California Drafting Guidelines Workgroup

Immunization will be a critical tool in controlling the ongoing COVID-19 pandemic. Widespread administration of a safe and effective vaccine has the potential to substantially reduce the health and societal impacts of the pandemic when combined with improved diagnostics, therapies, and non-medical interventions. However, immediately after COVID-19 vaccine(s) are authorized or approved by the FDA, the supply will be insufficient to immunize all persons who are willing to accept the vaccine. Therefore, a fair, equitable, evidence-based, and transparent policy is needed to prioritize those who should be offered the vaccine initially until the capacity to manufacture and administer the vaccine increases.

To maximize the benefits of immunization during the initial phase of distribution, the limited supply of COVID-19 vaccine will require a focused strategy. Vaccine administration will ramp up as the volume of vaccine doses available per month continues to increase, and the distribution strategy expands on a phased basis from a focused approach to broader populations.

The overarching aim of these guidelines is to reduce severe disease, deaths, and negative societal impacts due to the transmission of SARS-CoV-2. During Phase 1a, initial goals include preventing California's health system from being overwhelmed by maintaining essential health and emergency services and preventing severe illness those at highest risk.

These recommendations reflect that, at the time of initial availability, evidence will indicate that COVID-19 vaccine protects against COVID-19 disease. Evidence of the vaccine's impact on COVID-19 mortality will likely follow. However, current evidence is too limited as of December 2020 to determine whether or not the vaccine will protect against the spread of SARS-CoV2 infection to others.

Ethical Principles and Criteria for Vaccine Allocation

These guidelines are intended to support the initial phase (1a) of vaccine distribution in a way that can be ethically and effectively adapted to a range of plausible scenarios. Equity is a primary priority for the Drafting Guidelines Workgroup and the CDPH. Health equity "…is defined as the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically or geographically" [1]. Promoting equity is urged in all aspects of COVID-19 vaccination in California.

In developing these guidelines, the Workgroup drew upon ethical frameworks developed by national recommending bodies, including the National Academies of Science, Engineering, and Medicine (NASEM) [2], CDC's Advisory Committee on Immunization Practices (ACIP) [3, 4], and

others [5-7]. Each of these groups established an ethical framework to support their recommendations, which converge on five core principles: benefiting people and limiting harm; prioritizing equity; ensuring equal concern; promoting transparency; and prioritizing based on evidence.

Foundational Principles

Benefiting people and limiting harm is the responsibility to protect and promote the public's health and well-being by reducing risk of infection, severe disease, and death from COVID-19 among people who are at highest risk and those who are essential to critical societal functions.

Prioritizing equity ensures that allocation plans address disproportionate burdens experienced by the certain groups—which are strongly associated with race, ethnicity, occupation, and socioeconomic status—by mitigating inequities and giving priority to the worst off.

Ensuring equal concern requires that every person be considered and treated equally. Unless related to the first two ethical principles, differences between individuals or groups should not factor into allocation decisions.

Procedural Principles

Promoting transparency involves communicating openly and clearly with the public about how allocation strategies are developed and deployed, as well as updating the plan as new information becomes available.

Prioritizing based on evidence requires decisions about allocation to be based on the best available scientific evidence about the risks of disease, transmission, and societal impact.

Risk-based Allocation Criteria

These five ethical principles were used to develop risk-based allocation criteria for prioritizing groups, according to the members' risks of:

Negative societal impact: If members become ill with COVID-19 disease, to what extent would it directly compromise societal functions or risk the lives or well-being of other individuals?

Severe sickness and death due to COVID-19 disease: What is the likelihood that members will develop severe disease or die if they acquire SARS-CoV-2 infection?

Spreading disease: What is the likelihood that members will spread COVID-19 disease to others?

Acquiring SARS-CoV-2 infection: What is the likelihood that members will live or work in settings where they have a higher probability of being exposed to SARS-CoV-2?

As described above, the ability of current and future data to measure each these criteria was also considered in the prioritization.

The recommendations are summarized in the Figure below and described in detail thereafter.

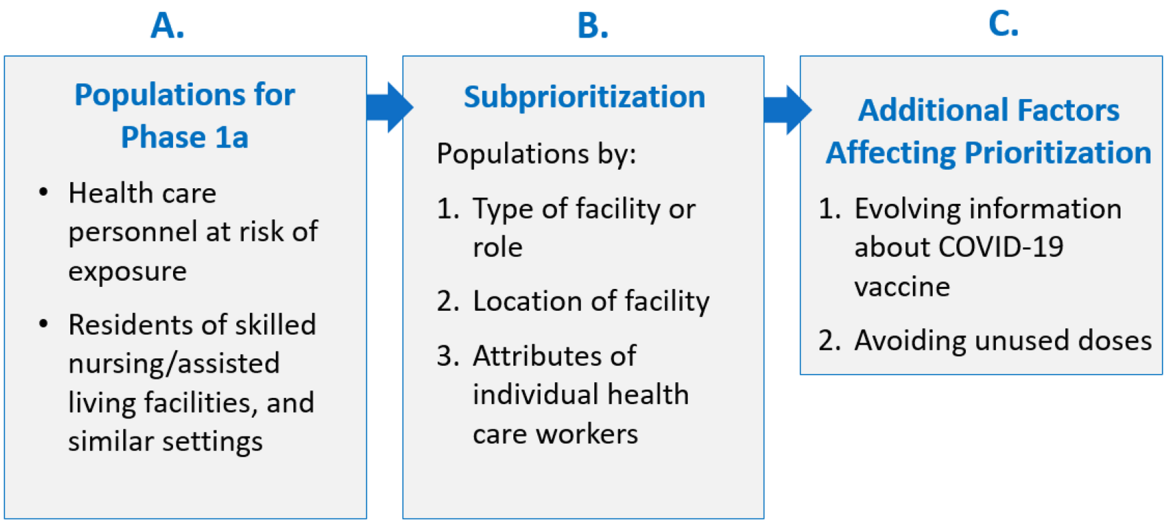

Figure: Summary of recommendations

A. Populations Prioritized for Vaccination During Phase 1a

Based on this ethical framework and the most up-to-date information about the COVID-19 pandemic and forthcoming vaccines, the Workgroup has identified two populations prioritized for vaccination during Phase 1a in California:

1. individuals who risk direct exposure to SARS-CoV-2 by working in health care or long-term care settings and
2. residents of skilled nursing facilities, assisted living facilities, and similar settings for individuals who are older or medically vulnerable. These include groups also identified by NASEM [2] and (ACIP) [3, 4, 8].

Individuals who risk direct exposure by working in health care or long-term care settings

Up to 2 million Californians risk exposure to SARS-CoV-2 through their work in health care or long-term care settings. As of December 1, 2020, approximately 245,000 COVID-19 cases and 858 COVID-19-associated deaths had been reported among U.S. health care personnel [8]. This group includes individuals who work in inpatient, outpatient, home-based, and community-based settings providing clinical care as well as non-clinical services (e.g., environmental services, patient transport, interpreters, laboratory workers, etc.). Allocation priority is based on the members' exposure risks during work, not outside of work.

This group is prioritized during Phase 1a because its members play critical roles in maintaining capacity of California's health system and sustaining health services during the COVID-19 pandemic, both for those with COVID-19 and for those who need care due to other causes.

According to the risk-based allocation criteria, members of this group tend to have high risks of:

1. negative societal impact, if they are unable to work due to SARS-CoV-2 exposure or infection;
2. spreading disease to others, particularly if they work in congregate residential or home-based care settings; and
3. acquiring infection, through contact with patients or residents who have COVID-19.

By staying healthy, members of this group can protect the health of others and help to reduce societal disruption. Prioritizing this target group in the initial phase may also help to expand access to vaccines across a range of different jobs and settings. It may also contribute to mitigating inequities, in that racial/ethnic minority groups are disproportionately represented among low-wage workers in this group.

Residents of long-term care facilities

Residents of skilled nursing facilities and assisted living facilities comprise less than 1% of the population of California (about 300,000-400,000 people), yet they represent 6% of the state's COVID-19 cases and 34% of COVID-19 deaths [9]. This group is also prioritized for vaccination in Phase 1a, because they have high risk of severe sickness and death, as older age and underlying medical conditions are associated with greater risks of hospitalization, ICU care, intubation, mechanical ventilation, or death due to COVID-19 [10-12]. They also have high risk of acquiring infection—and moderate risk of spreading disease—because they live in congregate settings, with limited ability to isolate and maintain social distance.

Recommendation A: Populations for Phase 1a

During Phase 1a of allocation, COVID-19 vaccine should be offered to the following persons in California:

- Persons at risk of exposure to SARS-CoV-2 through their work in any role in direct health care or long-term care settings.
    - This population includes persons at direct risk of exposure in their non-clinical roles, such as, but not limited to, environmental services, patient transport, or interpretation.
- Residents of skilled nursing facilities, assisted living facilities, and similar long-term care settings for older or medically vulnerable individuals.

B. Subprioritization During Phase 1a

During the initial phases of vaccine distribution, supplies will likely be insufficient to administer the COVID-19 vaccine to all individuals within the Phase 1a target groups who wish to receive it.

To ensure equitable allocation of the vaccine while supplies are scarce, health departments should subprioritize doses as needed to match the level of available supplies using three sequential ranked categories of persons exposed though work in health care or long-term care settings:

1. type of facility or role,
2. location of facility, and
3. attributes of individuals.

Recommendation B: Subprioritization During Phase 1a

- During Phase 1a, if there are not enough doses of COVID-19 vaccine for all who choose to receive them, then health departments should subprioritize doses as needed to match the level of available supplies in a sequential fashion using the following ranked categories:
    - Persons exposed though work in health care or long-term care settings, by:
        1. Type of facility or role
        2. Location of facility
        3. Attributes of individuals
- Health departments may reprioritize temporarily under limited circumstances described in Recommendation C.

B1. Type of facility or role

To maintain critical functions of the health care system, the first category for subprioritization during Phase 1a is the type of facility or occupational role, which the Workgroup has segmented into three tiers by applying the risk-based allocation criteria.

Recommendation B1: Subprioritization by type of facility or role

- If supplies are limited during Phase 1a, COVID-19 vaccines should be directed to as many tiers, and categories in each tier (e.g., hospitals) as possible to reach the prioritized populations.
- The tiers and categories in each tier are presented in ranked order.
- Persons immunizing the prioritized populations in a tier should be offered immunization during or before the same tier.

Tier 1

- Acute care, psychiatric and correctional facility hospitals
- Skilled nursing facilities, assisted living facilities, and similar settings for older or medically vulnerable individuals
    - Also, in concordance with ACIP, residents in these settings
- Paramedics, EMTs and others providing emergency medical services
- Dialysis centers

Tier 2

- Intermediate care facilities for persons who need non-continuous nursing supervision and supportive care
- Home health care and in-home supportive services
- Community health workers, including promotoras
- Public health field staff
- Primary Care clinics, including Federally Qualified Health Centers, Rural Health Centers, correctional facility clinics, and urgent care clinics

Tier 3

Other settings and health care workers, including

- Specialty clinics
- Laboratory workers
- Dental and other oral health clinics
- Pharmacy staff not working in settings at higher tiers

B2. Location of facility

The second category for subprioritization during Phase 1a is the location of facility. Counties that have the highest levels of certain social vulnerabilities, especially in less urban areas, have greater risk of becoming COVID-19 hotspots (i.e., locations with rapidly increasing COVID-19 incidence) than counties with the lowest levels [13, 14]. Inequities and disparities in social determinants of health faced by vulnerable communities can increase the risk of being exposed to SARS-CoV-2 and developing severe COVID-19 disease [2, 13, 15]. To promote equitable access, information regarding vulnerability of local populations—and the health systems that serve them—can be used to prioritize certain geographic areas for vaccine distribution.

California health departments should prioritize scarce doses of vaccine using the California Healthy Places Index (HPI) or comparable health department knowledge of local vulnerability and health systems. Vulnerability should be evaluated based on the location of residence of employees and clients (i.e., the catchment area) if different than the location of the facility. The HPI may have limited utility in less populous settings with fewer facilities, in which case health department knowledge of catchment areas may be applied.

Recommendation B2: Subprioritization by location of facility

- When there are inadequate doses to reach all workers in a tier or facility category (e.g., acute care hospitals), doses should be prioritized to facilities serving the greatest proportion of vulnerable persons in their catchment area, as measured by the HPI or comparable health department knowledge, followed by facilities serving fewer vulnerable persons.

B3. Attributes of individual health care workers

Attributes of individual health care workers should be used as the third ranked category for subprioritization. An individual's risk of occupational exposure to SARS-CoV-2 is the primary criterion, because exposure risk is linked to higher risks of acquiring infection, spreading disease, and negative impacts on the health system and society if those individuals are unable to work. The Occupational Health and Safety Administration provides criteria than can be used to stratify workers' relative risks of occupational exposure to SARS-CoV-2 [16].

After occupational exposure risk, other individual attributes that can be used for subprioritization include age, underlying medical conditions, and race or ethnicity. Older adults (65 and over) are at much greater risk of severe disease and death due to COVID-19 than younger people [11]. They are also more likely to have underlying health conditions and live in congregate settings, such as long-term care facilities [2, 17]. Adults of any age have a greater risk of severe disease and death due to COVID-19 if they have certain underlying medical conditions, (e.g., cancer, chronic kidney disease, chronic obstructive pulmonary disease, heart conditions, immunocompromised state from solid organ transplant, obesity, pregnancy, sickle cell disease, smoking, type 2 diabetes mellitus) [18, 19]. Certain racial and ethnic minority groups in the U.S. —including Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islander communities—are being disproportionately affected by COVID-19 incidence, risk of severe disease, and death [2, 13, 15, 20-26].

In accordance with current ACIP recommendations [8], subject to change, workers with documented acute SARS-CoV-2 infection in the preceding 90 days may choose to delay vaccination until near the end of the 90 day period in order to facilitate vaccination of workers who remain susceptible to infection. Current evidence suggests that reinfection is uncommon during this period after initial infection. Of note, previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination, and serologic testing for SARS-CoV-2 antibodies is not recommended prior to vaccination.

Recommendation B3: Subprioritization by attributes of individual health care workers

If there are not enough doses to reach all workers at risk in a facility, then

- **Health departments** may allocate doses for facilities—if information is available—to protect workers at higher risk of occupational exposure to SARS-CoV-2 before those at lower risk.
- **Local facilities** should consider offering doses of vaccine to workers using the following risk factors, in sequence:

- Occupational risk of exposure to SARS-CoV-2
- Descending age, in the following age groups:
    - 65 years and older
    - 55-64 years
    - Younger than 55 years

- Other attributes supported by evidence, including but not limited to underlying medical conditions, race, and ethnicity
    - To support immunization of these workers, facilities should provide extensive information and counseling.

C. Additional Factors Affecting Prioritization

In their prioritization of vaccine allocation, health departments may use additional factors related to (C1) evolving information about COVID-19 vaccine characteristics and (C2) minimizing disuse of scarce vaccine.

C1. Evolving information about COVID-19 vaccine characteristics

Vaccine characteristics that may limit the use or distribution of COVID-19 vaccine include, but are not limited to:

- Storage and handling requirements
- Vaccine safety and efficacy, in subgroups and general population
- ACIP Recommendations for use

Vaccine characteristics related to storage and handling that could affect prioritization include vaccine shipping and storage temperatures, minimum volume thresholds for shipment, and capacity to store large volumes of vaccine. For example, if the initial supplies of COVID-19 vaccine are a limited amount of a product that requires long-term storage at ultra-low temperatures and limited redistribution, these supplies may be directed preferentially to settings with appropriate storage capacity, such as hospitals or health departments.

Evidence about the vaccine's safety and efficacy in specific groups of people and the general population is critical for making allocation decisions [27]. However, much information will remain unknown when supplies are first available during Phase 1a—e.g., evidence about the vaccine's impact on the risk of acquiring or spreading the disease—so prioritization strategies may need to be adjusted in light of new and evolving information about the vaccine's safety and efficacy.

Further, ACIP recommendations for use or indications for use from FDA could impose age limits or other restrictions that could prevent administration of the vaccine to certain health care workers who otherwise would be targeted for initial doses.

Recommendation C1. Evolving information about COVID-19 vaccine characteristics

Health Departments may adjust prioritization to reflect or comply with available vaccine characteristics. However, prompt measures should be taken to revert to the original prioritization criteria and immunize persons delayed by these restrictions as soon as

circumstances permit, such as:

- Additional formulations become available
- Changes in authorized indications from FDA or in recommendations from ACIP or CDPH

C2. Minimizing disuse of scarce COVID-19 vaccine

All efforts should be taken to maximize demand for and avoid disuse of COVID-19 vaccine, especially when supplies are scarce. However, the actual acceptance rate of COVID-19 vaccine will not be known until a vaccine is available and offered, and surveys suggest that a substantial proportion of people who are offered the vaccine may not accept it [28, 29]. Given the current uncertainty of demand for vaccine, health departments may allocate doses on the assumption that immunization will be accepted by some but not all who are offered the vaccine, and then adjust later allocations based on the number of doses that are accepted.

Resources other than the supply of vaccine also affect the pace of immunization. There may be instances where vaccine is available for the next categories of facilities without delaying immunization in the higher category. For example, in the weeks it might take mobile immunization teams to visit hundreds of assisted living facilities in a populous county, current and ongoing supplies could be managed to accommodate immunization in other categories at the same time without delay in supplies to the mobile teams.

Recommendation C2. Minimizing disuse of scarce COVID-19 vaccine

To avoid wastage or disuse of scarce supplies and maximize their benefit to Californians:

- Health departments may allocate doses on the assumption that immunization will be accepted by some but not all who are offered the vaccine, and then adjust later allocations based on the number of doses that are accepted.
- After intensive and appropriate efforts to reach the groups prioritized at that moment, health departments and facilities may offer vaccine promptly to persons in lower priority groups when:
    - Demand subsides in the current groups, or
    - Doses are about to expire according to labeling instructions.
- Health Departments may temporarily adjust prioritization based on other resource constraints while continuing efforts to immunize higher priority groups as soon as feasible.

D. Closing Concerns, Distinct from Prioritization

D1. Promoting equity through outreach, access and support

Promoting equity should inform strategies for prioritizing allocation, broadening access to immunization, and providing communication, outreach, and counseling. Many persons from communities at high risk for COVID-19 may mistrust medical and government institutions—because of structural injustices or other causes—and therefore may be reluctant to receive the

vaccine. California's Community Vaccine Advisory Committee (CVAC) can suggest how to engage these communities, address their concerns, provide convenient access to the vaccine, and assist with messaging. As experience with the vaccine is gained, the CVAC can help inform CDPH of best practices for helping the vaccine reach members of communities at greatest risk for COVID-19.

To promote the equitable provision of Covid-19 vaccine, health departments are encouraged to track:

- uptake of vaccine
- efforts and approaches to reach and support high-risk groups
- accessibility to the vaccine

Health departments are encouraged, but not required, to also track declination of the vaccine.

D2. Addressing vaccine hesitancy

The mistrust of institutions, discussed in D1, is but one aspect of vaccine hesitancy, the delay or refusal of available vaccine services that is common and increasing [2]. Other causes of hesitancy include misinformation, disinformation, or uncertainty regarding vaccines in general or rapidly developed COVID-19 vaccines in particular.

Vaccine hesitancy can be reduced by building public trust and the provision of reliable information by trusted parties, including medical providers and community organizations [30]. CVAC's diverse member organizations and other trusted voices in California's medical and public health systems can address hesitancy through their communication and outreach.

D3. Anticipating potential reactions

Health departments and facilities are directed to ACIP guidance on potential symptoms after immunization [8]. COVID-19 vaccination is expected to elicit fever, headache, or myalgias in some recipients, which could contribute to personnel shortages after immunization. Mitigations might include staggering the delivery of vaccine so that personnel from a single department or unit are not all vaccinated at the same time. Staggering considerations may be more important following the second dose of vaccines that are more reactogenic after the second dose.

Facilities are encouraged to plan for personnel to have time away from work if they develop systemic symptoms following COVID-19 vaccination.

References

1. WHO. *Social determinants of health*. 2020; Available from: https://www.who.int/health-topics/social-determinants-of-health%23tab=tab_3.
2. NASEM, *Framework for Equitable Allocation of COVID-19 Vaccine*, ed. H. Gayle, et al. 2020, Washington, DC: The National Academies Press. 272.

3. Chamberland, M., *ACIP COVID-19 Vaccines Work Group: Ethical Principles for Phased Allocation of COVID-19 Vaccines*. 2020.
4. Lee, G.M., B.P. Bell, and J.R. Romero, *The Advisory Committee on Immunization Practices and Its Role in the Pandemic Vaccine Response.* JAMA, 2020. 324(6): p. 546-547.
5. E. Toner, et al., *Interim framework for COVID-19 vaccine allocation and distribution in the United States*. 2020, Johns Hopkins Center for Health Security: Baltimore, MD.
6. WHO, *Values Framework for the Allocation and Prioritization of COVID-19 Vaccination*. 2020, WHO: Geneva, Switzerland.
7. Emanuel, E.J., et al., *Fair Allocation of Scarce Medical Resources in the Time of Covid-19.* N Engl J Med, 2020. 382(21): p. 2049-2055.
8. ACIP COVID-19 Vaccines Work Group. *Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents*. 2020; Available from: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html.
9. Los Angeles Times. *Tracking the coronavirus in California nursing homes*. 2020; Available from: https://www.latimes.com/projects/california-coronavirus-cases-tracking-outbreak/nursing-homes/.
10. Ioannidis, J.P.A., C. Axfors, and D.G. Contopoulos-Ioannidis, *Population-level COVID-19 mortality risk for non-elderly individuals overall and for non-elderly individuals without underlying diseases in pandemic epicenters.* Environ Res, 2020. 188: p. 109890.
11. McClung, N., *Epidemiology of Individuals at Increased Risk of COVID-19 Disease (CDC Coronavirus Disease 2019 Response)*. 2020.
12. Nikolich-Zugich, J., et al., *SARS-CoV-2 and COVID-19 in older adults: what we may expect regarding pathogenesis, immune responses, and outcomes.* Geroscience, 2020. 42(2): p. 505-514.
13. Wallace, M., *Disparities in COVID-19 Incidence, Severity, and Outcomes (CDC Coronavirus Disease 2019 Response)*. 2020.
14. Dasgupta, S., et al., *Association Between Social Vulnerability and a County's Risk for Becoming a COVID-19 Hotspot - United States, June 1-July 25, 2020.* MMWR Morb Mortal Wkly Rep, 2020. 69(42): p. 1535-1541.
15. CDC. *Health Equity Considerations and Racial and Ethnic Minority Groups*. 2020; Available from: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.
16. OSHA. *Worker Exposure Risk to COVID-19*. 2020; Available from: https://www.osha.gov/Publications/OSHA3993.pdf.
17. Cohen, J., *The line is forming for a COVID-19 vaccine. Who should be at the front?*, in *Science*. 2020.
18. Sanyaolu, A., et al., *Comorbidity and its Impact on Patients with COVID-19.* SN Compr Clin Med, 2020. 2(8): p. 1-8.
19. CDC. *People with certain medical conditions*. 2020; Available from: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.
20. Gold, J.A.W., et al., *Characteristics and Clinical Outcomes of Adult Patients Hospitalized with COVID-19 - Georgia, March 2020.* MMWR Morb Mortal Wkly Rep, 2020. 69(18): p. 545-550.

21. Killerby, M.E., et al., *Characteristics Associated with Hospitalization Among Patients with COVID-19 - Metropolitan Atlanta, Georgia, March-April 2020.* MMWR Morb Mortal Wkly Rep, 2020. 69(25): p. 790-794.
22. Millett, G.A., et al., *Assessing differential impacts of COVID-19 on black communities.* Ann Epidemiol, 2020. 47: p. 37-44.
23. Price-Haywood, E.G., et al., *Hospitalization and Mortality among Black Patients and White Patients with Covid-19.* N Engl J Med, 2020. 382(26): p. 2534-2543.
24. Stokes, E.K., et al., *Coronavirus Disease 2019 Case Surveillance - United States, January 22-May 30, 2020.* MMWR Morb Mortal Wkly Rep, 2020. 69(24): p. 759-765.
25. CDC. *COVIDview Weekly Summary*. 2020; Available from: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html
26. CDC. *COVID-19: Hospitalization and death by race/ethnicity*. 2020; Available from: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html
27. Lipsitch, M. and N.E. Dean, *Understanding COVID-19 vaccine efficacy.* Science, 2020. 370(6518): p. 763-765.
28. Mullen O'Keefe, S., *One in three Americans would not get COVID-19 vaccine.* , in *Gallup News*. 2020.
29. Silverman, E., *STAT-Harris Poll: The share of Americans interested in getting Covid-19 vaccine as soon as possible is dropping*. 2020.
30. WHO. *Improving vaccination demand and addressing hesitancy*. 2020; Available from: http://awareness.who.int/immunization/programmes_systems/vaccine_hesitancy/en/.