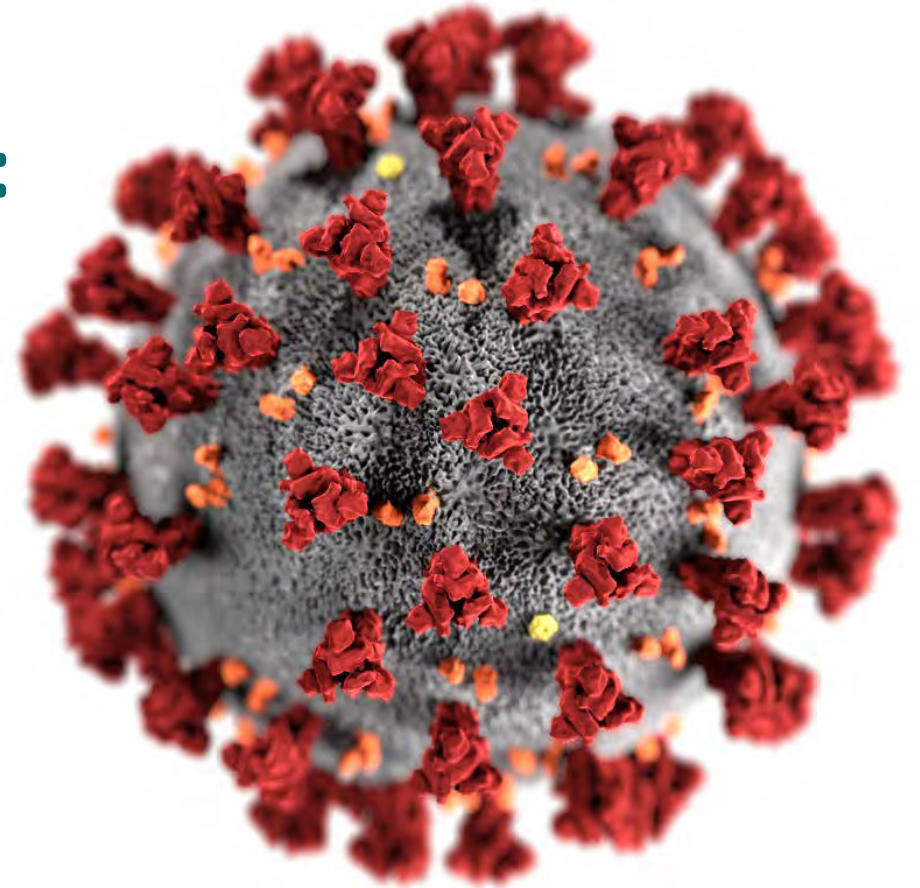



## Phase 1 allocation COVID-19 vaccine: Work Group considerations

**Kathleen Dooling, MD MPH**  
**September 22, 2020**

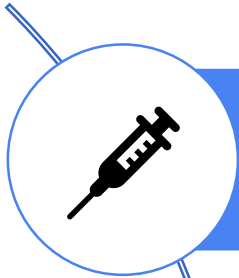


# Work Group Considerations: Goals of the COVID-19 Vaccine Program

- 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
- 

# Work Group Considerations: Proposed Guiding Principles

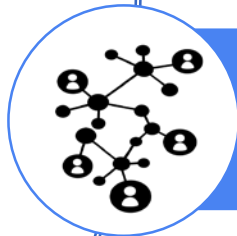
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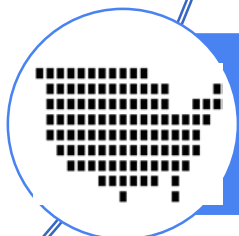
**Safety is paramount.** Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution



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

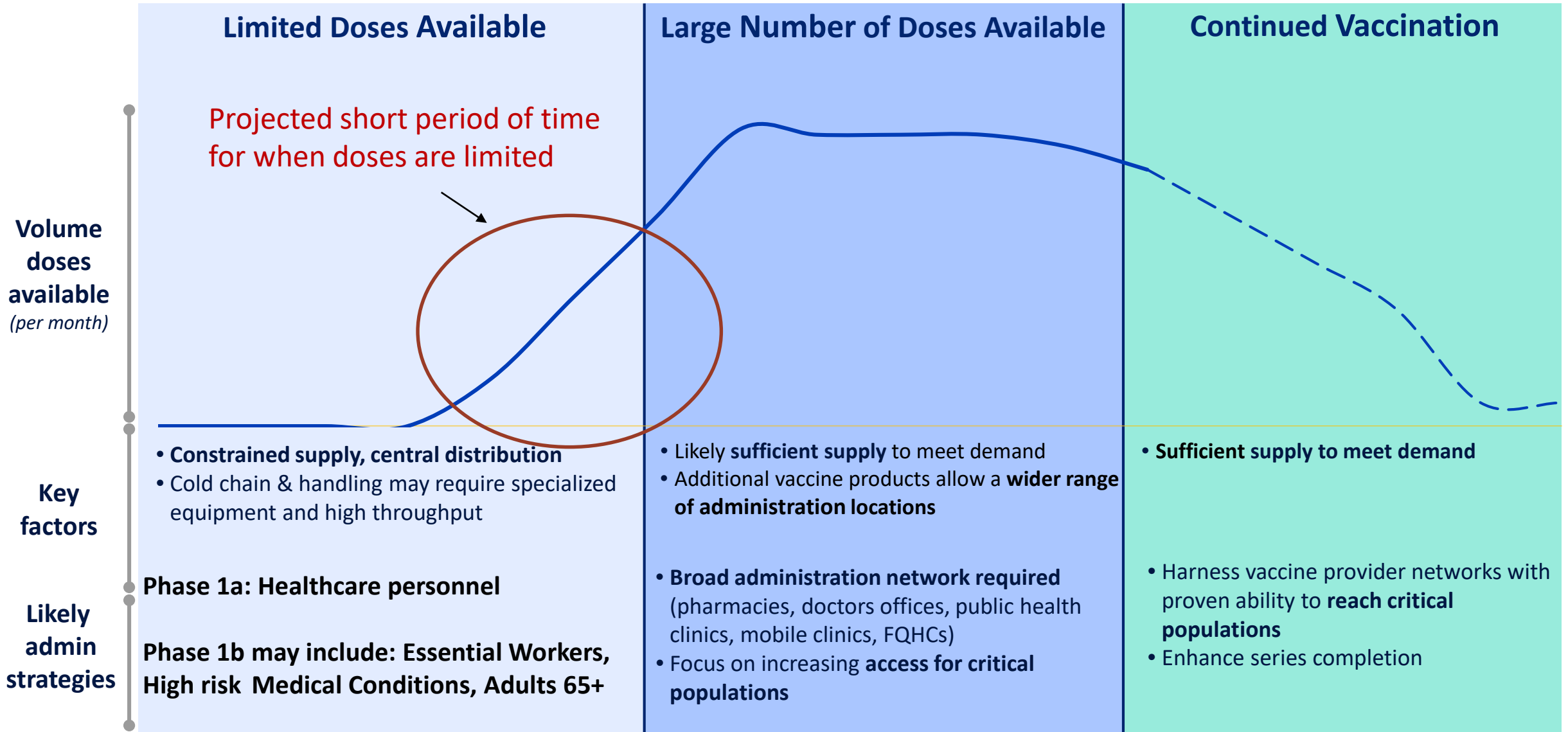


**Efficient Distribution.** During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical



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

# Administration of COVID-19 vaccine will require a phased approach



# Possible groups for Phase 1 vaccination

## August ACIP meeting

### Phase 1a:

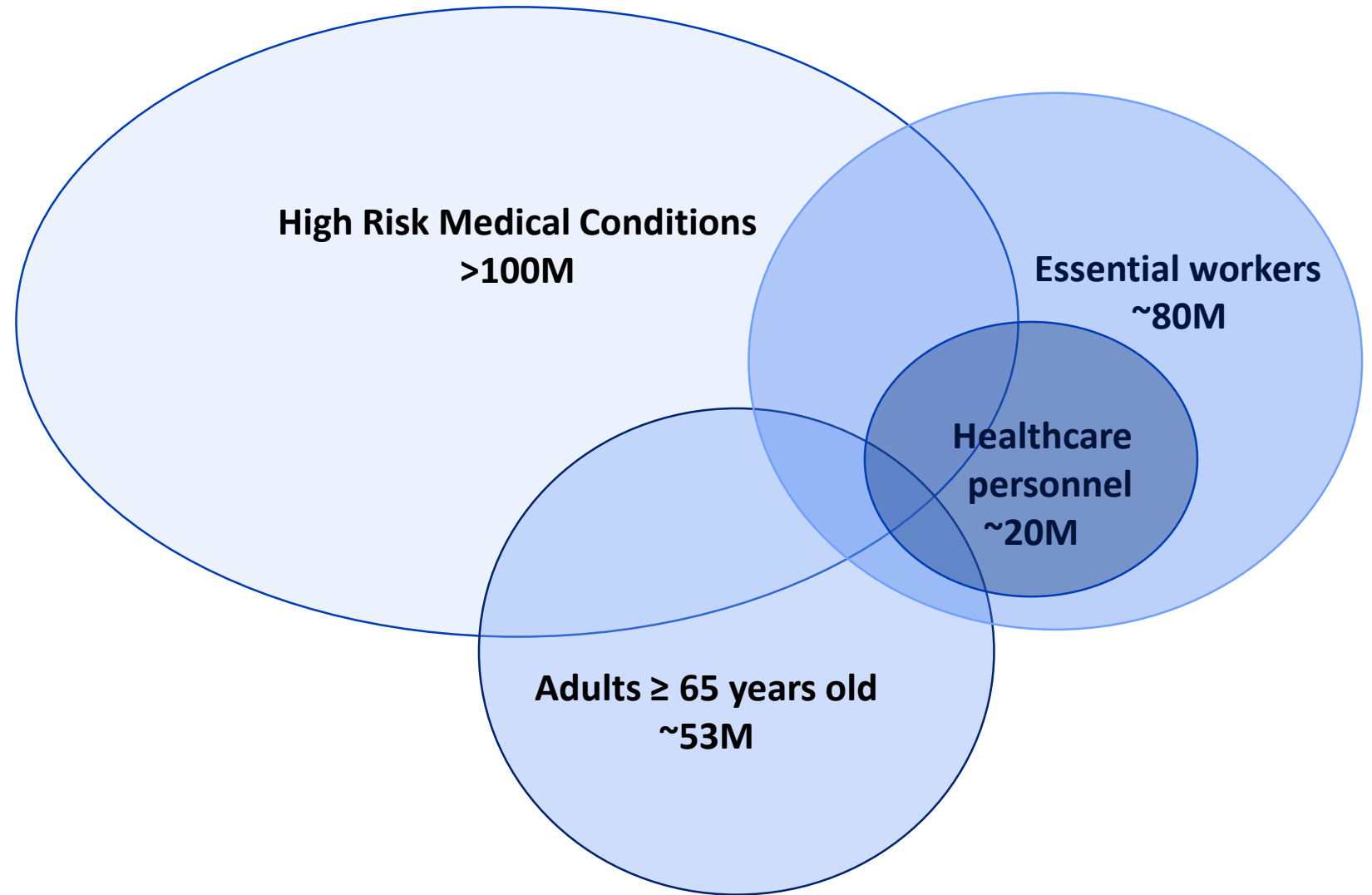
-HCP

### Phase 1b:

- Essential Workers
- High Risk Med Conditions
- Adults  $\geq$  65 years old

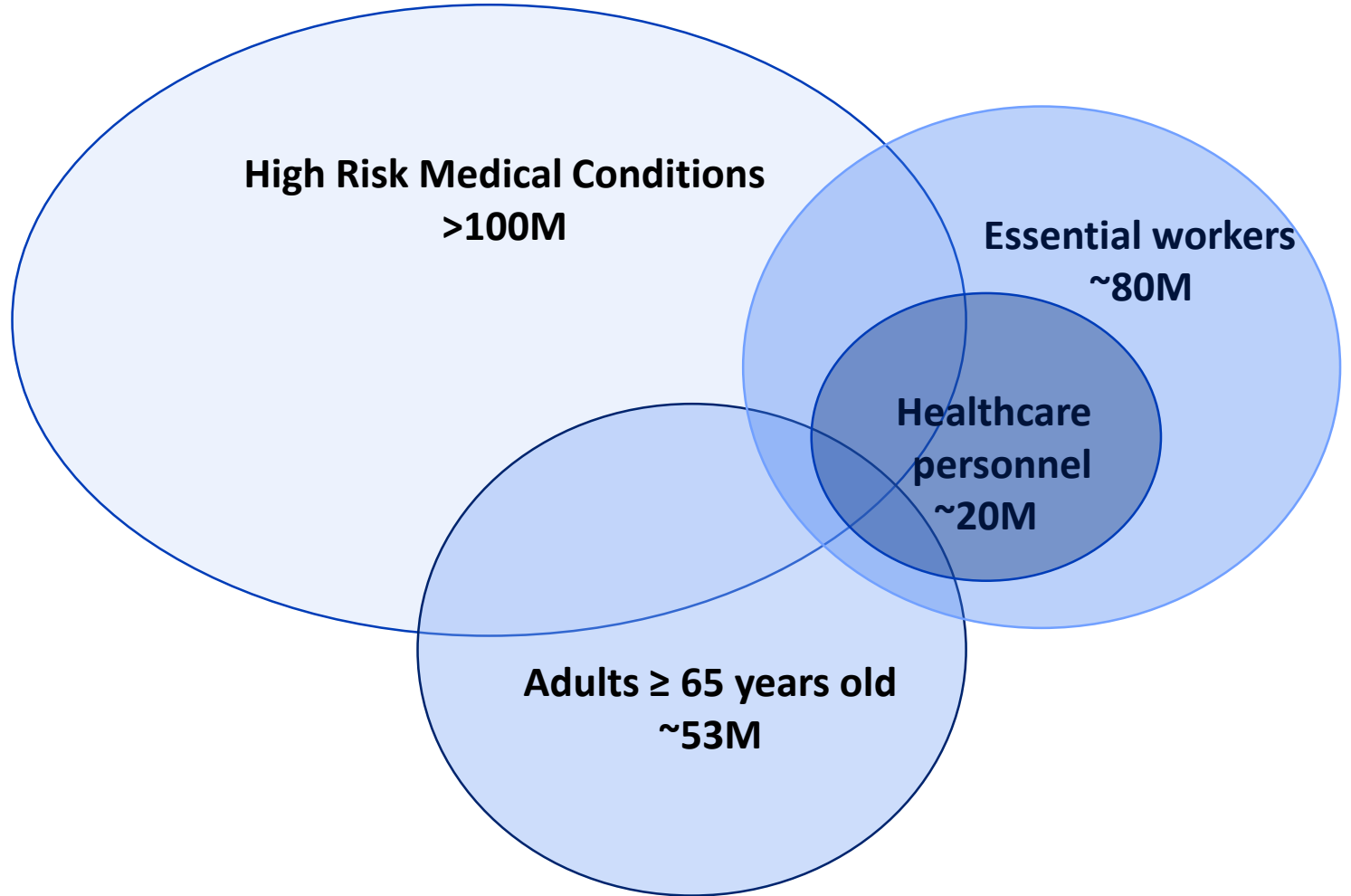
## September ACIP meeting

- Explore groups for phase 1b
  - risk for COVID-19
  - overlap between groups
  - racial and ethnic composition
- Summary of Work Group considerations



## Questions:

- 1) If constrained vaccine supply necessitates sequencing of groups in Phase 1b, what are the most important information gaps we need to fill for ACIP to make sequencing recommendations?
- 2) What is the correct balance of national guidance and local flexibility?



# Phase 1a: Healthcare personnel



# 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



# Healthcare personnel: Summary of Work Group Considerations

	EQUITY	VALUES	FEASIBILITY	ACCEPTABILITY	BENEFITS & HARMS
Support	<ul style="list-style-type: none"> <li>-↑ representation of some racial minority groups in subsets of HCPs</li> <li>-LTCF</li> <li>-home healthcare</li> </ul>	<ul style="list-style-type: none"> <li>-HCPS included as early phase group in all values-based allocation frameworks considered</li> </ul>	<ul style="list-style-type: none"> <li>-Large health systems have occupational health depts to facilitate vaccine clinics</li> <li>-May have -80C freezers</li> </ul>	<ul style="list-style-type: none"> <li>-Moderate/high rates of influenza vaccine acceptance.</li> <li>-high scientific literacy</li> </ul>	?
Challenge			<ul style="list-style-type: none"> <li>-Rural and LTCF, small clinics, home healthcare workers may be difficult to reach</li> </ul>		?

# Phase 1b: Essential workers (non-healthcare)



# 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 prioritized
- Sub-categories of essential workers may be prioritized differently in different jurisdictions depending on local needs

Estimated  
Population ~60M

## Examples:

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

# Essential Workers (non-healthcare): COVID-19 Risk

- By July 2020, 23 states reported outbreaks in 239 meat or poultry processing plants, resulting in ~16,000 cases in workers<sup>1</sup>
  - 9% of workers diagnosed as cases by May (range =3%-25%)
- By mid-September, Corrections and Detention Facilities reported ~126,000 cases in residents and ~27,000 cases in staff<sup>2</sup>
  - In an analysis of 16 U.S. prisons and jails, 56% identified their first case of COVID-19 among staff members as opposed to incarcerated/detained persons<sup>3</sup>
- In NYC, seroprevalence among Correctional facilities workers and Fire Department workers exceeded that of the general population<sup>4</sup>

1. MMWR July 10, 2020 [https://www.cdc.gov/mmwr/volumes/69/wr/mm6927e2.htm?s\\_cid=mm6927e2\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6927e2.htm?s_cid=mm6927e2_w)

2. UCLA COVID-19 Behind Bars Data Project

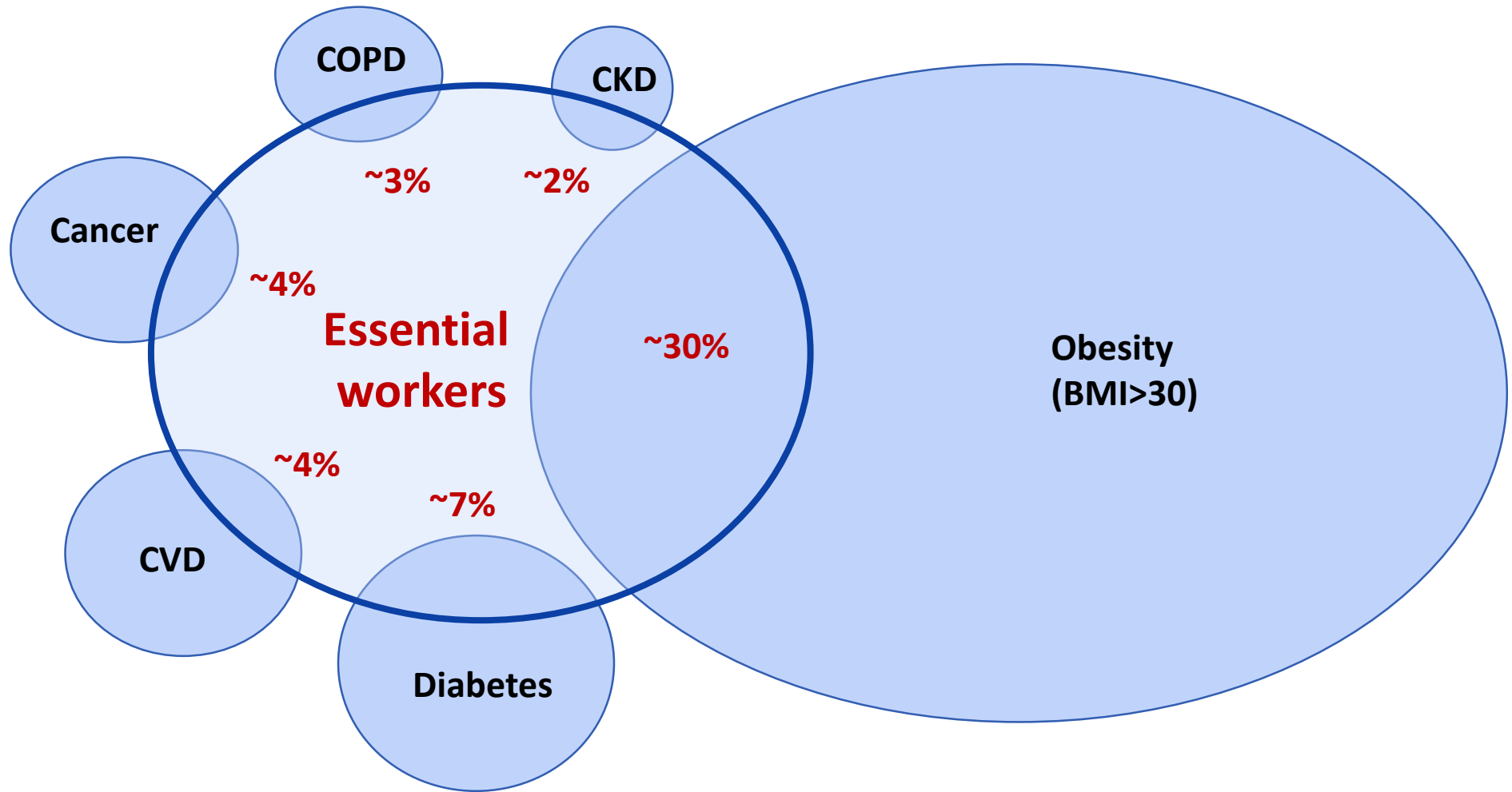
<https://law.ucla.edu/academics/centers/criminal-justice-program/ucla-covid-19-behind-bars-data-project>

3. Hagan et al. MMWR – projected publication date August 7. Results of Mass Testing for SARS-CoV-2 in 16 Prisons and Jails— Six U.S. Jurisdictions, April–May 2020

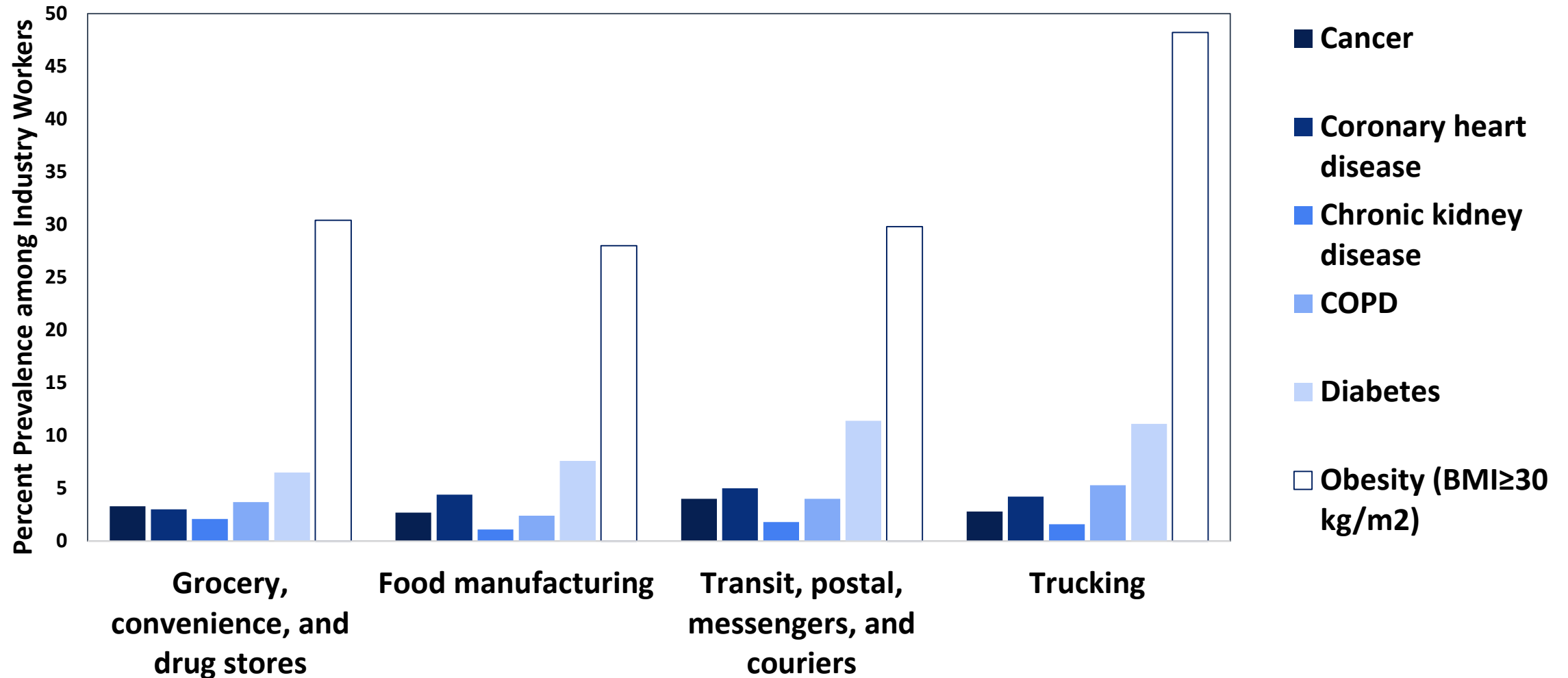
4. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-07/COVID-06-Oliver-508.pdf>



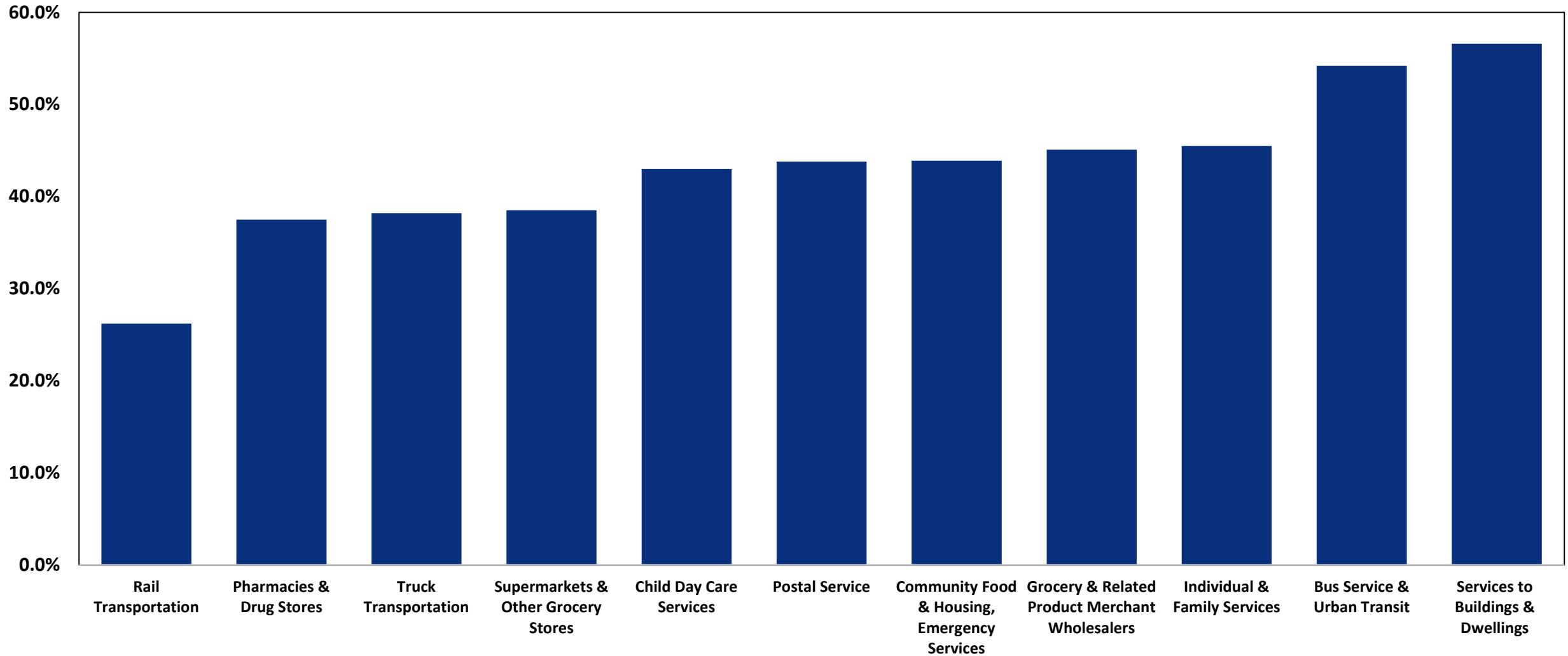
# Overlap: Essential Worker & High-Risk Medical Conditions



# Selected essential industries by high risk medical conditions

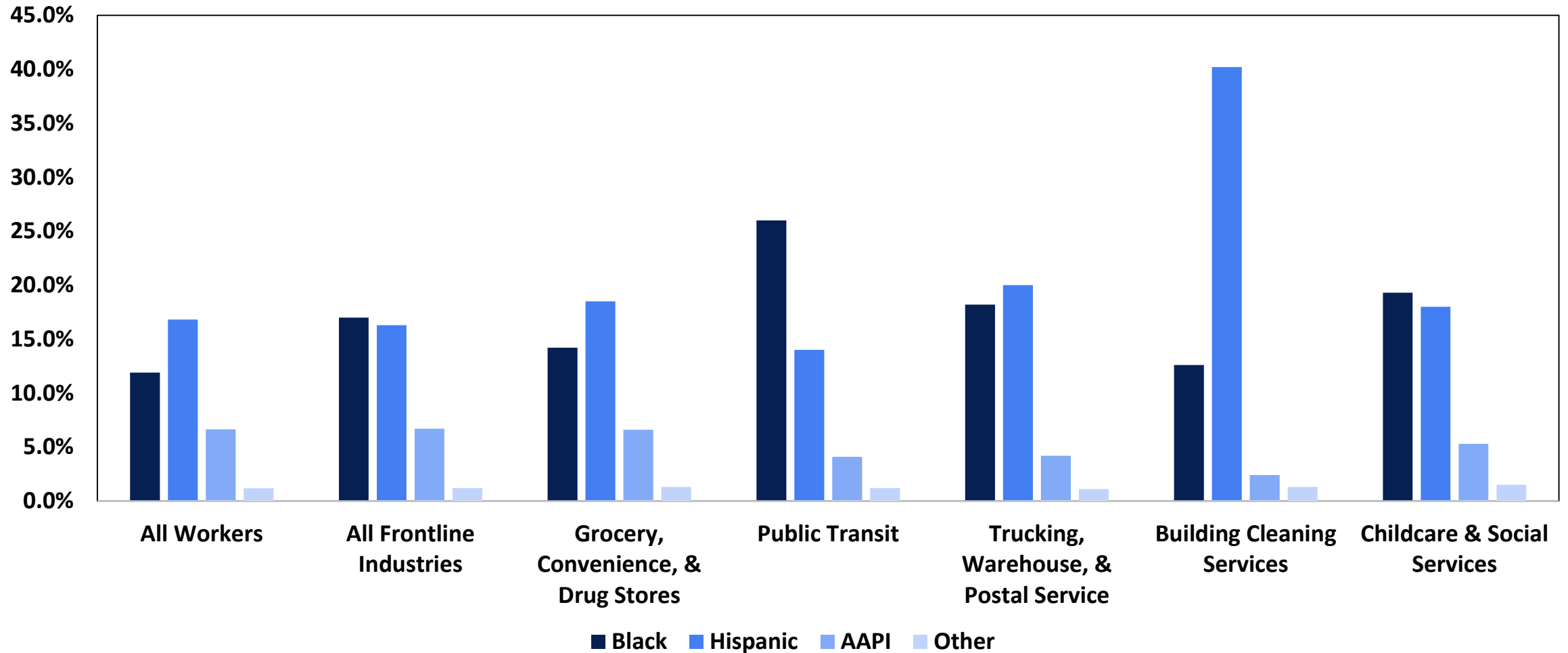


# Racial and Ethnic minorities in selected essential industries



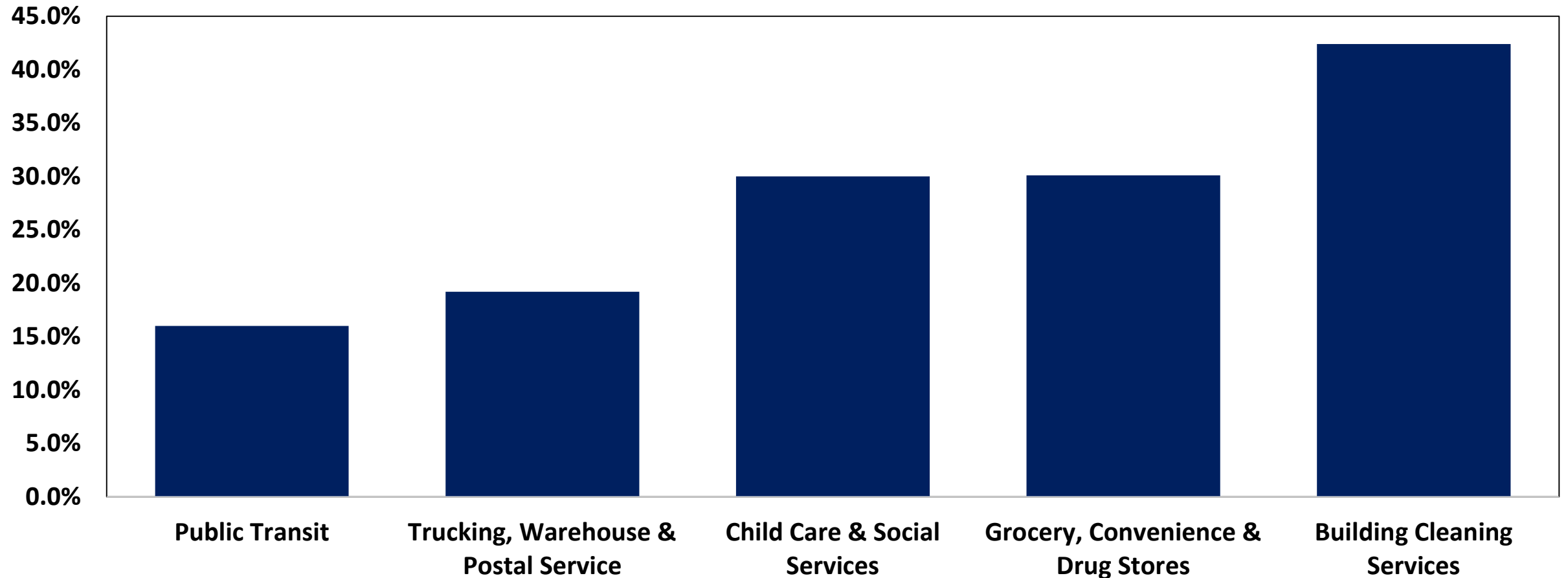
Source: American Community Survey. CEPRs Analysis of American Community Survey, <https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries/>

# Racial and Ethnic minorities in selected essential industries

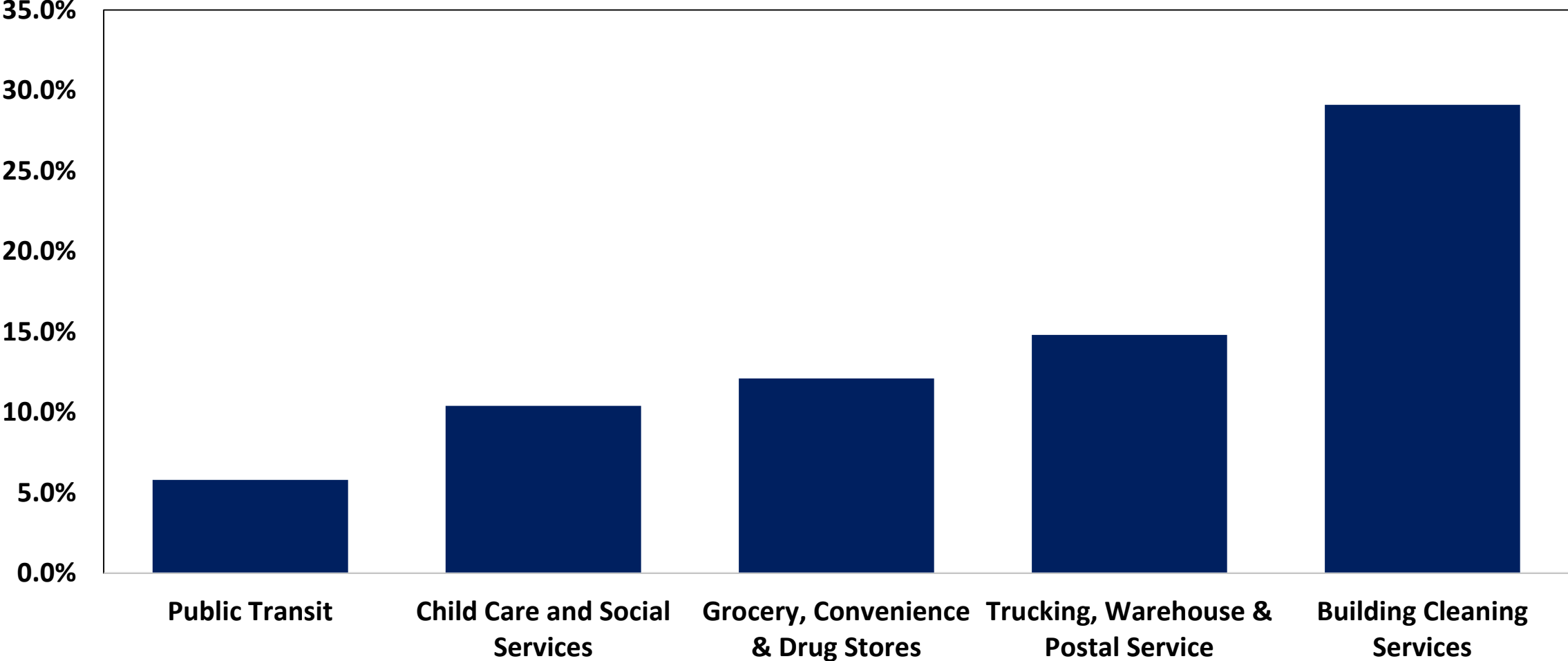




# ~23% of essential workers live in low-income families (income <2X poverty line)

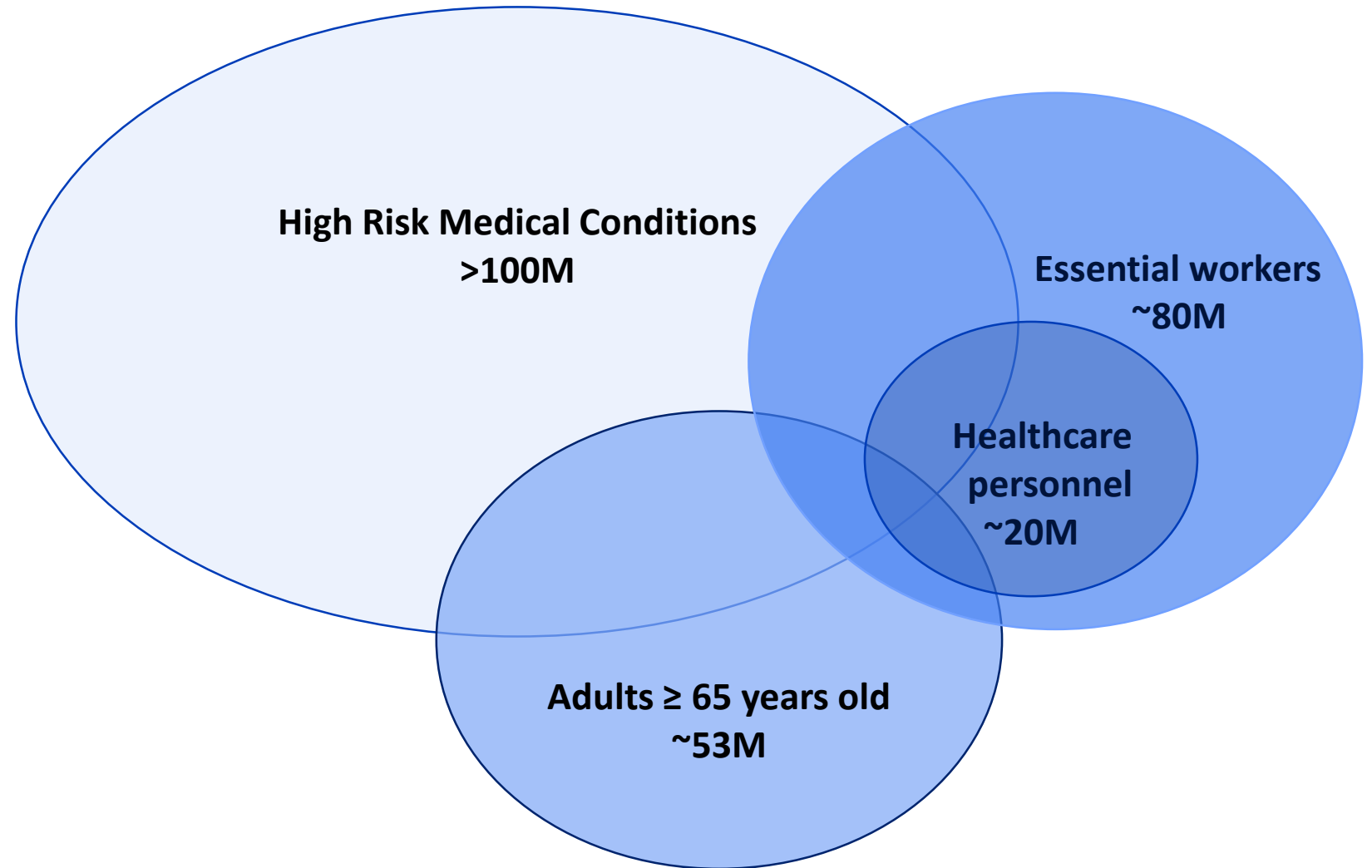


# ~10% of essential workers have no health insurance



Source: American Community Survey. CEPRs Analysis of American Community Survey, <https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries/>

# Overlap: essential workers and adults $\geq 65$ years



**~16% of essential workers are  $\geq 65$  years old or live with someone who is**

# Essential Workers: Summary of Work Group Considerations

	EQUITY	VALUES	FEASIBILITY	ACCEPTABILITY	BENEFITS & HARMS
Support	<p>↑ representation of racial and ethnic minority groups overall and within some essential industries decisions</p>	<p>-Allocation frameworks all recognize essential workers as early phase vaccine recipients</p>	<p>-Mobile workers -Mobile PODS may be deployed to worksites -States will have to make prioritization decisions (↑flexibility)</p>	-	?
Challenge		<p>-Allocation frameworks are not aligned regarding the specific industries in phase I vs. phase II</p>	<p>-States will have to make prioritization decisions (↑workload, potential for policy differences State to State)</p>		?
Unknown		<p>How do workers in individual industries value COVID-19 vaccination?</p>		<p>What is acceptability of COVID-19 vaccine among essential workers?</p>	

# Phase 1b: High risk medical conditions



# 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/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](https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w)

# High risk medical conditions: COVID-19 risk

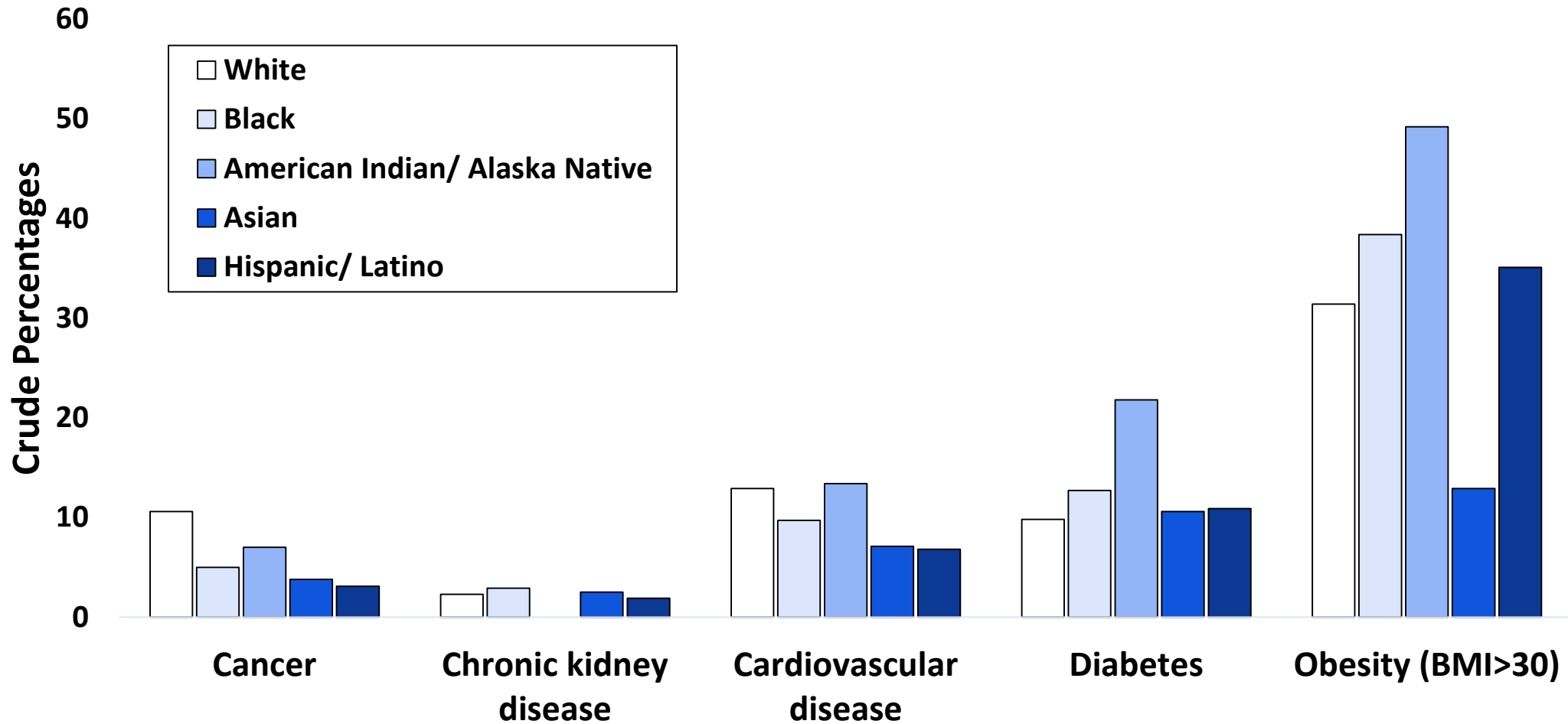
- Nearly 90% of hospitalized adults had at least one high risk medical condition, and over 60% had 3 or more<sup>1</sup>
- Obesity, chronic kidney disease, diabetes and hypertension are associated with hospitalization for COVID-19<sup>2</sup>
- Among hospitalized COVID-19 patients, the adjusted rate ratios for underlying medical conditions association with death ranged from 1.19 (diabetes) to 1.39 (immunosuppression)<sup>3</sup>

1. [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_5.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html)

2. Ko et al. *Clinical Infectious Diseases*, ciaa1419, <https://doi.org/10.1093/cid/ciaa1419>

3. Kim et al, *Clinical Infectious Diseases*, ciaa1012, <https://doi.org/10.1093/cid/ciaa1012>

# Prevalence of selected underlying conditions that increase risk for severe COVID-19 disease, by race and ethnicity



Source: National Center for Health Statistics, National Health Interview Survey, 2018  
Estimates were not available for Hawaiian/other Pacific Islanders or for chronic kidney disease among American Indian/Alaska Native



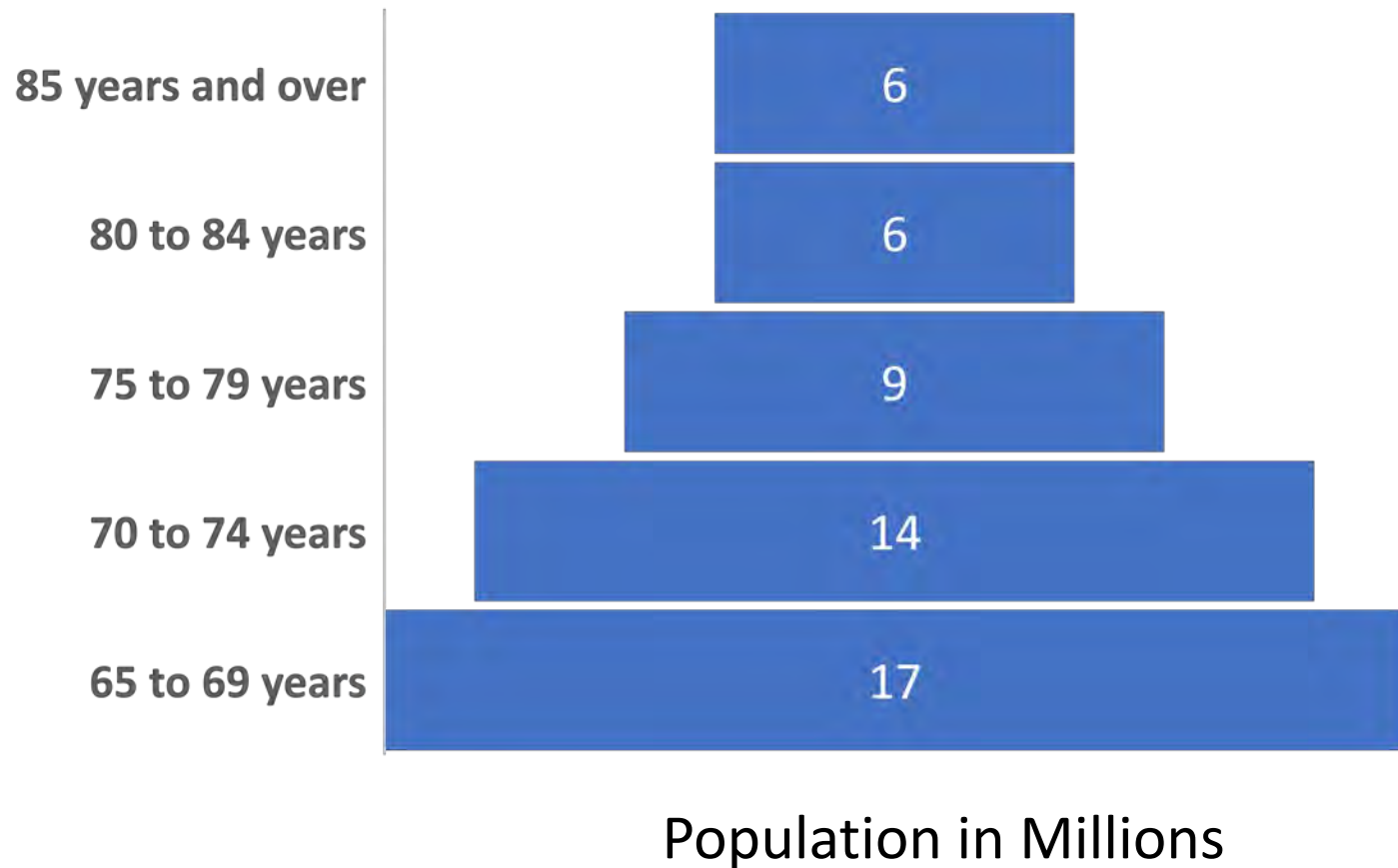
# High Risk Medical Conditions: Summary of Work Group Considerations

	EQUITY	VALUES	FEASIBILITY	ACCEPTABILITY	BENEFITS & HARMS
Support	↑ prevalence of diabetes and obesity among racial and ethnic minority groups	Allocation frameworks all support persons with high risk medical conditions as early phase vaccine recipients	-population with diagnosed medical conditions often connected with healthcare	-Moderate influenza vaccine coverage	?
Challenge	-diagnosis of condition may require access to healthcare		->100M group will require sub-prioritization -high degree of overlap between obesity and DM2 -difficult to assess medical eligibility in mass vaccination clinics		?
Unknown		How do adults with high risk medical conditions value COVID-19 vaccination?		What is acceptability of COVID-19 vaccine among persons with high risk medical conditions?	

# Phase 1b: Adults $\geq 65$ years



# Adults 65 years and older



Estimated  
Population ~53M

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

# Adults 65 years and older: COVID-19 Risk

- Adults 65 years and older represent 16% of COVID-19 cases but nearly 80% of COVID-19 deaths<sup>1</sup>
- Adults 65 years and older have the highest cumulative rate of COVID-19 associated hospitalizations<sup>2</sup>
- Older age is the strongest independent risk factor for in-hospital death<sup>3</sup>

1. <https://www.cdc.gov/covid-data-tracker/index.html#demographics>

2. [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html)

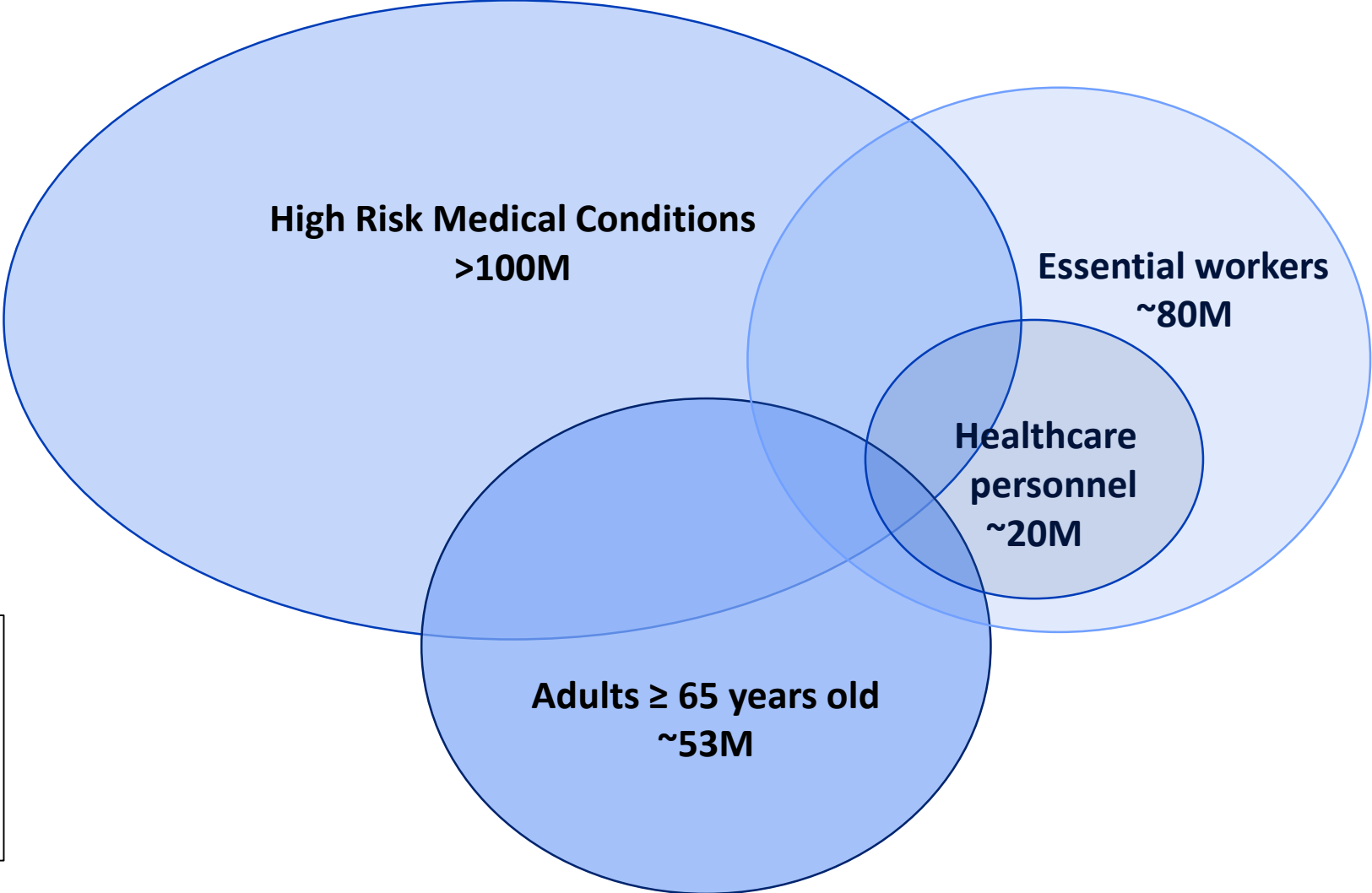
3. Kim *et al*, *Clinical Infectious Diseases*, ciaa1012, <https://doi.org/10.1093/cid/ciaa1012>

# Population 65 years and older by race and ethnicity

Race or Ethnicity	Total Population	65 yrs and older
Hispanic or Latino	17.8%	8.0%
Not Hispanic or Latino	82.2%	92.0%
White	61.1%	77.3%
Black	12.3%	8.9%
AI/AN	0.7%	0.5%
Asian	5.4%	4.2%
NH/PI	0.2%	0.1%
Two or more races	2.4%	0.9%



# Overlap: Adults $\geq 65$ years & High Risk Medical Conditions



➤ **~39%** of adults  $\geq 65$  years old have a high-risk medical condition for severe COVID-19

# Adults ≥65 years: Summary of Work Group Considerations

	EQUITY	VALUES	FEASIBILITY	ACCEPTABILITY	BENEFITS & HARMS
Support		Allocation frameworks support early vaccination of older persons, especially those living in congregate settings	-good healthcare access through Medicare -high proportion with a healthcare/pharmacy home	-Moderate influenza vaccine coverage	?
Challenge	Racial and ethnic minority groups under-represented among adults ≥65 years	National Academies: older adults living at home, without high risk conditions, for Phase II vaccination	-mobility and ability to attend a mass vaccination clinic may be impaired for some		?
Unknown		How do adults ≥65 years value COVID-19 vaccination?		What is acceptability of COVID-19 vaccine among adults ≥65 years?	

# Key Unknowns

- Vaccine characteristics
  - Magnitude and balance of benefits and potential risks
  - Storage/distribution/handling cold chain requirements
  - Vaccine efficacy/immunogenicity in younger and older adult
- The pathway to approval
  - Emergency Use Authorization (all adults vs younger adults)
  - Licensure
- The number of doses available at time of approval and rate of scale-up





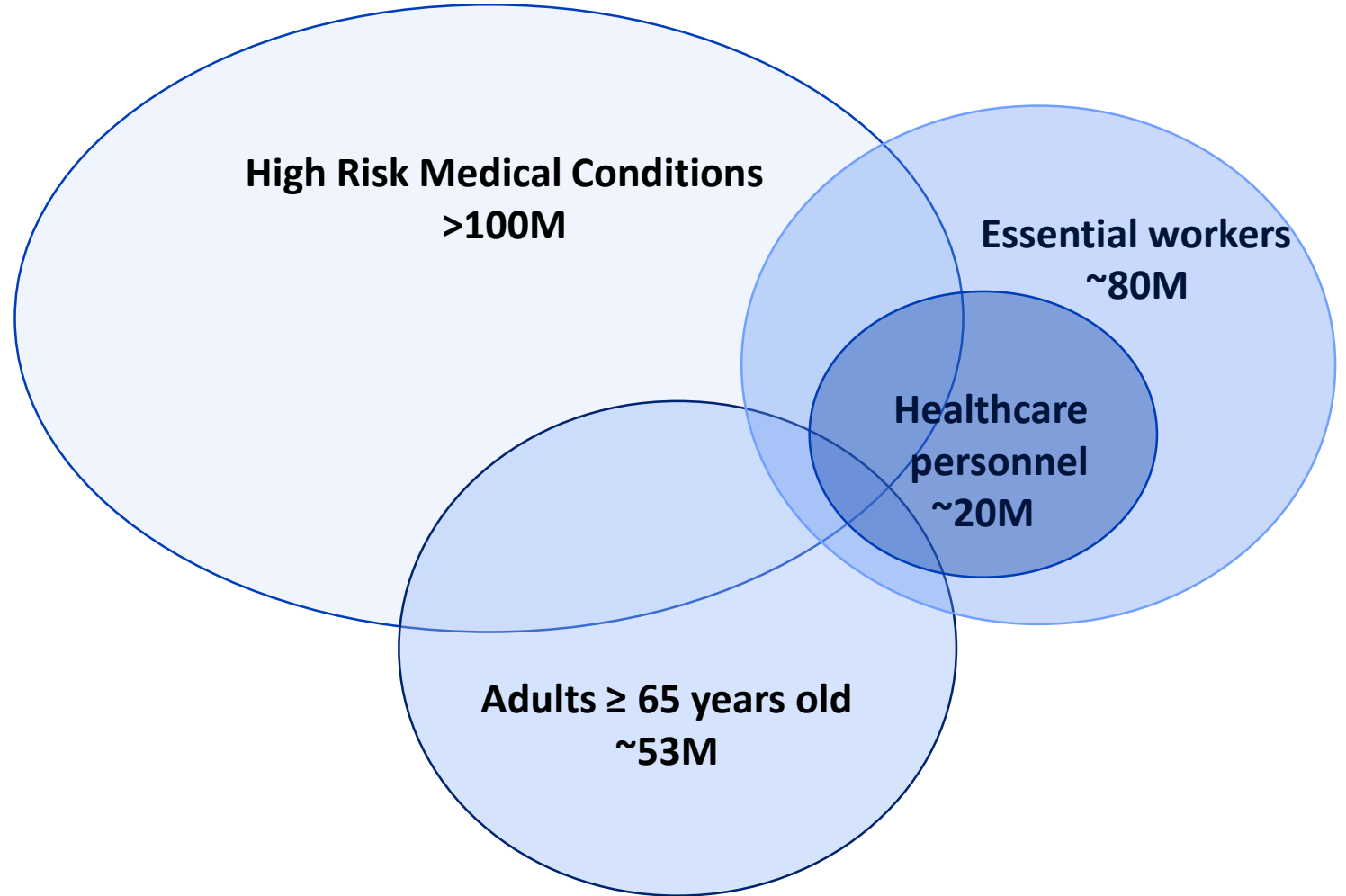
# Work Group Considerations: Next Steps

- Continue to build scientific understanding
  - epidemiology of the outbreak and risk in Phase 1 groups
  - modeling the impact of various vaccination strategies
  - interpretation of clinical trials safety data and plans for post-market safety monitoring
- Prepare Evidence to Recommendation Framework (EtR) for vaccines in Phase III clinical trials
  - prepare an equity domain to add to the EtR
  - gather evidence on value and acceptability of COVID-19 vaccine
  - once data are available from Phase III, GRADE safety and efficacy
  - prepare policy options for ACIP consideration



## Questions:

- 1) If constrained vaccine supply necessitates sequencing of groups in Phase 1b, what are the most important information gaps we need to fill for ACIP to make sequencing recommendations?
- 2) What is the correct balance of national guidance and local flexibility?



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