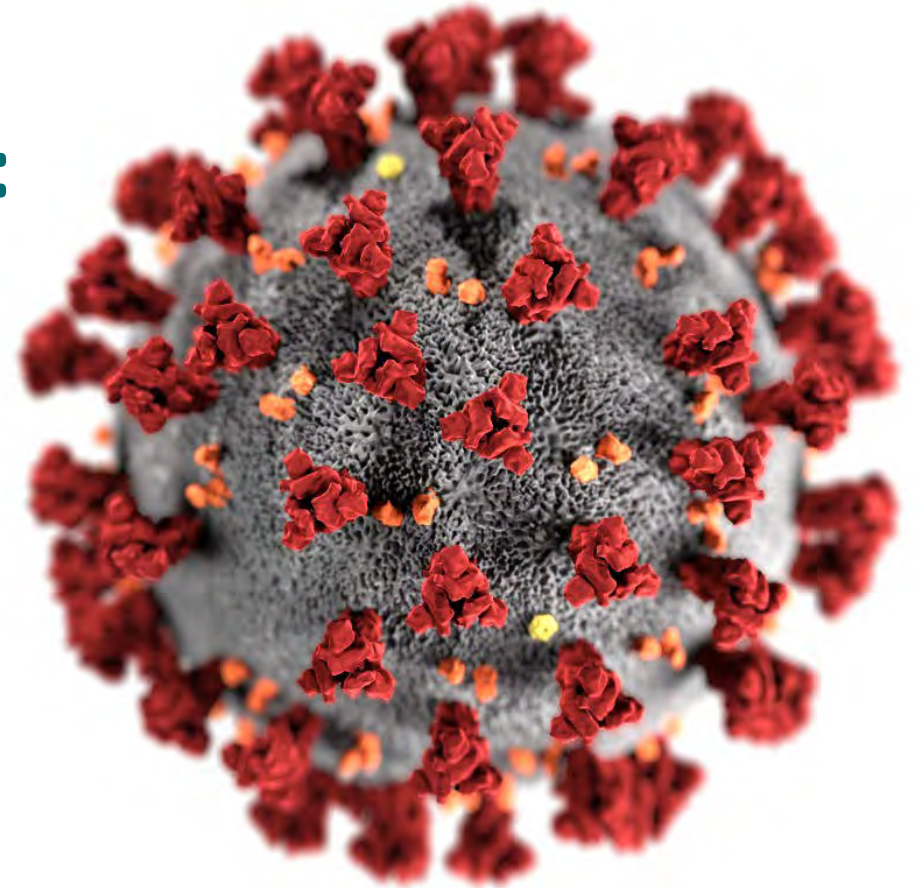


Phase 1 allocation COVID-19 vaccine: Work Group considerations

Kathleen Dooling, MD MPH
September 22, 2020

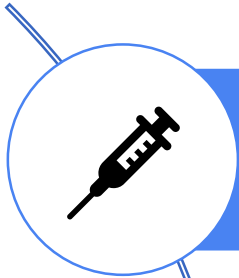


Work Group Considerations: Goals of the COVID-19 Vaccine Program

- 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

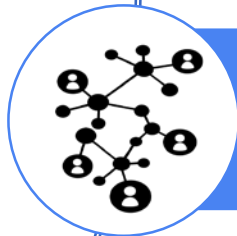
E
Q
U
I
T
Y



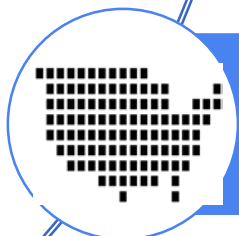
Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution



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

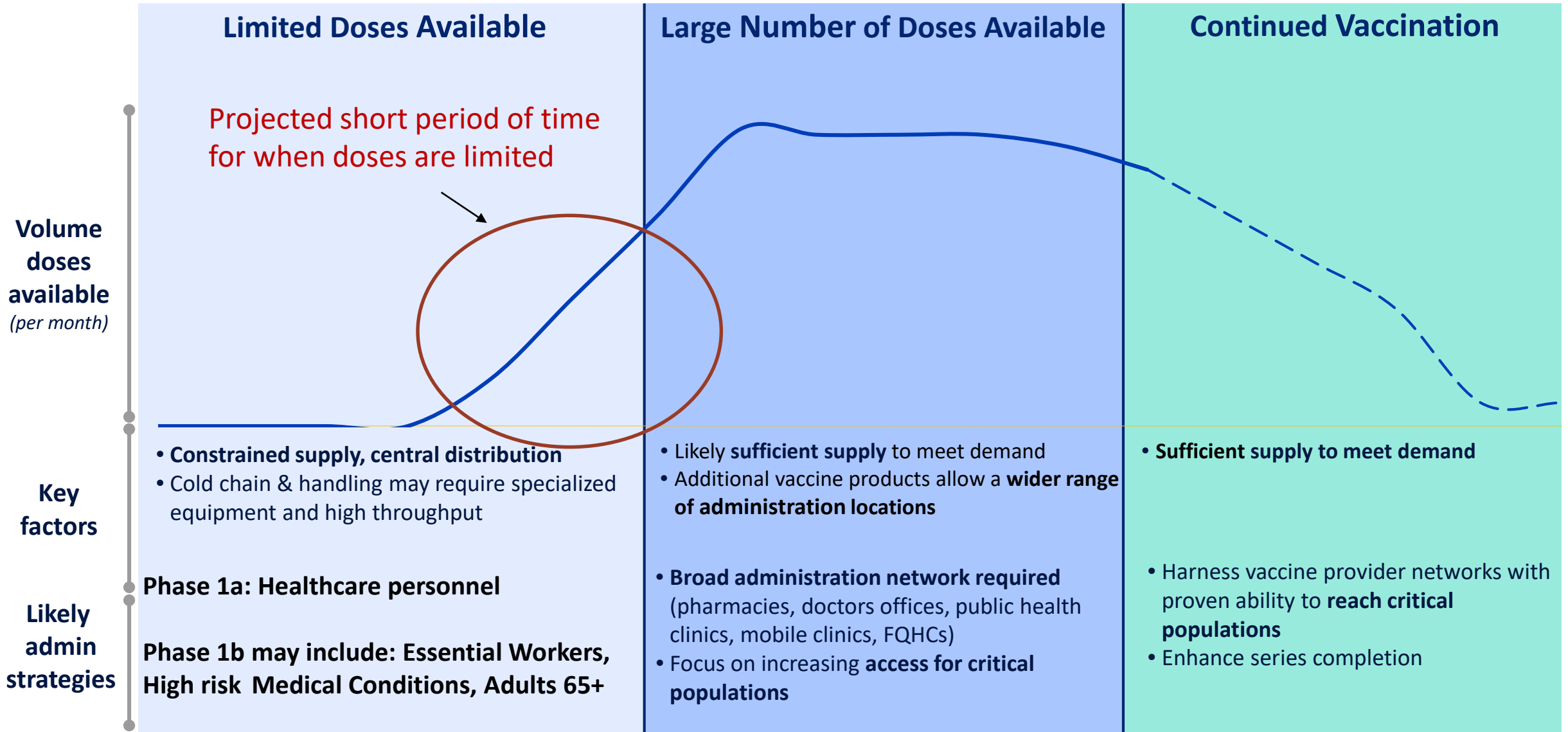


Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical



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:

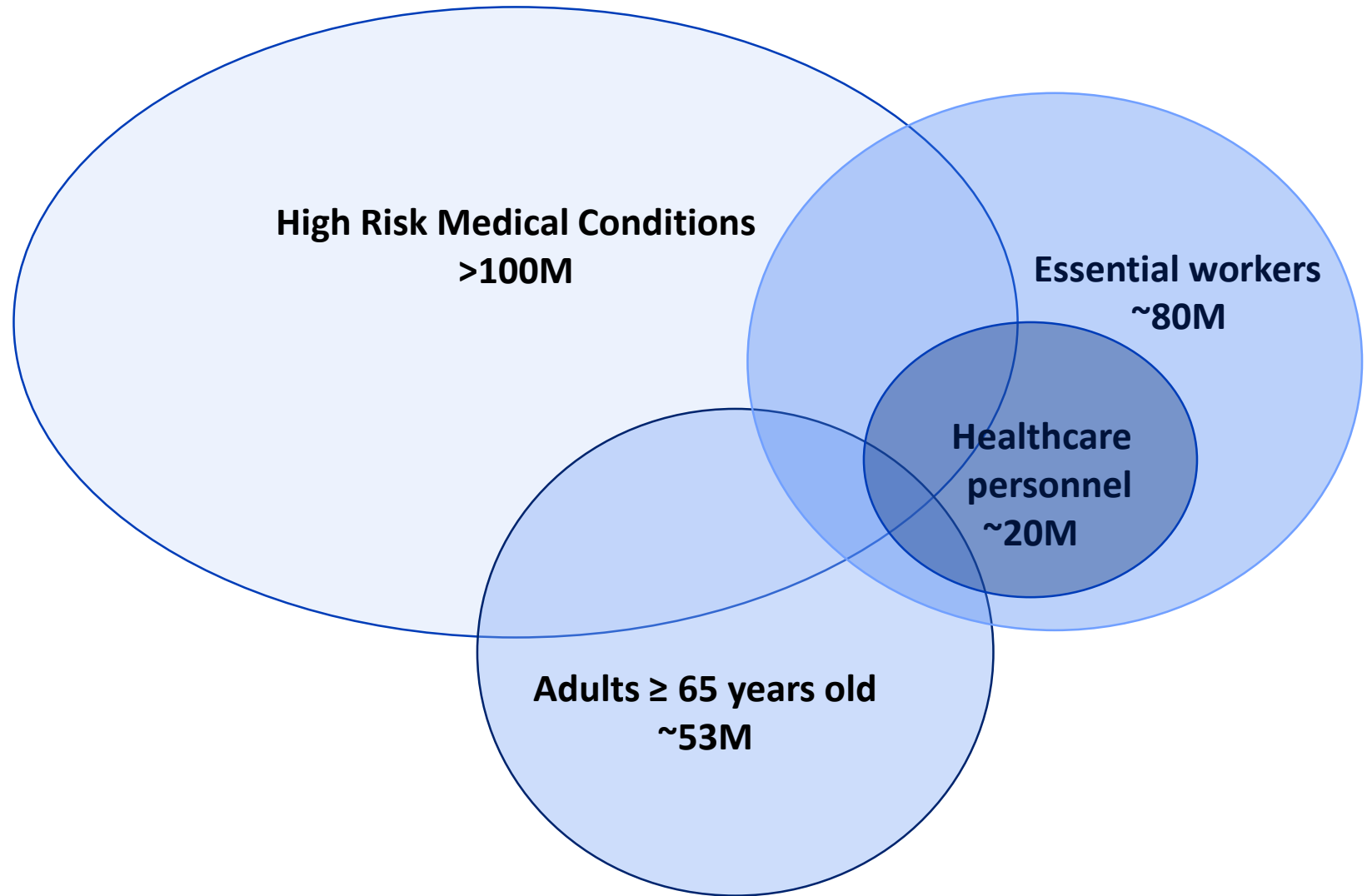
-HCP

Phase 1b:

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

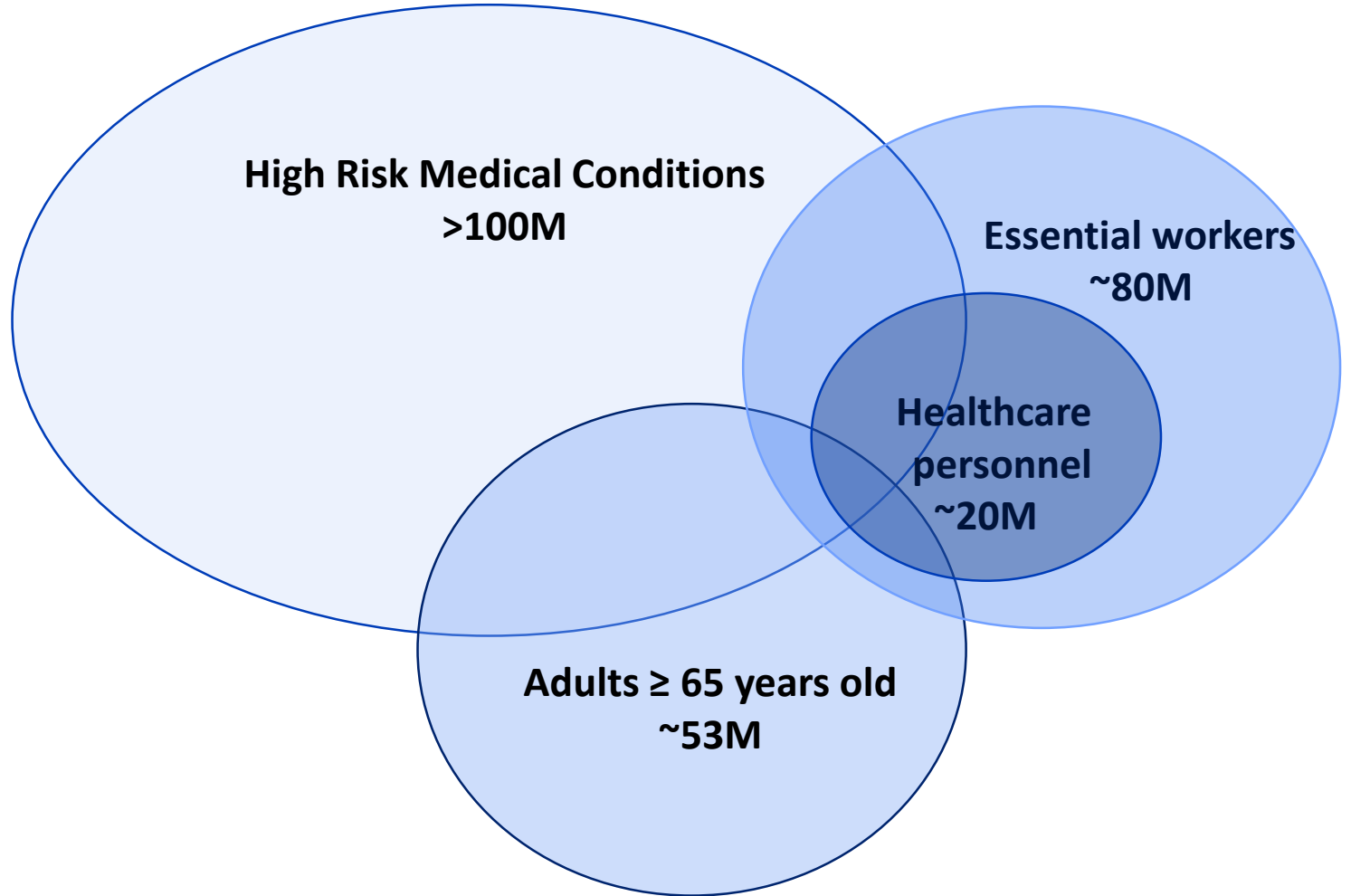
September ACIP meeting

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

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 workers¹
 - 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 staff²
 - 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 persons³
- In NYC, seroprevalence among Correctional facilities workers and Fire Department workers exceeded that of the general population⁴

1. MMWR July 10, 2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6927e2.htm?s_cid=mm6927e2_w

2. UCLA COVID-19 Behind Bars Data Project

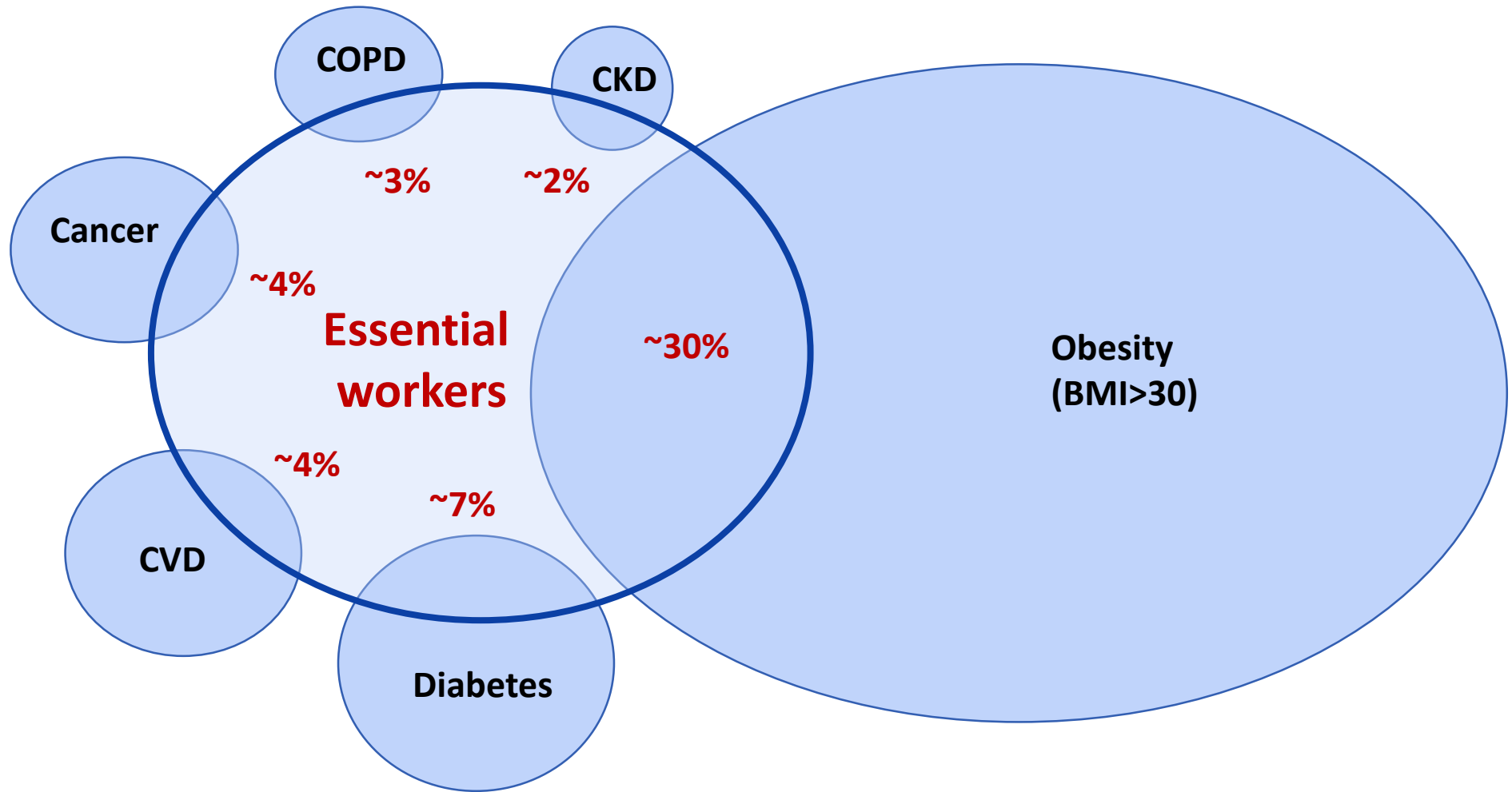
<https://law.ucla.edu/academics/centers/criminal-justice-program/ucla-covid-19-behind-bars-data-project>

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

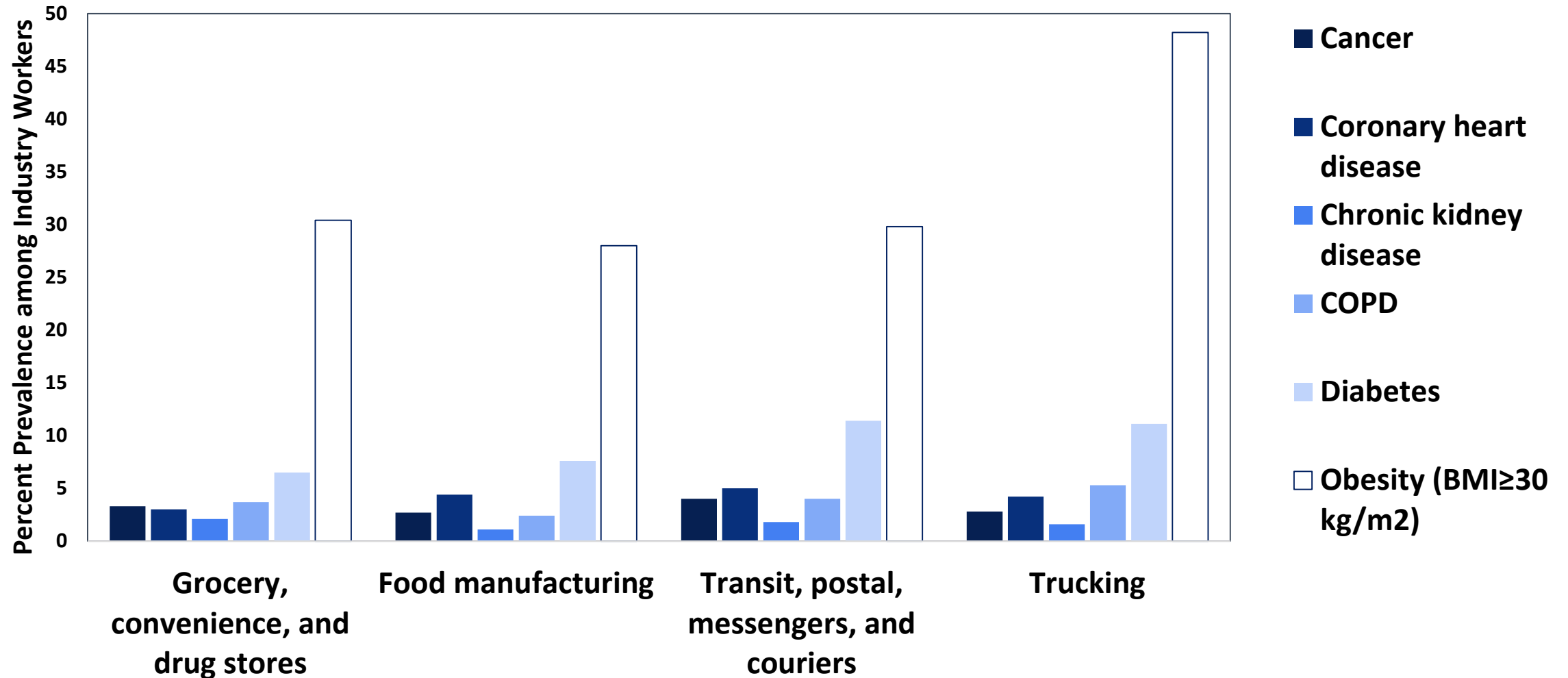
4. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-07/COVID-06-Oliver-508.pdf>



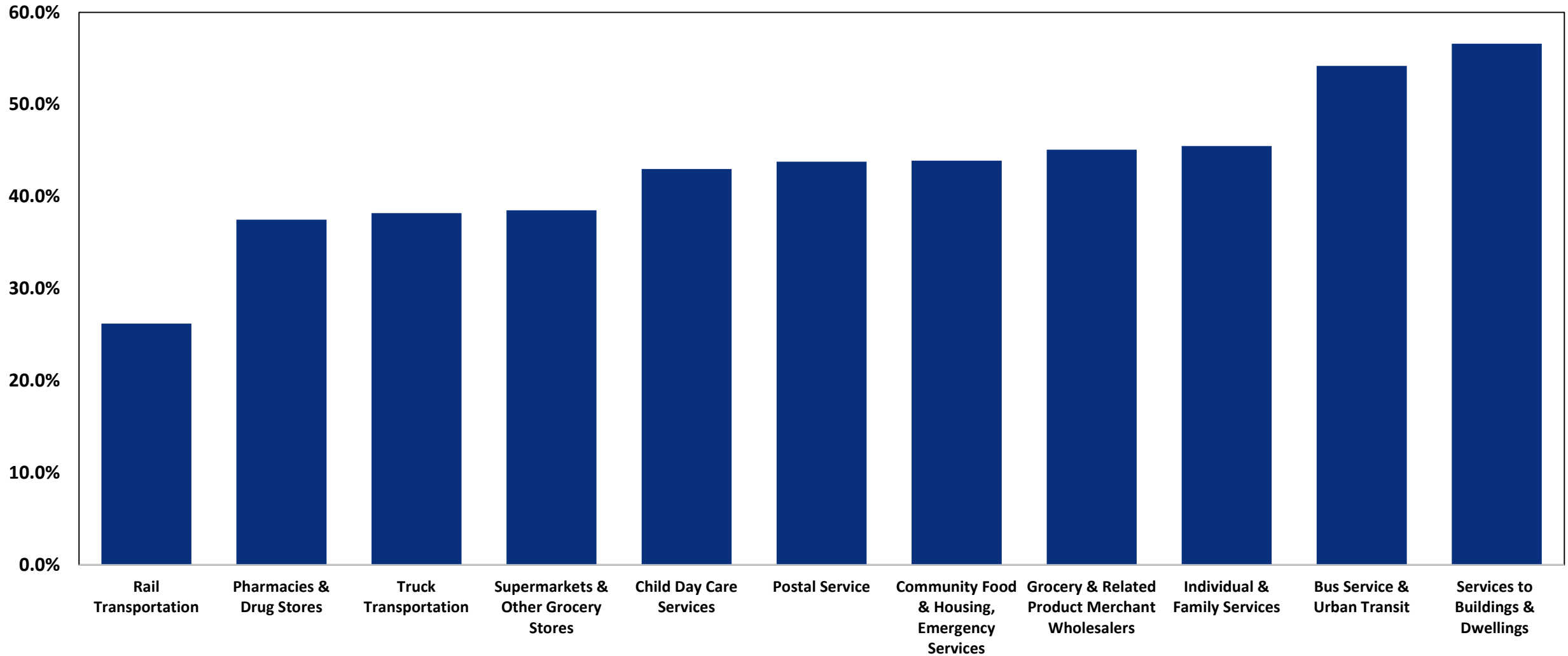
Overlap: Essential Worker & High-Risk Medical Conditions



Selected essential industries by high risk medical conditions

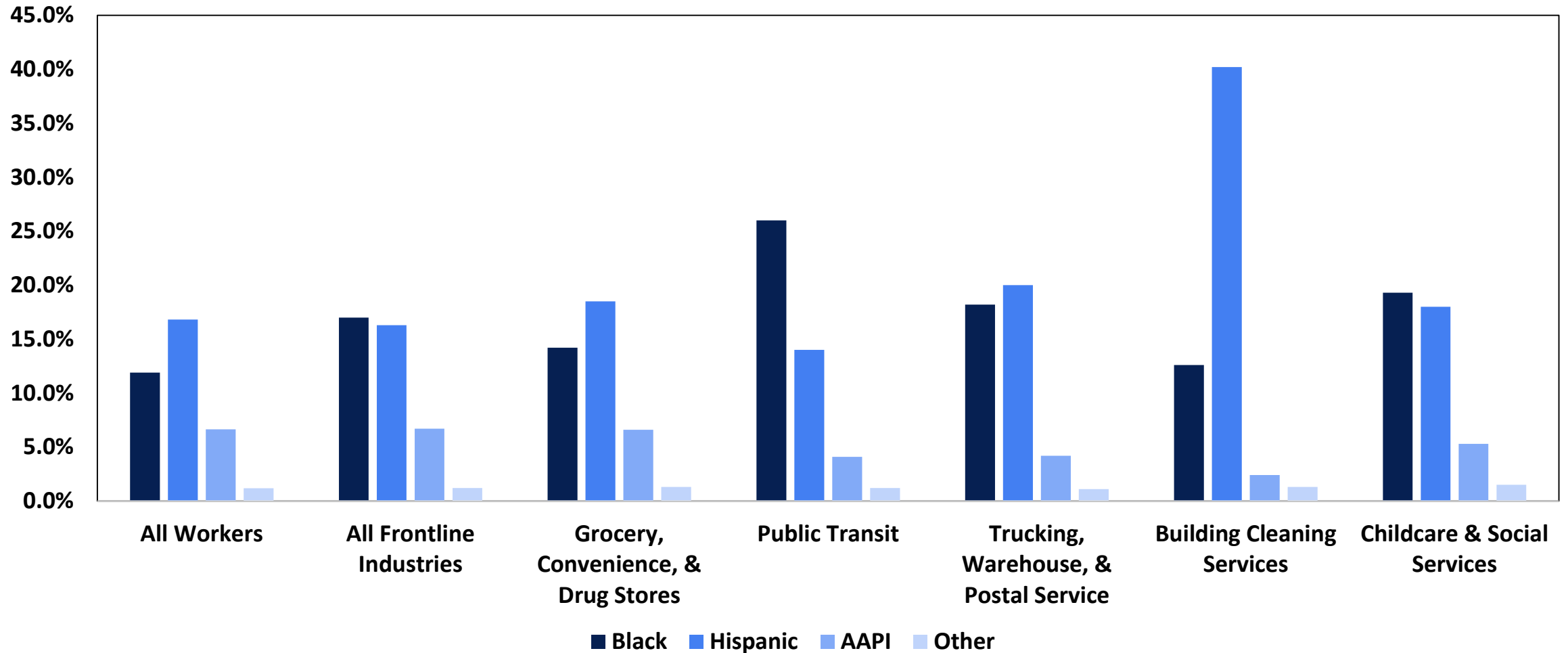


Racial and Ethnic minorities in selected essential industries

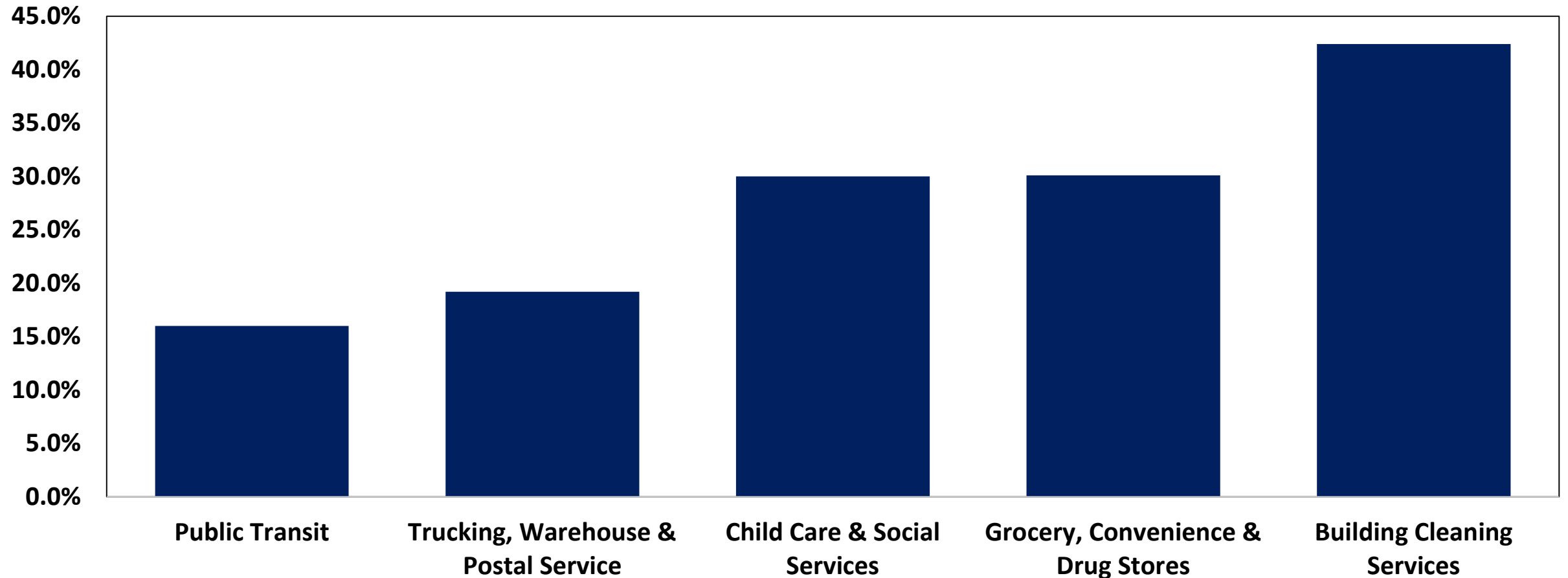


Source: American Community Survey. CEPRs Analysis of American Community Survey, <https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries/>

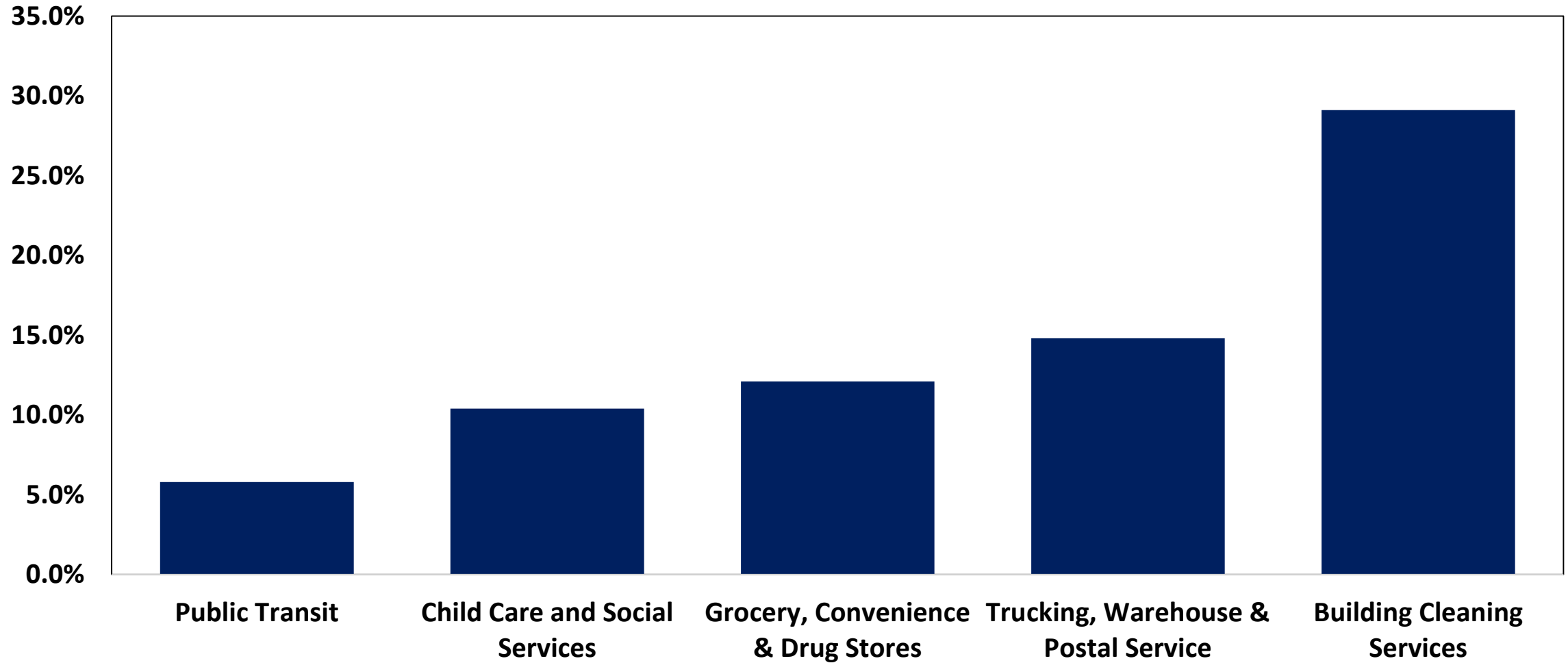
Racial and Ethnic minorities in selected essential industries



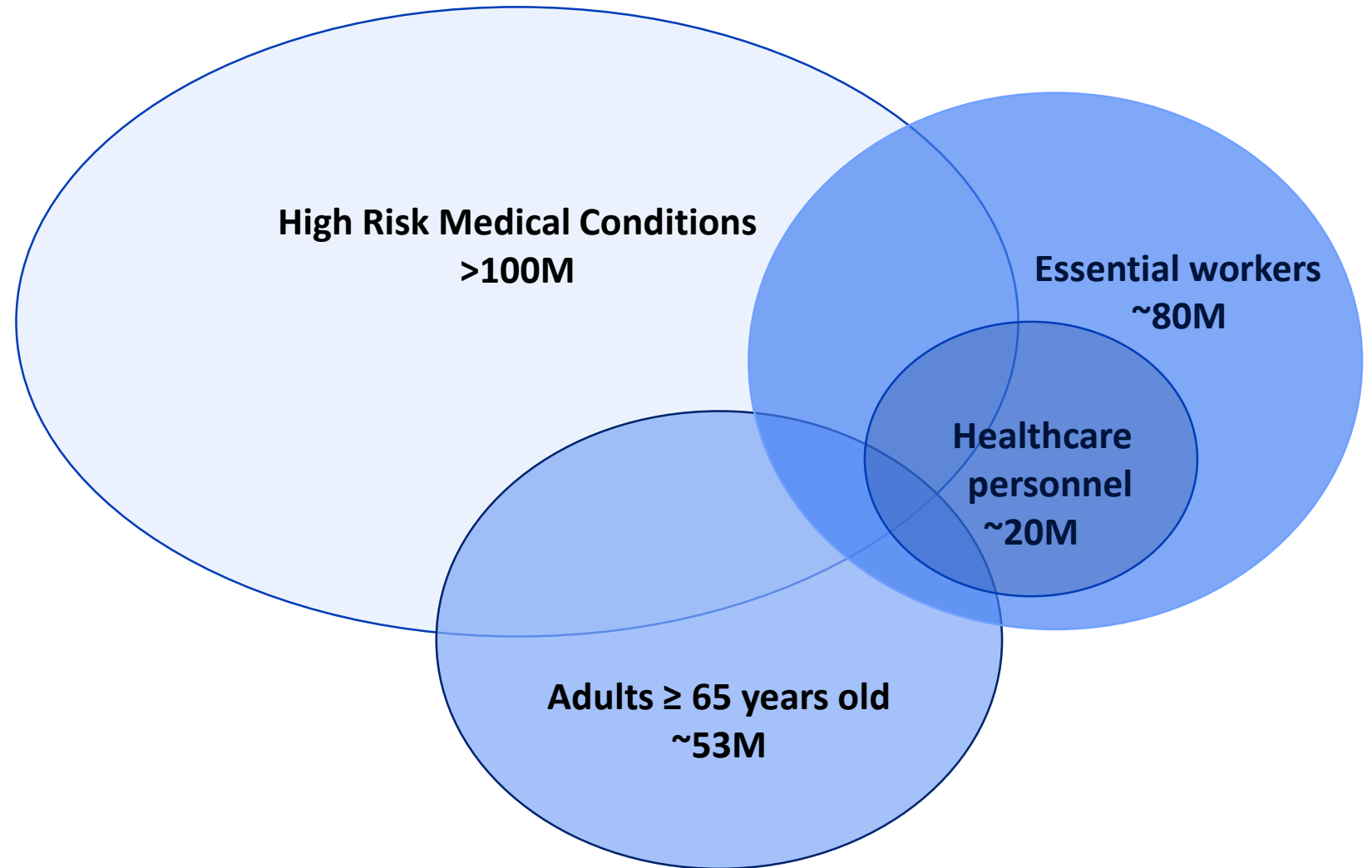
~23% of essential workers live in low-income families (income <2X poverty line)



~10% of essential workers have no health insurance



Overlap: essential workers and adults ≥ 65 years



~16% of essential workers are ≥ 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/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w

High risk medical conditions: COVID-19 risk

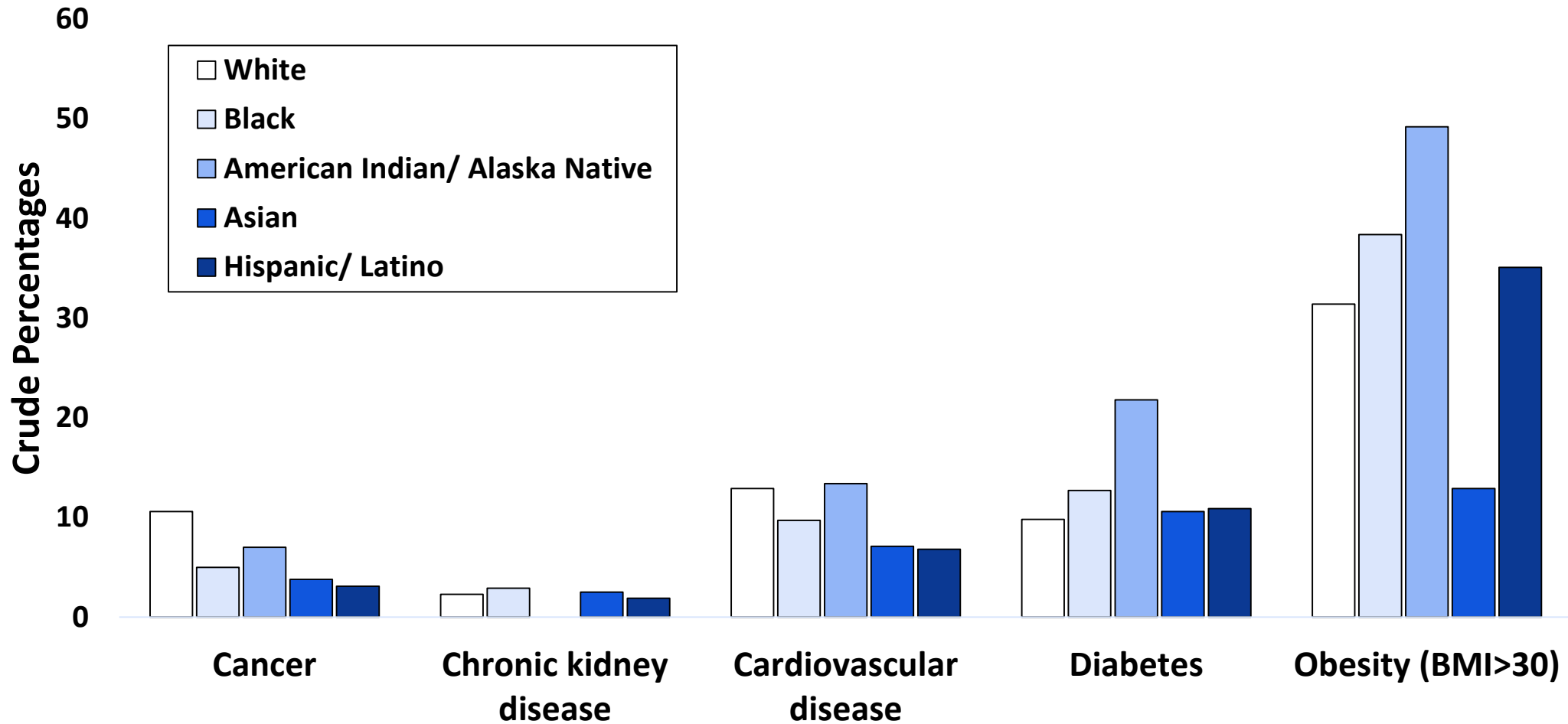
- Nearly 90% of hospitalized adults had at least one high risk medical condition, and over 60% had 3 or more¹
- Obesity, chronic kidney disease, diabetes and hypertension are associated with hospitalization for COVID-19²
- Among hospitalized COVID-19 patients, the adjusted rate ratios for underlying medical conditions association with death ranged from 1.19 (diabetes) to 1.39 (immunosuppression)³

1. 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

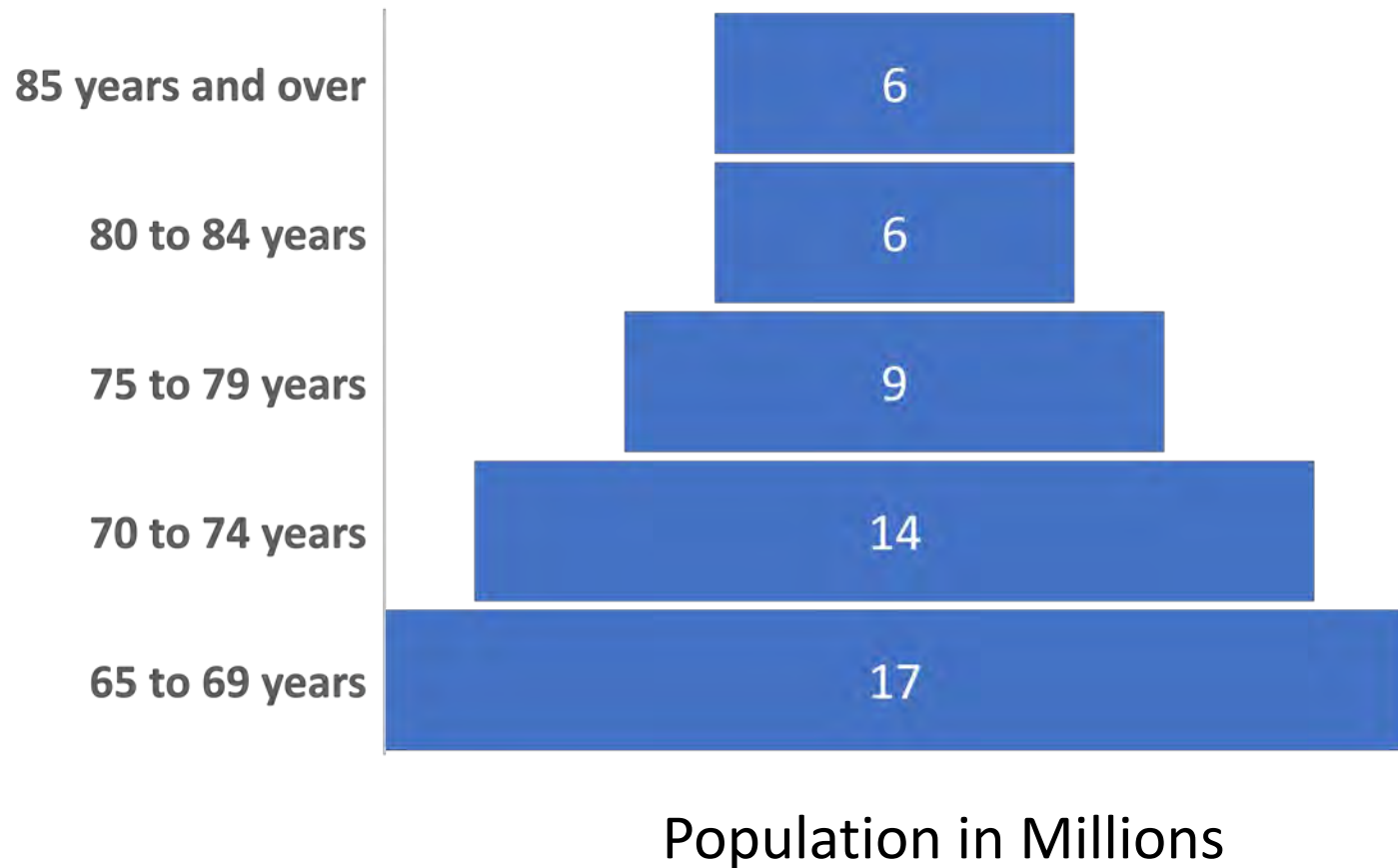
High Risk Medical Conditions: Summary of Work Group Considerations

| | 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 ≥ 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 deaths¹
- Adults 65 years and older have the highest cumulative rate of COVID-19 associated hospitalizations²
- Older age is the strongest independent risk factor for in-hospital death³

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

2. https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

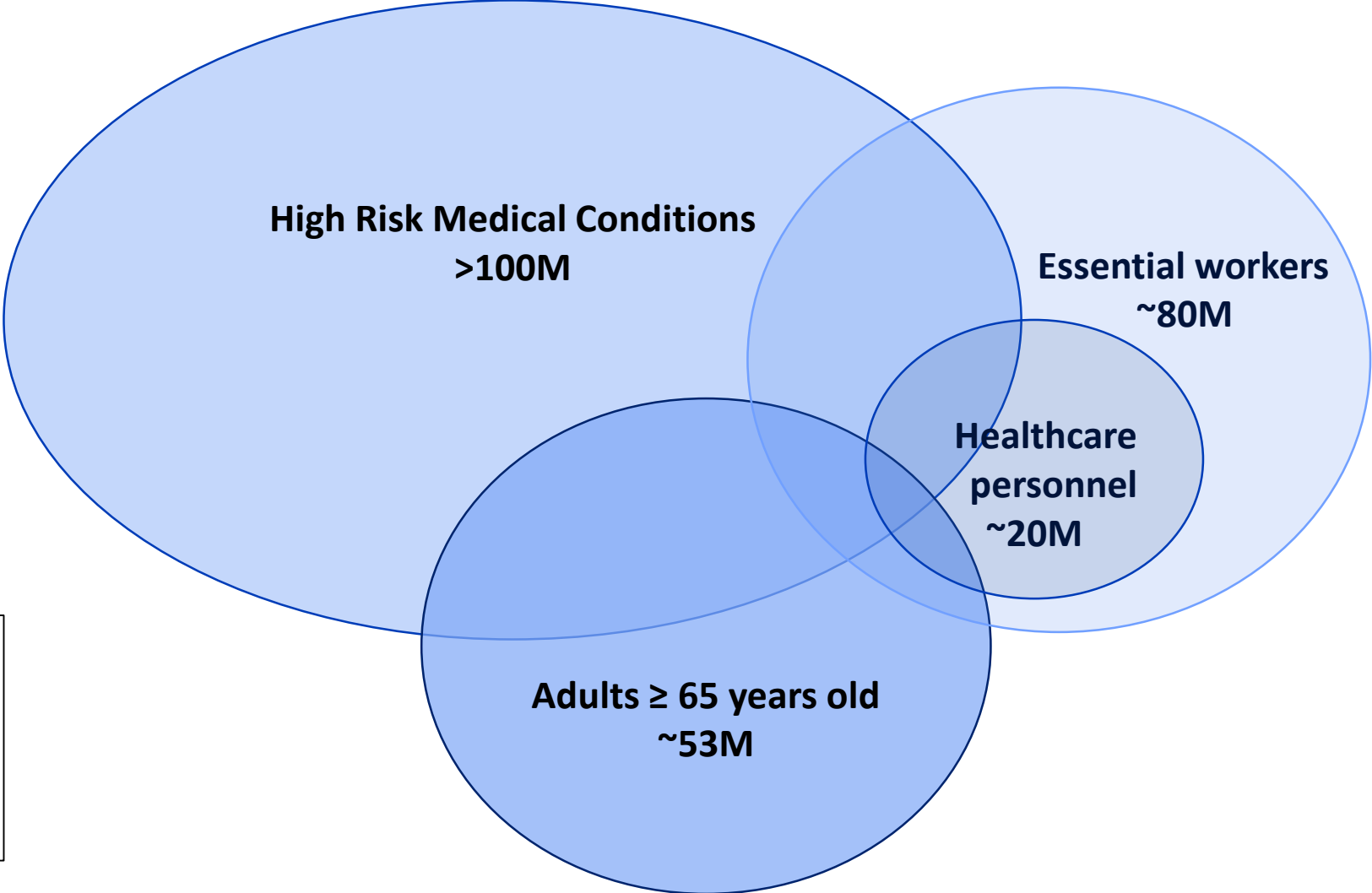
3. Kim *et al*, *Clinical Infectious Diseases*, ciaa1012, <https://doi.org/10.1093/cid/ciaa1012>

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 ≥ 65 years & High Risk Medical Conditions



➤ **~39%** of adults ≥ 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



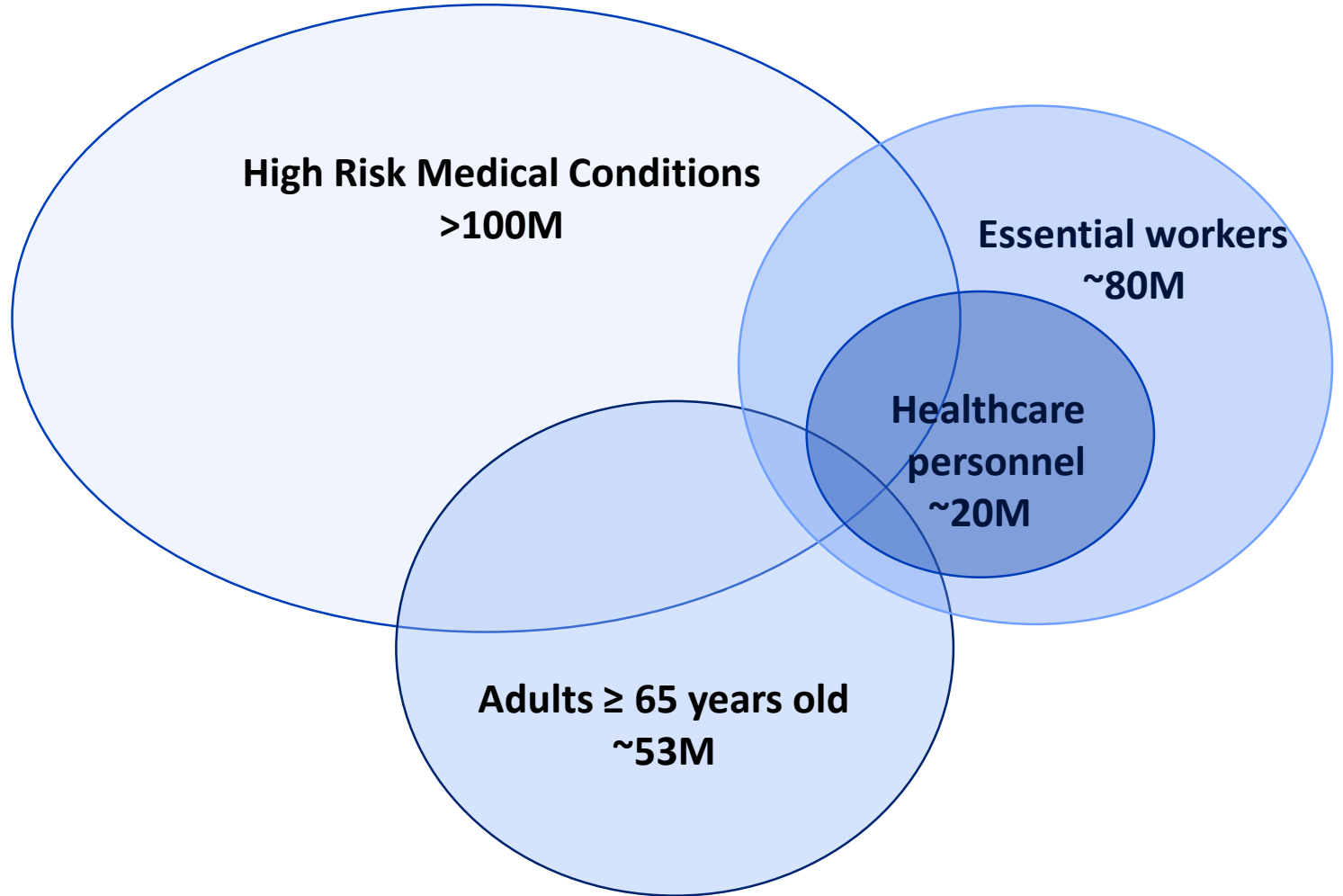
Work Group Considerations: Next Steps

- 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?



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?

