



**A Preliminary Plan for Phased Implementation of COVID-19 Vaccination
for the State of Colorado**

Recommendations from the GEEERC Medical Advisory Group

October 8, 2020

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I. Introduction

The SARS-CoV-2 virus (COVID-19) pandemic has taken an unprecedented toll on individuals, the healthcare system, the economy, and society. An effective vaccine or vaccines will be critical to slow the spread of the virus, enable a safe re-opening of the economy, and allow society to return to what will be a new normal. The long-term goal of Colorado's COVID-19 vaccination program will be to vaccinate every eligible person in the state. However, in the near-term, it is highly likely that any approved or authorized vaccines will be in extremely short supply. Therefore, a system must be developed that addresses allocation of initially scarce vaccines to critical populations, implementation of a vaccination program, and vaccine hesitancy, while also accounting for the health inequities observed in the COVID-19 pandemic.

Multiple national and international groups are actively working on recommendations for critical populations and phased implementation of COVID-19 vaccination. In the United States, the National Academies of Science, Engineering, and Medicine (NASEM) released their preliminary recommendations for critical populations on September 1, 2020.¹ The Advisory Committee for Immunization Practices (ACIP), a committee within the Centers for Disease Control and Prevention (CDC) that routinely makes vaccine recommendations, is currently deliberating their recommendations for a phased implementation of a COVID-19 vaccine across critical populations (the release date for these recommendations is not yet clear).² The CDC interim playbook for the COVID-19 Vaccination Program highlights a phased implementation of vaccination across critical populations based on the available supply of the vaccine (limited, larger number of doses, and sufficient supply for the entire population). Finally, the WHO has issued a report detailing the ethical underpinnings of defining specific critical populations.³

At the time of this report, formal guidelines for defining critical populations and implementing a COVID-19 vaccination have not been issued by federal groups. Therefore, the phased implementation of vaccination described in this document will be subject to change when federal agencies approve their final recommendations. The goal of this report is to align our phased approach with federal efforts as closely as possible while still accounting for Colorado-specific considerations and to match expansion of vaccine eligibility through the population with expanding vaccine availability.

This preliminary report details the ethical principles and a preliminary phased approach for vaccine allocation that should guide our planning efforts and implementation. Based on current CDC plans, vaccines will be distributed from manufacturers and pharmacy distributors directly to vaccine providers (e.g. individual practitioners, retail pharmacies, healthcare institutions, local public health agencies, etc.). However, the Colorado Department of Public Health and Environment (CDPHE) will guide vaccine distribution to specific jurisdictions within the state. Therefore, the recommendations within this report should be used to plan allocation of a scarce vaccine based on estimates of critical populations at the local level, and to guide providers in deciding which patients to vaccinate as the vaccine supply evolves.

II. The Scientific Process

The Food and Drug Administration (FDA) holds the primary responsibility for approving all medications, vaccines, and medical devices in the United States. For decades, the FDA has utilized rigorous clinical trials that incrementally advance knowledge from safety in a small group of healthy volunteers (Phase I trials) to ongoing safety and efficacy data in a small groups of people some of whom may have the condition or exposure of interest (Phase II trials), and finally to large studies with hundreds to thousands of participants meant to obtain reliable efficacy data and prove ongoing safety (Phase III trials). While the process can be complex, it is the cornerstone of the healthcare establishment and ensures patients receive safe and effective



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therapies. The sanctity of this unbiased scientific process is the foundation of healthcare and a key ingredient to both providers and patients being able to trust medicine.

There have been extensive discussions about when a COVID-19 vaccine might become available and the mechanism by which it might first be released. The Emergency Use Authorization (EUA) power of the FDA was created in 2004 specifically to address the need for novel therapeutics for potential chemical, biologic, radiologic, or nuclear attacks/emergencies. While the authorizing language for EUAs has evolved over time, it was not intended for vaccines that would be administered to an entire population. EUAs during the COVID-19 pandemic have a complex history. For example, the EUA for hydroxychloroquine was issued based on limited data only to be withdrawn when its efficacy and safety for COVID-19 were called into question. There have also been significant concerns about possible political influence in the EUA for convalescent plasma. However, it is not impossible to envision a situation in which an EUA may be feasible and appropriate for a COVID-19 vaccine. Many clinical trials have pre-determined interim analyses by Data Safety Monitoring Boards (DSMBs) for the explicit purpose of evaluating for potential excess harm or an extremely large beneficial effect. These rigorously planned and executed interim analyses sometimes can provide sufficient clinical data to warrant stopping a trial due to harm or marked benefit but these decisions must be guided by the highest levels of scientific integrity.

The scientific bar to justify an EUA for a COVID-19 vaccine would have to be incredibly high to maintain public trust in the system and in the vaccine. An EUA or full approval that even appears to be influenced by politics or other non-scientific concerns will cause irreparable long-term harm to the vaccination programs, perceptions of vaccine safety, and trust in public health. If a vaccine authorization is thought to be driven by anything but the highest scientific standards, it will destroy trust in the FDA, the general approval process, COVID-19 specific vaccination programs, and potentially all vaccination programs in the future. The number of people vaccinated early through an EUA process may be offset by the potential for large portions of the US population losing trust in and forgoing vaccines in the future. It is for these reasons that we strongly recommend that the highest scientific standards guide all aspects of vaccine authorization/approvals and Colorado's specific vaccination programs.

III. Ethical Principles

The key mission for our vaccine administration planning is to establish an ethically defensible and fair allocation system that is both transparent and unbiased. Critical to the process of developing a vaccine strategy are the core principles of fairness, transparency, consistency, proportionality, accountability, duty to care, and the duty to steward resources especially when scarce.⁴ At no point should decisions to deny vaccines be based on age, gender, race, ethnicity, ability to pay, disability status, national origin, primary language, immigration status, sexual orientation, gender identity, HIV status, religion, veteran status, "VIP" status, housing status, or criminal history other than as described in the vaccination phases. The goal is to vaccinate all eligible individuals as quickly as possible. However, certain populations who may be at higher risk for severe disease or members of a critical workforce may receive higher vaccine priority if the supply is limited. In developing a structure for vaccine prioritization, several ethical principles were used to guide the process:

- Save the most number of lives - Throughout the pandemic, saving the most number of lives has been a guiding public health principle.
- Maintain societal function and cohesion during and after the pandemic – The pandemic has fractured multiple areas of society and, at times, pitted some groups against others. Maintaining strong social cohesion after the pandemic is critical for a return to normal and should be considered in the vaccine allocation process.



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- Reciprocity - Some individuals and groups put themselves at risk of contracting COVID-19 through their work or societal function (e.g. healthcare workers, first responders, grocery store workers, etc.). Reciprocity would hold that these individuals should receive higher priority for a vaccine due to the increased risk they incur by providing essential societal services.
- Multiplier Effect - Some individuals serve a critical societal function in caring and securing the lives of others (e.g. firefighters and healthcare workers). By preventing these individuals from becoming ill, they may then continue to save other lives.
- Equity - The COVID-19 pandemic has exacerbated health inequities and with communities of color experiencing increased risk of infection as well as severe disease and death.⁵⁻⁹ Equitable allocation and distribution of a COVID-19 vaccine is critical to addressing these inequities.

IV. Vaccine Allocation Phases^a

Extensive work at understanding how to prioritize different populations for a pandemic vaccine has already been done by the CDC, the WHO, and other groups in preparation for a potential influenza pandemic.^{2, 3, 10-12} As stated, ACIP and the NASEM are currently finalizing their recommendations for critical populations and we will align these recommendations with federal guidance when available.¹ Additional modifications to this proposed phased approach may be required when a vaccine actually becomes available. Therefore, we propose a preliminary framework to provide more granular allocation plans, inform current planning and modelling efforts, identify key data elements that need to be collected, and to be able to pivot rapidly if needed once details of an approved vaccine are available. When considering critical populations for vaccine prioritization, there are four key groups to consider:

- Critical Workforce - This group includes healthcare workers, firefighters, emergency medical services, police officers, and critical public health personnel. These individuals often have the highest risk of exposure to COVID-19 through their work and care critical to maintaining essential societal functions. Moreover, members of this group are often able to save the lives of others, providing instrumental value to society.
- Essential Workers - For Colorado, essential workers were defined in the Governor's Fourth Updated Public Health Orders 20-24 issued on April 9, 2020.¹³ Essential workers are those that work for a critical business and are deemed essential by that business. Examples of essential workers include grocery store workers, food service workers, transportation personnel, electric and water workers, teachers, vaccine manufacturing personnel, etc. Essential workers may bear increased risk of exposure to COVID-19, may be a vector of infection to more vulnerable populations, and are essential to societal function.
- Individuals at Risk for Moderate to Severe Disease and Death - Some individuals are at significantly higher risk of developing moderate to severe disease and dying from COVID-19.¹⁴⁻¹⁷ The list of conditions that confer a high-risk of severe disease is evolving. Key risk factors currently include residence in a nursing or long-term facility, age ≥ 65 years, obesity, diabetes, active cancer, etc.
- General Public – Adults 18-64

In general, the goal is to try to match progressively increasing population size in each phase with a corresponding increase in vaccine availability through increased manufacturing. It would not make sense to have an extremely large phase early in the vaccination process before a sufficient supply were available.

^a One stage in the series of the overall vaccination process



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- We recommend the following approach to vaccination implementation with sequential phases of critical populations with increasing number of eligible individuals matching increases in vaccine availability as shown in Table 1 and Appendix A.

This approach may be modified as more knowledge regarding vaccine efficacy and the virus itself becomes available.

TABLE 1: Vaccination Phases

Phase	Category	Members
1A	Critical workforce	Inpatient Healthcare Workers ^B (including those at assisted living and nursing facilities)
		Outpatient Healthcare Workers ^C (including home health workers and outpatient pharmacists)
1B	Critical workforce	Emergency Medical Services Firefighters Police Officers Public Health Personnel ^D
1C	Highest risk individuals	Residents/patients of assisted living, long-term care, and nursing facilities ^E
2A	Essential workers (I) (Appendix C)	Essential workers with direct interaction with the public, in high-density work places, or in pandemic essential roles ^F
2B	Higher risk individuals ^A (Appendix D)	Adults ≥ 65 years Adults with obesity (BMI ≥ 30) Adults with diabetes Adults with chronic lung disease ^G Adults with significant heart disease ^H Adults with chronic kidney disease requiring dialysis Adults with active cancer Adults with immunocompromised state Incarcerated adults Adults living in group homes Adults experiencing homelessness Adults who received placebo during a COVID-19 vaccine clinical trial
3	Essential worker (II) (Appendix C)	Essential workers without direct interaction with the public or in high-density settings ^I
4	General public	Adults 18-64 without high-risk conditions

^AThe classification of high-risk conditions is constantly evolving and modifications to the list of potential high-risk conditions will be updated over time.

^BInpatient healthcare workers would include individuals working at nursing and residential facilities. Inpatient healthcare workers specifically refers to those with direct patient care responsibilities (physicians, nurses, pharmacists, respiratory therapists, physical therapists, etc.), patient support responsibilities (e.g. social workers, case managers, chaplains, etc.) those involved in processing patient samples (e.g. phlebotomists, laboratory technicians, etc.), and hospital support personnel with contact with patient care areas (e.g. environmental services staff). See Appendix B for a definition of healthcare workers.

^COutpatient healthcare workers would include similar categories as inpatient healthcare workers as well as home health workers, outpatient pharmacists, and primary vaccine providers. See Appendix B for a definition of healthcare workers.

^DKey public health personnel may include primary vaccine providers and contact tracers if their position results in increased risk of exposure.



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^ENot including patients in a dedicated hospice facility. Patients in hospice facilities would be vaccinated with the general public.

^FFront facing essential workers are those who have direct interaction with the public (e.g. grocery store workers, teachers and childcare workers, transportation personnel, correctional officers, public-facing staff at essential business, etc.) and those who work in high density areas with high-risk of transmission (e.g. food service industry workers, meatpacking workers, migrant farm workers, agricultural workers, postal workers, individuals involved in the manufacturing of a COVID-19 vaccine, etc.).

^GCOPD, chronic hypoxic respiratory failure and other severe lung diseases.

^HSignificant heart disease includes heart failure, coronary artery disease, moderate to severe pulmonary hypertension, and other cardiomyopathies.

Some groups of essential workers (e.g. some banking services that operate remotely, core utility and electrical services, telecommunications and data center personnel, other public health personnel, etc.) may not have increased risk of exposure to COVID-19 through their jobs.

There are certain key populations that are not yet part of this staged system. We anticipate that military personnel will be vaccinated by the federal government. Children and pregnant women are not included in this preliminary phased approach as the current vaccine trials exclude children and pregnant women. We anticipate some guidance from the federal government about safety and efficacy in these important populations at the time of an emergency use authorization or full approval and plan to incorporate children and pregnant women, if appropriate, at the time of actual implementation.

- **We recommend using the definition of essential workers as described in Colorado's Fourth Updated Public Health Order 20-24 from April 9, 2020 with the addition of teachers and other school staff.**

In this order, "critical business" are defined and workers employed or contracted to these businesses can be deemed essential.¹³ Additionally, the proposed framework divides essential workers into two separate groups based on the core ethical principles already delineated. Essential workers, by definition, have instrumental value but not all have increased risk of exposure, as some may be able to work from home or have very limited interaction with the public. The principle of reciprocity would only apply to those who have increased risk of contracting COVID-19 when their job requires interacting with large numbers of people. Therefore, essential workers with increased risk of exposure due to their work are given higher priority.

Within Phase Allocations

It is highly probable that initial releases of the vaccine will not be sufficient to vaccinate all individuals in Phase 1 or even in Phase 1A.

- **We recommend using a combination of risk of exposure, and risk of severe disease or death in determining within phase allocations. Specifically, we recommend (see Appendix A):**
 1. **Prioritizing inpatient healthcare workers before outpatient healthcare workers if there is an insufficient supply to vaccinate all of Phase 1A due to potentially higher risk of exposure.**
 2. **Prioritizing patients at higher risk of severe COVID-19 related disease and death over critical workforce members who do not have a high-risk condition if there is insufficient supply to vaccinate a sub-phase (e.g. not enough for all inpatient healthcare workers or not enough for all individuals in Phase 1B).**
 3. **Prioritizing essential workers with a condition that puts them at higher risk for severe disease and death followed by essential workers without high-risk conditions if there is insufficient vaccine supply for all public facing or high-density essential workers (Phase 2A).**



4. **Prioritizing individuals with high-risk conditions (Phase 2B) who live in communities with the highest positivity and transmission rates of COVID-19 over high-risk individuals who do not live in a hotspot if there is not enough vaccine for all individuals in Phase 2B.** Phase 2B vaccines are likely to be provided by traditional vaccine providers (e.g. individual practitioners, retail pharmacies, etc.). Therefore, if there are insufficient vaccine supplies for all of Phase 2B, we recommend that CDPHE guide the distribution of vaccines to vaccine providers in geographic areas with higher COVID-19 positivity and transmission rates for the initial phases of Phase 2B vaccinations.
5. **Prioritizing Phase 3 and Phase 4 individuals based on areas with higher COVID-19 positivity and transmission rates if vaccine shortages still exist when Phase 3 and 4 are activated.**

In summary, within phase allocations for Phase 1-2A will be based on identifying individuals at high-risk for severe disease and death (see definitions in Appendix D for Phase 2B conditions). For example, if there were insufficient vaccines to vaccinate all inpatient healthcare workers with a single vaccine distribution, older healthcare workers (≥ 65 years), those with obesity, those with diabetes, etc. would receive the highest priority. Within phase allocations for Phase 2B-4 would be based on prioritizing distribution of vaccines to communities with high positivity and transmission rates. Identifying communities with the highest rates of transmission is based on effective contact tracing which necessitates rapid test turnaround times as well as equitable access to testing throughout Colorado.

V. Vaccination Outside of Phase Approach

It is clear that the spread of COVID-19 has significant regional variation. In Colorado, Eagle and Summit Counties saw an early spike in COVID-19 cases followed by Denver County and other metropolitan areas. Regional spread can often be linked to rapid transmission within certain communities or certain industries (e.g. meat packing). Identifying hotspots (areas of high positivity rates and rapid transmission) can guide within phase allocation in the overall prioritization approach (See Section IV). However, we also recommend that CDPHE and local public health agencies monitor for the emergence of areas of high positivity and/or high transmission rates. Areas of rapid and high transmission could quickly overwhelm local health systems especially in rural areas with limited access to hospitals and other forms of healthcare.

- **We recommend that CDPHE and local public health agencies attempt to direct vaccines to emerging hotspots based on up-to-date positivity and transmission rates.**

There are multiple logistical hurdles that will need to be overcome to design a system of early hotspot identification. Geographic targeting of communities or industries relies on widespread availability and access to testing, adequate testing supplies, and rapid turnaround time for results. Once a hotspot is identified, CDPHE would partner with local public health agencies and potentially community health workers who have relationships with residents within a hotspot to determine the optimal delivery method (e.g. mobile vaccination teams, local health centers, a public health location dedicated to vaccination, etc). While targeting hotspots has the potential to slow spread within specific areas, we recognize that it may not be possible due to limited vaccine supply, insufficient testing, local resistance, etc. However, we recommend that early local and state planning efforts incorporate targeting areas of high transmission if possible.

VI. Implementation of COVID-19 Vaccination Program

There are numerous logistical hurdles to implementing a successful pandemic vaccination program. Some of the issues stem from the large number of unknowns regarding any potential vaccine. Multiple COVID-19 vaccines are currently in development with varying characteristics. Some vaccine candidates require ultra-low cold chain management (-80°C) and others require



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two doses separated by 21-28 days. Some vaccines rely on an mRNA vector, a novel vaccine approach, which might engender more anxiety among recipients. Many of these issues cannot be resolved until a determination is made as to which vaccine will be authorized/approved and made available to Colorado. However, in early planning stages, the CDC has already issued guidelines to states on potential solutions to the ultra-low cold storage issue and recommended developing systems to track patients to ensure they receive all doses in a vaccination program. Currently, CDPHE is already developing systems to track multi-dose vaccines to ensure an individual receives the required number of doses at the appropriate time intervals of the same vaccine.

We recommend that:

- **CDPHE and local public health agencies develop estimates for the size of each critical population described in the phased allocation plan.** Currently, there are little data as to the size of each phase and sub-phase for Colorado. Therefore, efforts must be made to approximate the size of each phase and sub-phase as soon as possible. While state-level estimates are important, local/county data are even more important as eventual dissemination of a vaccine will be based on these local needs. With adequate data, when CDPHE learns how many doses of a vaccine will be distributed to Colorado, there can be a rough estimate of how many phases can be vaccinated based on a specific dispersal size and how best to distribute those vaccines throughout the state.
- **CDPHE and local public health authorities continue efforts to engage local vaccine providers in preparation for a COVID-19 vaccination campaign.** CDPHE has previously worked with local public health authorities to design a vaccine implementation plan most recently modelled after pandemic influenza. During the COVID-19 pandemic, a major hurdle will be enrolling providers (individual, retail pharmacy, etc.) and educating them about the phased approach to vaccine allocation. The CDC requires that all interested COVID-19 vaccine providers register with the Immunization Information Systems (IIS). CDPHE and local public health authorities are already engaging with local providers and we recommend that this work continue to ensure that individual vaccine providers are prepared to meet CDC data collection requirements, to track patients for multi-dose vaccines, to have appropriate personal protective equipment for staff, and to handle ultra-low cold storage needs if necessary.
- **CDPHE develop a system of communicating which phase should be vaccinated at a given time to all vaccine providers and that efforts be made to educate and train on vaccine providers on the prioritization approach.** While delivery to inpatient healthcare facilities will be fairly straightforward, delivery to additional populations may be more challenging. CDPHE and local public health agencies have already developed some plans for delivery to other populations within Phase 1 as part of prior pandemic influenza planning. Beyond Phase 1, it is not yet entirely clear how vaccines will be distributed throughout the state. Based on CDC guidance, we expect vaccines to be delivered directly to end users (practitioners, retail pharmacies, local public health agencies, etc.) directly from manufacturers. CDPHE will be able to provide guidance on where vaccines should go throughout the state and the size of each allotment. However, the final decision on which patients should be vaccinated will likely fall on individual vaccine providers.
- **CDPHE develop contingency vaccination plans if traditional vaccination routes (e.g. provider offices) close or become inaccessible.** During the first COVID-19 surge in March - May 2020, many primary healthcare facilities switched to telehealth services and stopped many preventative healthcare visits. As such, it is possible that when COVID-19 vaccine becomes available to larger portions of the general public, the State could be in another surge situation. Therefore, contingency plans should be



developed for the scenario that another stay home order exists and/or primary care centers are operating in limited capacity.

VII. Healthcare Equity

CDPHE and this advisory group acknowledge that long-standing systemic racism, including economic and environmental injustice, has created negative health outcomes. These systematic biases influence a person's health more than individual behaviors and affect marginalized communities, particularly people of color, more than other communities. To realize a future where all Coloradans have the opportunity to thrive, we must be leaders in undoing government policies and practices that have contributed to these inequities and creating new ones that ensure equity.

One cannot discuss the COVID-19 pandemic without also discussing the disproportionate toll it has taken on communities of color including Black, Hispanic, and Indigenous populations.^{6, 7, 17} Based on CDPHE data, Hispanic people accounted for 38% of all hospitalizations related to COVID-19 while comprising only 22% of the State's population. In May, more than 50% of hospitalized patients with COVID-19 were Hispanic. Similarly, Black patients accounted for 10% of COVID-19 hospitalizations while making up only 4.6% of the State's overall population.⁵ These health inequities need to be considered at every level of the COVID-19 response. Vaccination programs could exacerbate inequities if not done in an equitable and fair manner, and if concerns about vaccine hesitancy (see Section VIII) among communities of color are not addressed.

This group, and others, have considered multiple approaches to addressing some of the COVID-19 inequities through a vaccination program. Early community engagement revealed multiple key concerns within some communities. Some community members were enthusiastic about outright prioritization of communities of color due to historically poor access to healthcare and current COVID-19 outcome gaps. However, there was also a strong opposing voice from some who believed that a prioritization of minority populations could be viewed as "more research" and that the vaccine would be tested on them with the legacy of the Tuskegee Syphilis Study, the case of Henrietta Lacks, etc. weighing heavily on their concerns.^{18, 19} Based on this feedback, there is significant concerns that explicit prioritization of race/ethnicity could have long-term ramifications for societal cohesion, could exacerbate vaccine hesitancy among communities of color, could affect future vaccination efforts, and would potentially face legal challenges that could derail the entire vaccination plan. However, healthcare inequities experienced by communities of color during the COVID-19 pandemic cannot be ignored, and drove the inclusion of equity as a core principle for vaccine allocation. Therefore, equity considerations were built into all recommendations:

- Members of communities of colors with high-risk conditions are more likely to live with healthcare workers who are at higher risk of exposure to COVID-19.²⁰ Therefore, prioritizing healthcare workers in general will confer some protection to individuals at high-risk who live in multi-generational homes.
- In the early phases of the pandemic, long-term care facility, assisted living facility, skilled nursing facility and home health staff often suffered from extremely limited access to personal protective equipment. Furthermore, the residents in these facilities were at extremely high-risk for becoming infected and transmitting the virus to their caregivers. Communities of color are overrepresented in this workforce.²¹ For example, in Colorado, 26% of home health aides self-identify as Hispanic and 9% as non-Hispanic Black, exceeding the general population.²² By including these critical workers in Phase 1A, we acknowledge the important work they do, the risk they take, and the inequities exacerbated by the overrepresentation of individuals from communities of color.



- Essential workers, especially those who directly interact with the public or work in high density areas (Phase 2A), are at higher risk of exposure to COVID-19. Communities of color are disproportionately represented in these essential categories (e.g. grocery store, migrant farm/agricultural, transportation, meat packing, correctional officers, etc.) and are more likely to live with high-risk individuals in multi-generational homes, further exacerbating COVID-19 related inequities.^{20, 23} For example, 35% of restaurant cooks and food preparation workers and 43% of janitorial staff self-identify as Hispanic.²² 15% of food processing workers (e.g. butchers) self-identify as non-Hispanic Black.²² Therefore, prioritizing public facing and high-density essential workers could reduce some of the inequities already seen in the COVID-19 pandemic.
- Prioritizing individuals at high risk for severe disease and death (Phase 2B) addresses the ethical principle of trying to save the most number of lives. However, there is ample data to show that communities of color have disproportionately higher rates of high-risk conditions (e.g. obesity, diabetes, heart disease, etc.) and tend to live in either high-density areas or in multigenerational homes which can increase risk of COVID-19 exposure.^{7, 8, 16, 20, 24} For example, in Colorado 12% of Hispanic individuals, 11% of non-Hispanic Black individuals, and 5% of non-Hispanic White individuals have diabetes.²⁵ Similarly, 30% of Hispanic and non-Hispanic Black adults are obese compared to 21% of non-Hispanic White adults.²⁵ Therefore, using high-risk conditions to prioritize certain populations will address some of the drivers of healthcare inequities seen thus far.
- Several hotspots have been tied to industries that have higher percentages of individuals from communities of color (e.g. meat packing plants). Furthermore, positivity and transmission rates have been higher in communities of color. It has been theorized that due to numerous historical inequities and some cultural norms, communities of color are more likely to live in higher density communities and in multi-generational homes. Therefore, a system of targeting vaccines to areas and industries with high positivity and transmission rates as either a within phase criteria or as a system separate from the phased approach would potentially address some of the healthcare inequities evident in the pandemic.
- **We recommend that access to testing be made more equitable and that metrics be established to ensure adequate dissemination of a vaccine to health centers and pharmacies in all communities once a vaccine becomes widely available. If certain communities have higher positivity and transmission rates, we would recommend greater allocation to vaccine providers in those areas.**

VIII. Vaccine Hesitancy

Despite vaccine safety being one of the most studied topics in medicine, there is growing evidence of vaccine hesitancy in our community. Some reports estimate that anywhere from 30-50% of individuals have significant concerns about a COVID-19 vaccine, with higher rates among underrepresented minorities. Vaccine hesitancy among underrepresented minorities has multiple drivers including but not limited to historically poor access to healthcare, concerns about immigration documentation status, the lack of racial/ethnic diversity in vaccine clinical trials, historical experimentation being conducted on minority populations without their consent (e.g. Tuskegee Syphilis Study), etc. Unfortunately, these populations are also the ones most affected by the COVID-19 pandemic. CDPHE and other organizations in Colorado have already developed robust community engagement groups and equity response teams to address concerns around vaccine development and safety.

- **We recommend engaging with community leaders (political, religious, social, etc.) throughout the state to raise awareness of the importance of vaccination efforts and**



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to dispel rumors and misinformation campaigns that have become increasingly prevalent.

- **We recommend engaging with local community healthcare workers to determine optimal means of communicating the importance of a vaccination program and its safety as they often develop extremely close trusting relationships with the populations with whom they work.**

Vaccine hesitancy within specific communities may not be the only hurdle faced by a COVID-19 vaccination program. There is some concern about vaccine hesitancy among healthcare workers as well. The speed of development and testing as well as recent concerns about political influence in the approvals process has raised the possibility of healthcare workers avoiding a COVID-19 vaccine. Vaccine hesitancy among healthcare workers would only exacerbate hesitancy among the general population and have long-term effects on other vaccination programs. As stated in Section II, only by abiding by the highest scientific standards can a COVID-19 vaccine and the FDA approvals process gain the trust of healthcare workers. We recommend CDPHE communicate openly with healthcare workers and institutions regarding concerns about the potential for an early EUA. We also recommend CDPHE, the GEEERC, and the GEEERC Medical Advisory Group develop a transparent process of evaluating and communicating vaccine data with healthcare workers as they become available. If the state can address vaccine hesitancy among healthcare workers, then healthcare worker vaccination could be used to combat hesitancy among the general population. Before a vaccine becomes available to this group, healthcare workers and public safety officers will be vaccinated first. One possible avenue of addressing safety concerns among the general population is demonstrating high vaccination rates among healthcare workers - "If my doctor got it, it must be safe". We would suggest highlighting the prioritization approach to demonstrate the number and scope of people being vaccinated prior to the vaccine becoming available to the general public.

IX. Conclusion

The COVID-19 pandemic has fundamentally changed the way society functions and a safe and effective vaccine is critical to returning to a new normal. Trust in a vaccine's safety and efficacy is essential for buy-in from healthcare professionals, public health leaders, and the general public. Therefore, the highest unbiased scientific standards must be maintained throughout the approvals process. The vaccine allocation system itself must be transparent, fair, equitable, and just. We have proposed a phased approach that combines "what you do" (i.e. profession) with "who you are" (individual risk factors) with prioritization based on societal function, instrumental value, saving the most lives, and equity. These recommendations are meant to provide guidance for state level distribution to local jurisdictions and to provide primary vaccine providers with guidance on who to vaccinate and when.



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Members

Name and Credentials	Affiliations
Anuj Mehta, MD (Chair)	Assistant Professor of Medicine Pulmonary and Critical Care Medicine National Jewish Health Denver Health and Hospital Authority University of Colorado School of Medicine
Michelle A. Baron, MD	UCHealth Senior Medical Director, Infection Prevention and Control Professor of Medicine Division of Infectious Diseases University of Colorado Denver
Stephen Cantrill, MD (GMAG Chair)	GEEERC Member Emergency Medicine Denver Health and Hospital Authority (retired)
Jessica Cataldi, MD MSCS	Assistant Professor of Pediatrics Section of Pediatric Infectious Diseases University of Colorado School of Medicine
Matthew F. Daley, MD	Senior Investigator Institute for Health Research Kaiser Permanente Colorado Associate Professor of Pediatrics University of Colorado School of Medicine
Aseel Dalton, RPh, LLM, PhD	Visiting Scholar, Senior Research Fellow Yale Interdisciplinary Center for Bioethics Ethics Committee Denver Health and Hospital Authority
John M. Douglas, Jr., MD	Executive Director Tri-County Health Department
Gina Febbraro, MPH	Colorado Department of Public Health and Environment Director of Strategy and Performance Prevention Services Division
Cecile Fraley MD	Pediatrician/CEO Pediatric Partners SW
Patrick J. Gaughan	Senior Vice President Chief Values Integration Officer Centura Health
Allison Kempe, MD	Ergen Family Endowed Chair in Pediatric Outcomes Research Professor of Pediatrics University of Colorado School of Medicine



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	Director of ACCORDS (Adult and Child Consortium for Health Outcomes Research and Delivery Science) University of Colorado School of Medicine Children’s Hospital Colorado
Eric Lavonas, MD MS	Eric Lavonas, MD, MS Emergency Medicine Denver Health and Hospital Authority Medical Toxicologist, Rocky Mountain Poison and Drug Safety Professor of Emergency Medicine University of Colorado School of Medicine
Gabriel Lockhart, MD	Assistant Professor of Medicine Pulmonary and Critical Care Medicine National Jewish Health
Daniel Matlock, MD	Associate Professor of Medicine Department of Medicine Division of Geriatrics University of Colorado
Sean O’Leary, MD MPH	Professor of Pediatrics Sections of Pediatric Infectious Diseases and General Academic Pediatrics University of Colorado Anschutz Medical Campus/Children’s Hospital Colorado
Peter Pons, MD	GEEERC Member Emergency Medicine Denver Health and Hospital Authority (retired) Professor Emeritus, Emergency Medicine University of Colorado School of Medicine
Heather Roth	Colorado Department of Public Health and Environment Disease Control and Public Health Response Division
Jeffrey Sankoff, MD	Assistant Medical Director Emergency Medicine Denver Health and Hospital Authority Associate Professor of Emergency Medicine University of Colorado School of Medicine
Judith C. Shlay, MD, MSPH	Associate Director, Denver Public Health Denver Health and Hospital Authority Professor of Family Medicine, University of Colorado Denver, School of Medicine
Barbara Statland, MD	Hospitalist, Ethics Committee Co-Chair Denver Health and Hospital Authority Associate Professor of Medicine University of Colorado School of Medicine



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Appendix A: Vaccination Phases with Within Phase Allocation Recommendations

Phase	Category	Members	Within Phase Allocation
1A	Critical workforce	Inpatient Healthcare Workers ^B (including those at assisted living and nursing facilities)	Individuals with conditions that increase risk of severe COVID-19 related disease and death ^I
		Outpatient Healthcare Workers ^C (including home health workers and outpatient pharmacists)	Individuals with conditions that increase risk of severe COVID-19 related disease and death ^I
1B	Critical workforce	Emergency Medical Services Firefighters Police Officers Public Health Personnel ^D	Individuals with conditions that increase risk of severe COVID-19 related disease and death ^I
1C	Highest risk individuals	Residents/patients of assisted living and nursing facilities ^E	Individuals with conditions that increase risk of severe COVID-19 related disease and death ^I
2A	Essential worker (I)	Essential workers with direct interaction with the public, in high density work places, or in pandemic essential roles ^F	Individuals with conditions that increase risk of severe COVID-19 related disease and death ^I
2B	Higher risk individuals ^A	Adults ≥ 65 years Adults with obesity (BMI ≥30) Adults with diabetes Adults with chronic lung disease ^G Adults with significant heart disease ^H Adults with chronic kidney disease requiring dialysis Adults with active cancer Adults with immunocompromised state Incarcerated adults Adults living in group homes Adults experiencing homelessness Adults who received placebo during a COVID-19 vaccine clinical trial	Distribution to areas of higher COVID-19 positivity and transmission rates
3	Essential worker (II)	Essential workers without direct interaction with the public or in high density settings ^I	Distribution to areas of higher COVID-19 positivity and transmission rates
4	General public	Adults 18-64 without high-risk conditions	Distribution to areas of higher COVID-19 positivity and transmission rates



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^AThe classification of high-risk conditions is constantly evolving and modifications to the list of potential high-risk conditions will be updated over time.

^BInpatient healthcare workers would include individuals working at nursing and residential facilities. Inpatient healthcare workers specifically refers to those with direct patient care responsibilities (physicians, nurses, pharmacists, respiratory therapists, physical therapists, etc.), patient support responsibilities (e.g. social workers, case managers, chaplains, etc.) those involved in processing patient samples (e.g. phlebotomists, laboratory technicians, etc.), and hospital support personnel with contact with patient care areas (e.g. environmental services staff).

^COutpatient healthcare workers would include similar categories as inpatient healthcare workers as well as home health workers, outpatient pharmacists, and primary vaccine providers.

^DKey public health personnel may include primary vaccine providers and contact tracers if their position results in increased risk of exposure.

^ENot including patients in a dedicated hospice facility. Patients in hospice facilities would be vaccinated with the general public.

^FFront facing essential workers are those who have direct interaction with the public (e.g. grocery store workers, teachers and childcare workers, transportation personnel, correctional officers, public-facing staff at essential business, etc.) and those who work in high density areas with high-risk of transmission (e.g. food service industry workers, meatpacking workers, migrant farm workers, agricultural workers, postal workers, individuals involved in the manufacturing of a COVID-19 vaccine, etc.).

^GCOPD, chronic hypoxic respiratory failure and other severe lung diseases.

^HSignificant heart disease includes heart failure, coronary artery disease, moderate to severe pulmonary hypertension, and other cardiomyopathies.

^ISome groups of essential workers (e.g. banking services, core utility and electrical services, telecommunications and data center personnel, other public health personnel, etc.) may not have increased risk of exposure to COVID-19 through their jobs.



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Appendix B: Definition of Healthcare Worker

The Code of Colorado Regulations, Standards for Hospitals and Health Facilities, General Licensure Standards (6 CCR 1011-1 Chapter 2), healthcare workers are defined as

Any employee or direct contractor who has the potential for exposure to clients of the facility or agency and/or to infectious materials, including bodily substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air are subject to this Part 11. Such positions that may have the potential for exposure include, but are not limited to, licensed independent practitioners; students and trainees; individuals who directly contract with the facility or agency to provide services; home care personnel; individuals aged 18 or older who are affiliated with the facility or agency, but do not receive wages or other remuneration from the facility or agency; and persons not directly involved in client care but potentially exposed to infectious agents that can be transmitted to and from the individual providing services and clients of the facility or agency.²⁶

The definition for healthcare workers applied to the facility mandate requiring 90% of healthcare workers to receive the annual influenza vaccine. For the purposes of COVID-19 vaccinations, we recommend using the same definition:

- Physicians (MD/DO)
- Advanced Practice Providers (NP/PA)
- Nurses (RN/LPN)
- Medical Assistants
- Medical Technicians
- Respiratory Therapists
- Pharmacists
- Laboratory Technicians processing human samples
- Phlebotomists
- Radiology Technicians
- Social Workers
- Case Managers
- Behavioral Health Providers if seeing patients in-person
- Home Health Aids/Technicians including workers at non-medical home care agencies who work in client homes
- Environmental Services Technicians
- Food Service Technicians
- Dieticians/nutritionists
- Mortuary Services

This list is not exhaustive but providers within one of these groups must have or be at risk for contact with patients or patient samples. For example, radiologists who participate in patient exams would receive higher priority but those whose sole responsibility is reading films without patient contact might not receive higher priority. Hospital administration or human resources personnel who do not have a direct patient care role would not receive extra prioritization. The final decision as to which personnel are at high-risk will fall onto individual facilities.



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Appendix C: Definition of Essential Worker

Defining essential workers is a complex process. We recommend adapting the definition of “critical business” from the Colorado Public Health Order 20-24 detailing the “Stay at Home” order, last updated on April 9, 2020.¹³ As detailed in the prioritization approach, essential workers are divided into two groups based on whether (1) engage with the public, work in high-density areas, or are mission critical to the pandemic efforts or (2) are defined as an essential worker but are not public facing. We have divided the list based on the categories from Public Health Order 20-24 recognizing that most healthcare operations fall into Phase 1. Additionally, some groups are classified as not public facing despite some interaction with the public. We placed some groups, like hotel workers, into the non-public facing given the ability for contactless operations and the low volume of interaction during a pandemic. The list below is meant to serve as an example and is not exhaustive. It is meant to provide guidance to CDPHE for vaccine allocation on the local level based on estimating the size of each phase and to individual vaccine providers in deciding which patients will receive a vaccine in each phase of vaccination effort.

		Essential Workers	
		Public Facing, High-Density Areas, or Mission Critical to the Pandemic (Phase 2A)	Not Public Facing, Working in High-Density Areas, or Mission Critical to the Pandemic (Phase 3)
Healthcare Operations		Medical whole sale and distribution ^A	Veterinary care and livestock services
		Pharmaceutical and biotechnology companies if working on the pandemic response including vaccine manufacturing ^A	
		Medical supplies and durable medical equipment technicians and suppliers ^A	
		Blood banks ^A	
Critical Infrastructure		Public transportation	Utilities and electricity
		Businesses and organizations that provide food, shelter, social services or other necessities to economically disadvantaged persons or persons with functional needs	Road and railways
			Oil and gas
			Public water and wastewater
			Telecommunications and data centers
Critical Manufacturing		Food processing and manufacturing	Hotels and places of accommodation
			Chemicals unless necessary for the pandemic response
		Medical equipment/components ^A	Computer and computer components
		Pharmaceuticals ^A	Sanitary products
		Telecommunications	



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		Microelectronics/semiconductors
		Agriculture/farm equipment manufacturing
		Household paper products
Critical Retail	Grocery stores	Marijuana dispensary
	Farm and produce stands	Liquor stores
	Gas stations and convenience stores	Firearms stores
	Restaurants and bars ^B	Establishments that sell products that support working from home
	Establishments engaged in retail sale of food or other critical household products	
Critical Services	Building cleaning and maintenance	Trash, compost, and recycle collection
	Teachers	Mail and shipping services
	Other school staff	Self-services laundromats and garment and linen cleaning services for critical business
	Child care services	Automobile rental, sales, and repair
	Warehouse/distribution and fulfillment centers	Animal shelters and boarding services
	In-person pastoral services for individuals in crisis or end-of-life	Zoological facilities
		Moving services
News Media		Newspapers
		Television
		Radio
Financial and Professional Services		Banking and credit institutions
		Insurance and payroll
		Financial markets
		Professional services such as legal, title companies, accounting services, real estate appraisals and transactions



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Providers of Basic Necessities to Economically Disadvantaged Populations	Homeless shelters	
	Food banks	
	Human services providers whose function includes the direct care of patients in state-licensed or voluntary funded programs	
Construction		Housing
		Skill trades such as electricians or plumbers
Critical Services to Maintain Safety, Sanitation and Critical Operations	Disinfection services ^A	Building code enforcement
		Security
		Snow removal
		Bail bonds agents
		Pest control
Government	Critical government functions ^A	
	Postal Workers	

^APandemic essential services

^BSubject to public health orders on restaurant and bar opening and closures



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Appendix D: Definition of High-Risk Conditions for Severe COVID-19 Disease and Death

The conditions that define an individual as high-risk for severe COVID-19 disease and death are still being defined. Using several retrospective studies, the CDC has compiled a list of conditions that likely increase the risk of severe COVID-19 related disease.¹⁴ As new information about the virus and pandemic emerges, this list will be modified and updated to incorporate the latest scientific data. As of now, the CDC and other sources define high-risk conditions as^{8, 14, 16, 17}:

- Adults \geq 65 years old
- Active cancer
- COPD
- Chronic hypoxic respiratory failure
- Immunocompromised state
- Obesity (BMI \geq 30)
- Serious heart conditions (heart failure, active coronary artery disease, or cardiomyopathies)
- Sickle cell disease
- Diabetes
- Adults with chronic kidney disease requiring dialysis