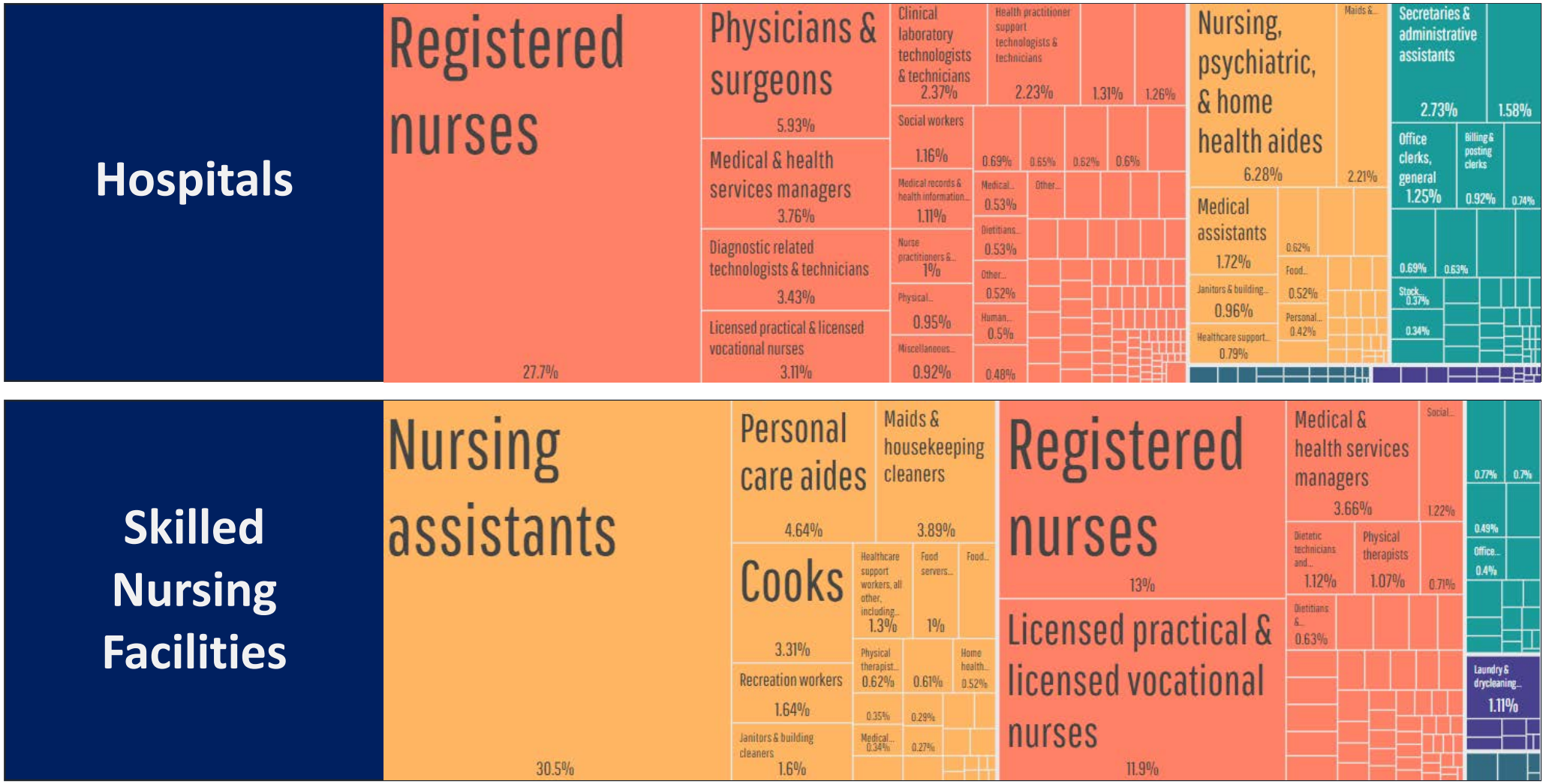
Estimated Population ~17-20M

Examples:

- Hospitals
- Long term care facilities (assisted living facilities & skilled nursing facilities)
- Outpatient
- Home health care
- Pharmacies
- EMS
- Public health

https://www.bls.gov/ooh/healthcare/home.htm

Composition of healthcare workforce varies widely by setting



https://datausa.io/profile/naics/hospitals https://datausa.io/profile/naics/nursing-care-facilities

Essential Workers
(non Healthcare)

- Workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily
- Workers who cannot perform their duties remotely and must work in close proximity to others should be been prioritized
- Sub-categories of essential workers may be prioritized differently in different jurisdictions depending on local needs

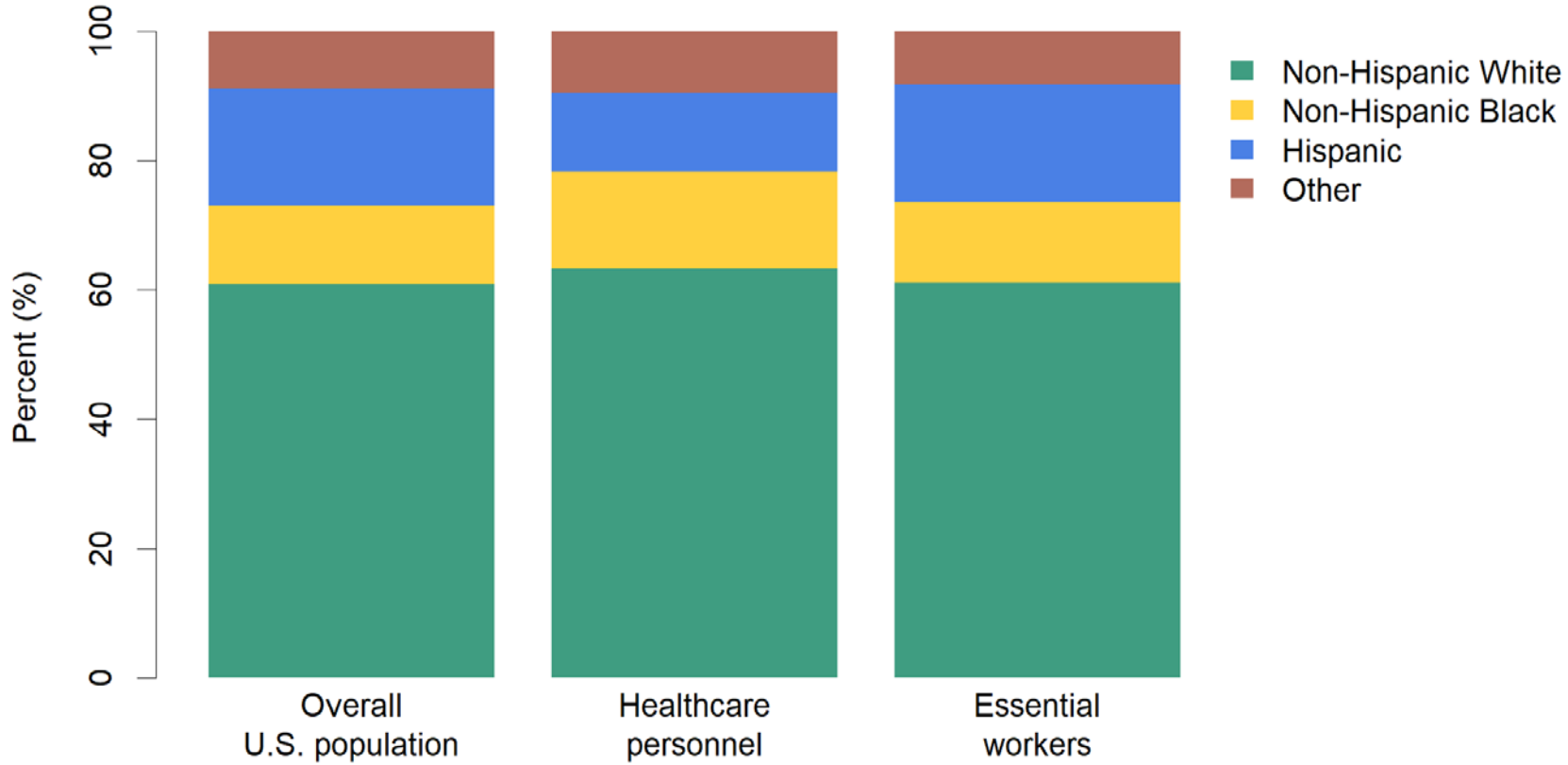
Estimated Population ~60-80M

Examples:

- Food & Agriculture
- Transportation
- Education
- Energy
- Water and Wastewater
- Law Enforcement

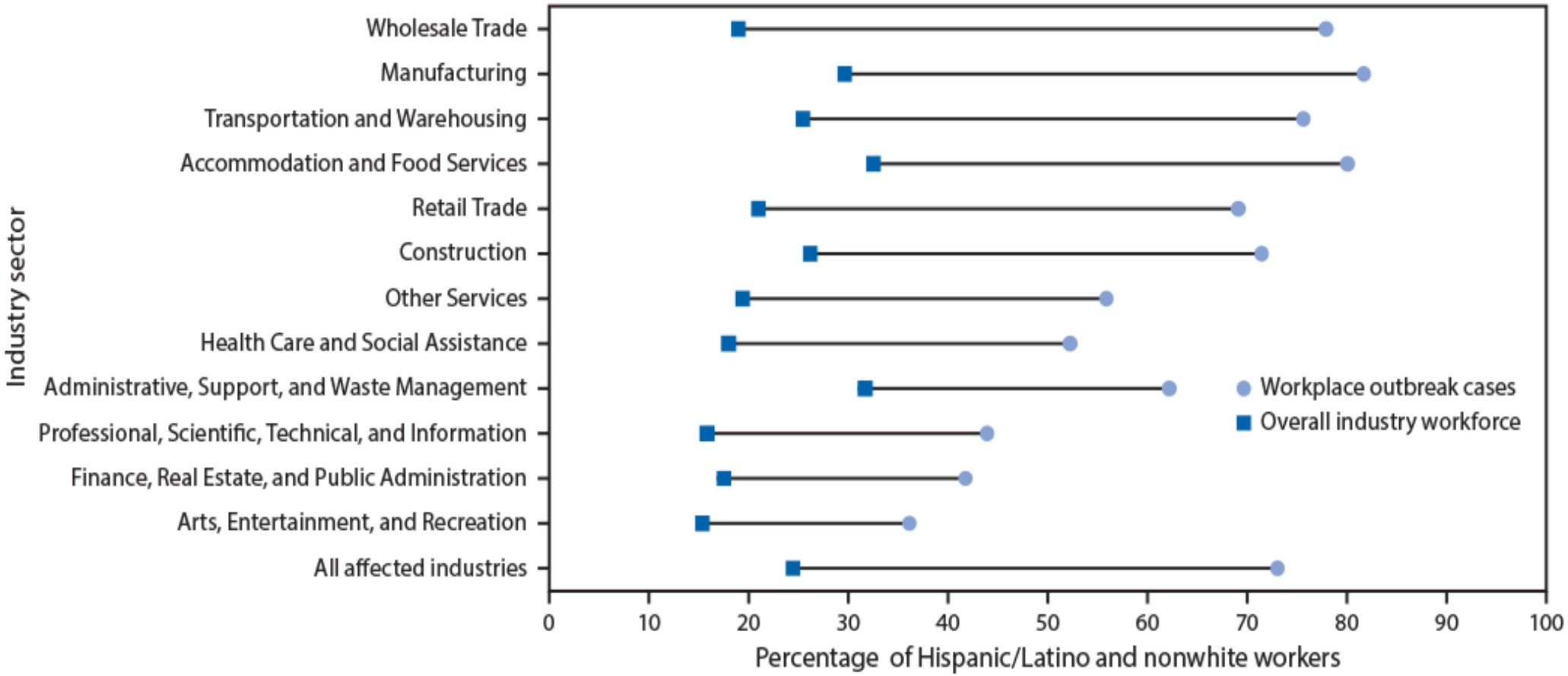
https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce

Healthcare personnel and essential worker race/ethnic composition is similar to U.S. population (self-report, NHIS)



National Health Interview Survey (NHIS) details – data from 2016, 2017 and 2018, Analysis: Modeling Section, COVID-19 Response, CDC

Hispanic and non-White workers accounted for 73% of workplace outbreak-associated COVID-19 cases in Utah



Bui DP, McCaffrey K, Friedrichs M, et al. Racial and Ethnic Disparities Among COVID-19 Cases in Workplace Outbreaks by Industry Sector — Utah, March 6–June 5, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1133–1138. DOI: http://dx.doi.org/10.15585/mmwr.mm6933e3

Adults with medical conditions at higher risk for severe COVID-19*

- Cancer
- Chronic kidney disease
- Chronic obstructive pulmonary disease (COPD)
- Immunocompromised state from solid organ transplant
- Obesity (BMI of 30 or greater)
- Serious heart conditions (heart failure, coronary artery disease or cardiomyopathies)
- Sickle cell disease
- Type 2 diabetes mellitus

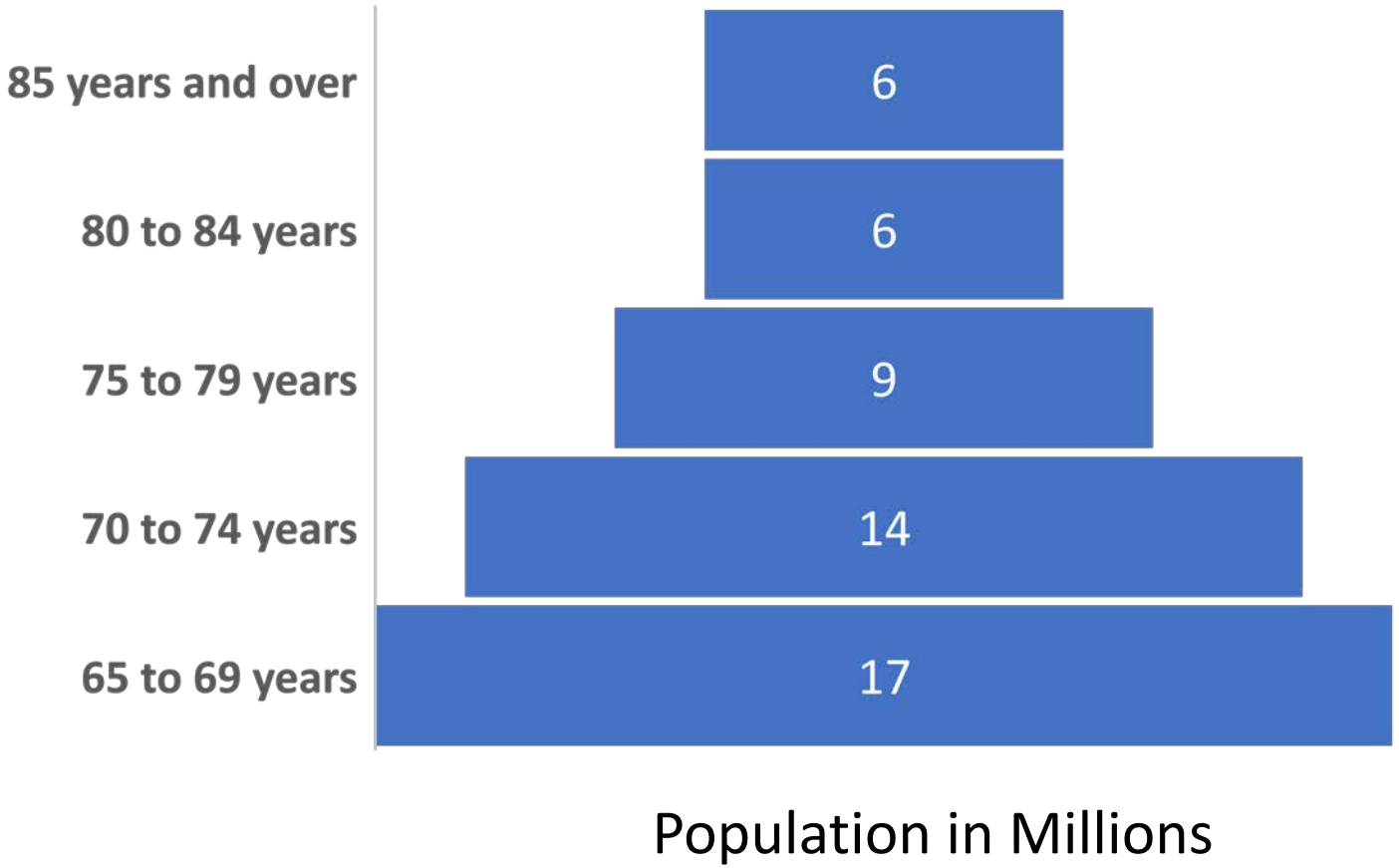
Estimated Population >100M

Examples‡	% Population
Obesity	31%
Diabetes	11%
COPD	7%
Heart Condition	7%
Chronic kidney	3%

* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html

‡ https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w

Adults 65 years and older

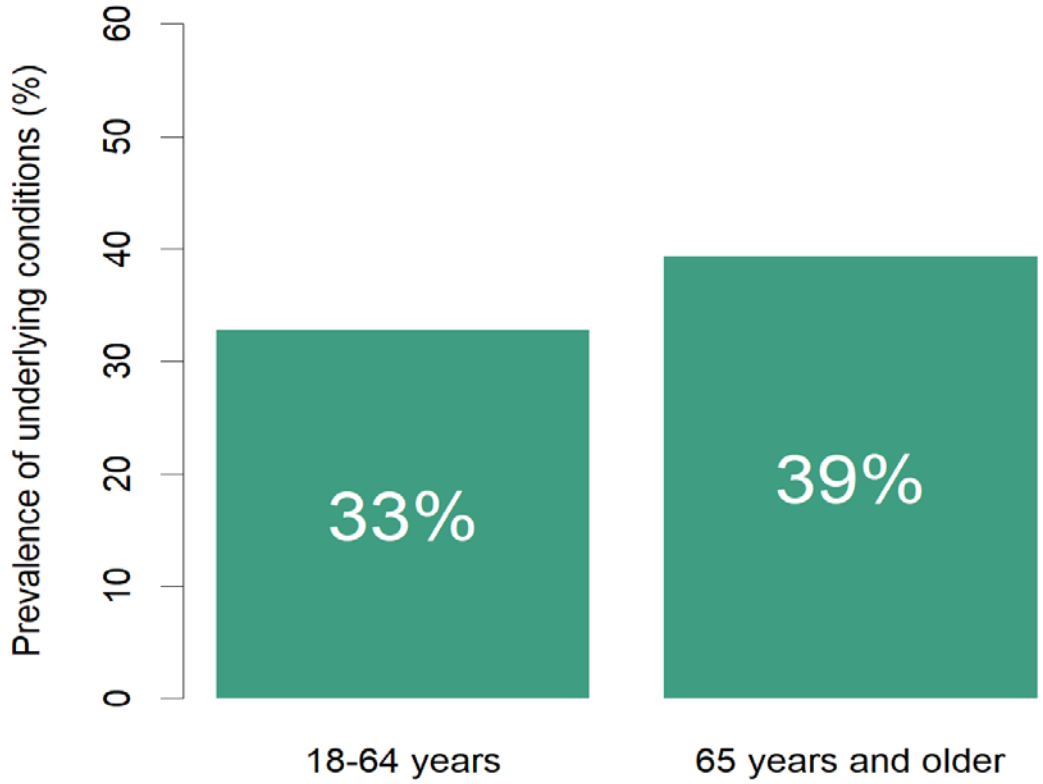


Estimated Population ~53M

- 16% of the U.S. population
- ~3M person live in long-term care facilities

United States Census Bureau https://www.census.gov/topics/population/older-aging.html
https://www.cdc.gov/nchs/fastats/nursing-home-care.htm

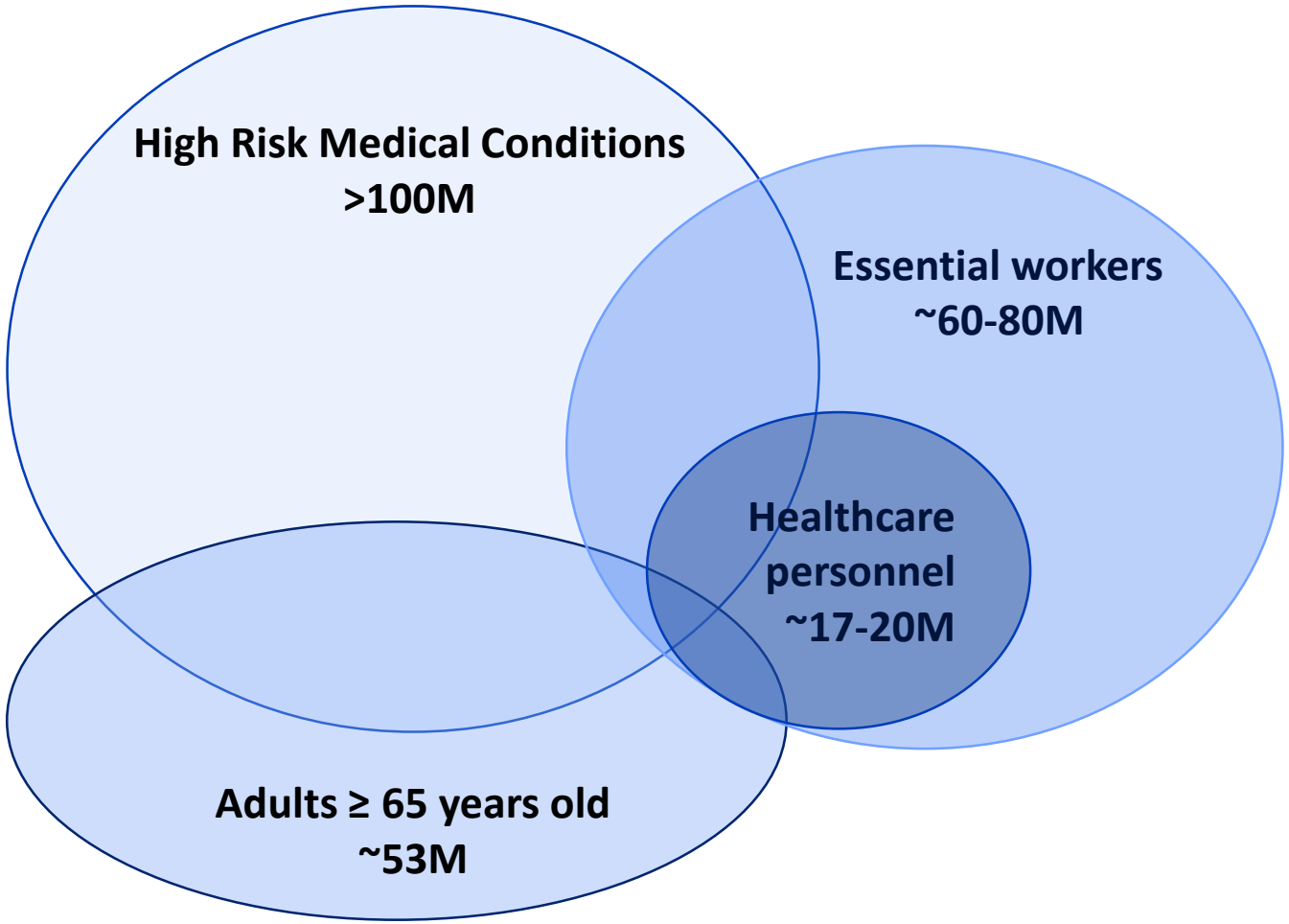
The proportion with COVID-19 high risk medical conditions is similar among younger and older adults (NHIS, self-report)



National Health Interview Survey (NHIS) details – data from 2016, 2017 and 2018, Analysis: Modeling Section, COVID-19 Response, CDC

Summary: Groups for early phase vaccination

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



Work Group Considerations

Epidemiology, Feasibility of Implementation, Equity & Ethics

Work Group Interpretation: Implementation challenges & implications for distribution of initial vaccine

- A COVID-19 vaccine that requires distribution and storage at -20°C, followed by 7 days (max) at 2-8°C, will require diligent vaccine management to minimize waste

- The storage, distribution and handling requirements of a -70°C vaccine will make it very difficult for community clinics and local pharmacies to store and administer

  - **will necessitate most vaccine be administered at centralized sites with adequate equipment and high throughput**

  - **vaccinating healthcare personnel at centralized sites with high throughput is the best allocation of initial supply**

Work Group Interpretation: Implementation challenges & implications for distribution of initial vaccine

- Workers at long-term care facilities are a priority among healthcare personnel and achieving high coverage is important and may be resource intensive
- Mass vaccination clinics will be difficult to conduct in the setting of social distancing.
- Healthcare homes, such as provider offices or pharmacies, could be better suited to provide vaccination if recommendations are based on individual risk factors such as age or underlying medical conditions.

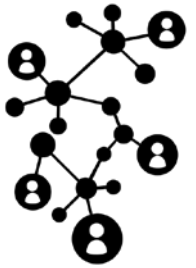
- Challenges to equitable vaccine administration:
  - Reaching rural areas
  - Racial and ethnic minorities
  - Populations with limited access to vaccines

Identifying groups for interim prioritization of initial COVID-19 vaccine

Key Unknowns:

- Vaccine performance: the magnitude of benefits and potential risks, for younger and older adults
- Possibility of multiple vaccines with differing profiles
- The pathway to approval: emergency use authorization or full licensure
- The timing of vaccine availability
- The number of doses available and rate of scale-up

Importance of identifying priority groups



Strengthen distribution networks

Create communication strategies

Develop state/ local microplans

Implement safety and effectiveness evaluations

Next Steps for the COVID-19 Vaccine Work Group: Develop and vote on an interim prioritization schema for initial COVID-19 vaccine

- Review clinical trial data for candidate vaccines, as they become available
  - Safety data, including plans for post-approval safety surveillance
  - Immunogenicity and efficacy data
- Review epidemiologic data for risk of COVID-19 disease and severity by race/ethnicity
- Review results of focus groups and other public engagement regarding COVID-19 vaccines
- Review equity frameworks for allocating vaccine

Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Tier 1:

- Those most essential in sustaining the ongoing COVID-19 response
- Those at greatest risk of severe illness and death, and their caregivers
- Those most essential to maintaining core societal functions

Tier 2:

- Those involved in broader health provision
- Those who face greater barriers to access care if they become seriously ill
- Those contributing to maintenance of core societal functions
- Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

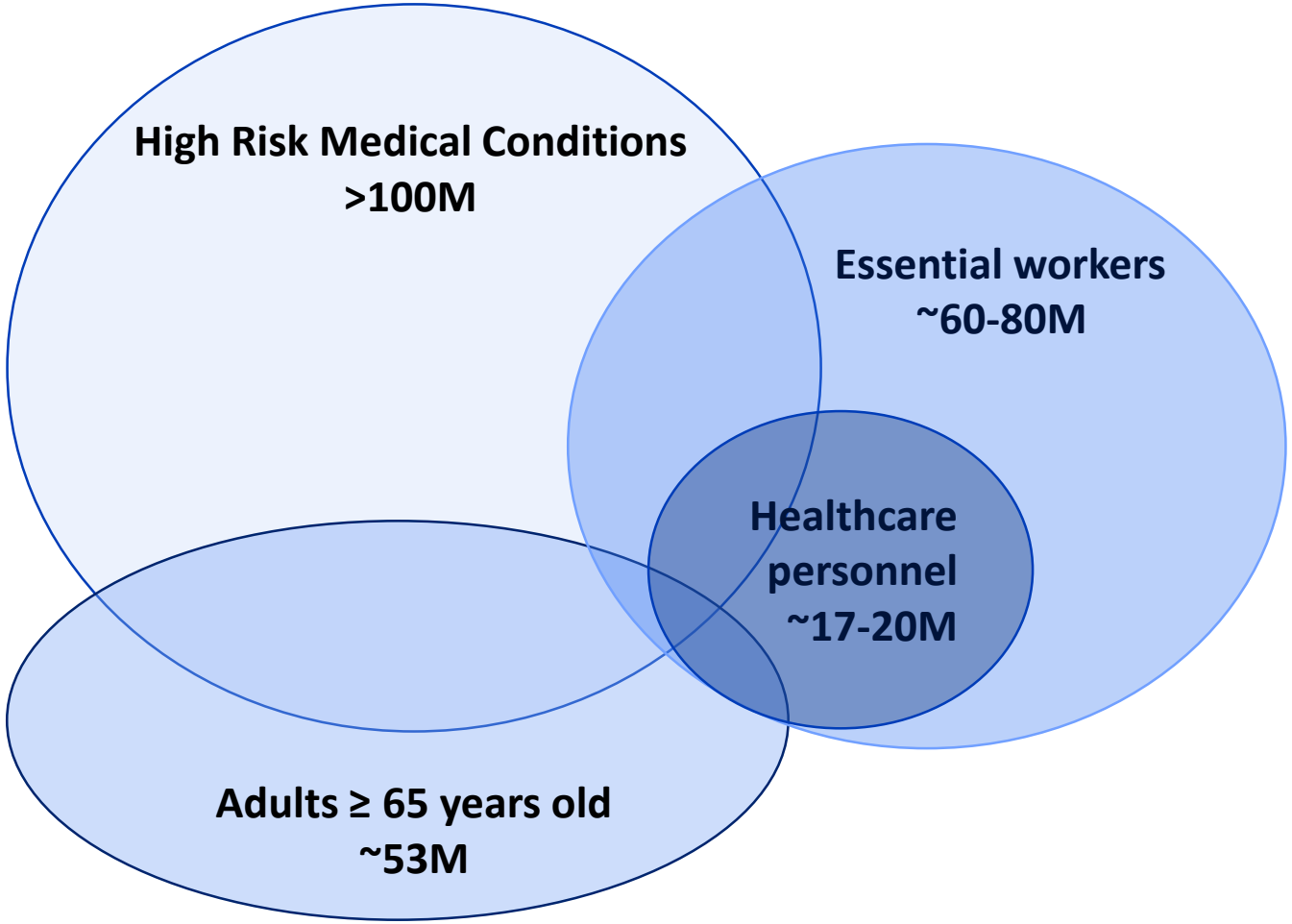
"The purpose of this report is to offer an ethics framework that can be used to make decisions about the allocation of a SARS-CoV-2 vaccine during the initial period of scarcity in the United States and make related suggestions about vaccine distribution."

https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-covid-19-vaccine-allocation-and-distribution-in-the-us

Questions:

1) Given the information presented thus far (epidemiology, values, acceptability, feasibility) do you agree that initial doses of COVID-19 vaccine should be allocated to healthcare personnel?

2) If supply remains constrained, due to vaccine or distribution limitations, do you agree with vaccinating essential workers next as supply permits?



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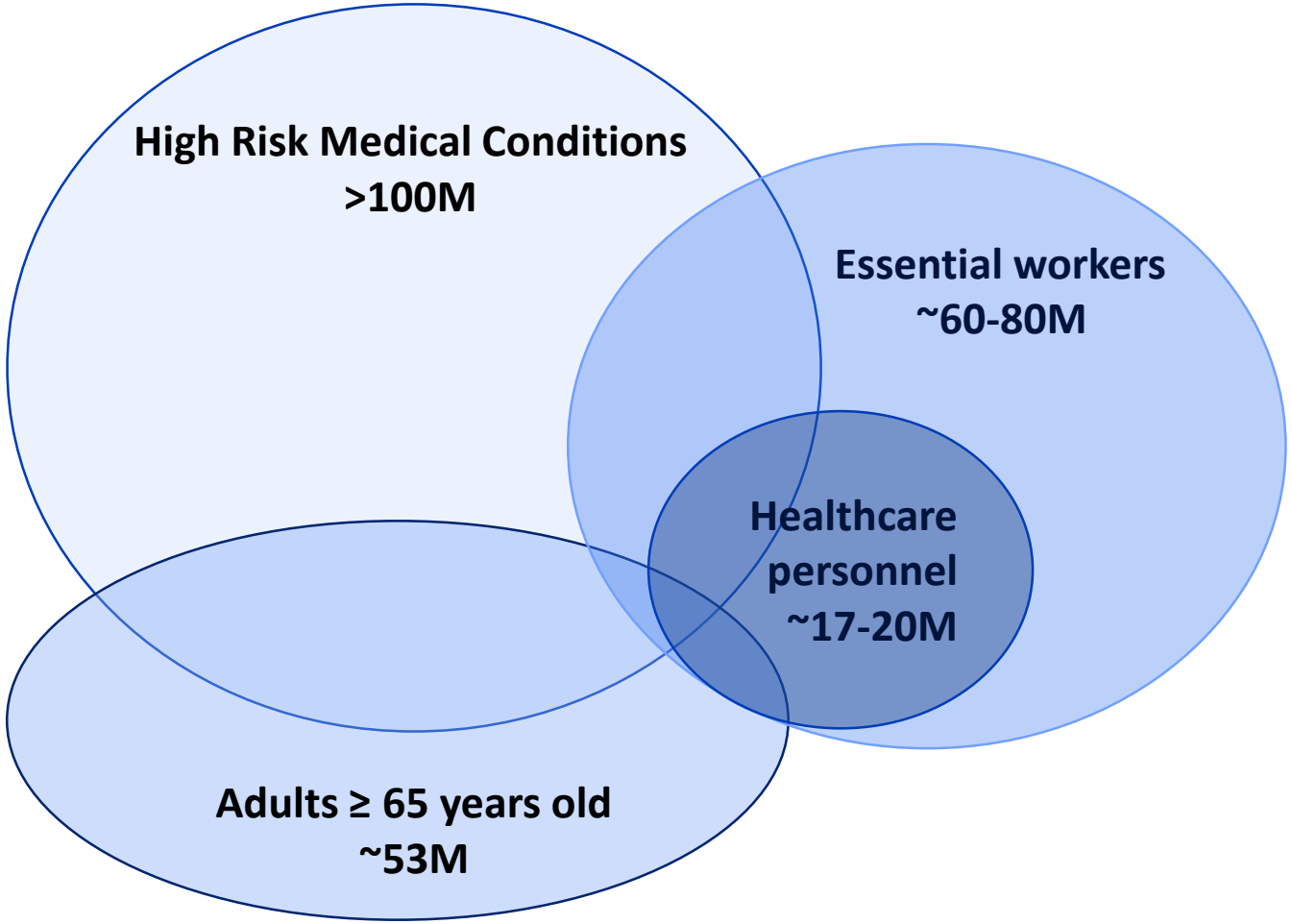

Background slides

ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

EQUITY

Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution

Inclusive clinical trials. Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable

Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand