

2207 **Applying the Framework for Equitable Allocation of COVID-19
Vaccine in Various Scenarios**

2208 At the time of writing, no COVID-19 vaccine has been approved for use in the U.S.
2209 population, although a number of clinical trials are underway. There are many uncertainties
2210 regarding if and when vaccines against COVID-19 will become available, under what regulatory
2211 framework they will be approved for first use, what their ultimate product profiles will be (e.g.,
2212 in terms of efficacy among different age groups, dosage schedule(s), and safety/adverse
2213 reactions), as well as the schedule and timelines for expanding vaccine supply availability (e.g.,
2214 when doses will become available and how quickly supply will expand). Chapter 2 of this report
2215 outlined the foundational principles and allocation framework to be used in guiding the fair and
2216 equitable use of scarce COVID-19 vaccine supply. This section envisions potential scenarios that
2217 federal, state, local, tribal, and territorial (SLTT) authorities may face in the use of new COVID-
2218 19 vaccines. Consequently, this section starts with describing the best scenario. Subsequently,
2219 the section identifies the possible and, in some cases, probable, deviations from this ideal
2220 scenario.

2221

AN ADAPTABLE AND DYNAMIC FRAMEWORK

2222 It is important to emphasize that, whenever they become available, COVID-19 vaccines
 2223 will be added to an already complex (and evolving) mix of public health strategies that include:
 2224 nonpharmaceutical interventions (NPIs) (such as mask usage, physical distancing, hand washing,
 2225 etc.); expanded diagnostic testing linked to contact tracing, isolation, and quarantine (TTIQ)
 2226 strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-
 2227 spreading events; and the deployment of therapeutic measures that mitigate morbidity and
 2228 mortality and, ultimately, curtail transmission from those who do become infected (CDC, 2020;
 2229 IOM, 2004; CDC, 2017). The principle that public policy should be evidence-based is essential
 2230 to guiding the allocation of scarce countermeasures.

2231 Box 6 outlines some of the key uncertainties regarding COVID-19 vaccines. Given these
 2232 uncertainties, SLTT authorities will need to be ready for varied and sometimes unexpected
 2233 scenarios in determining how best to use their federal allocation.

2234

BOX 6**Uncertain Factors Affecting Vaccine Allocation**

- Number and timing of available vaccine doses
- Number of available vaccine types
- Vaccine efficacy (overall and in different groups)
- Vaccine safety (overall and in different groups)
- Vaccine uptake (population acceptance, overall and in different groups)
- Epidemic conditions when vaccine becomes available
- Vaccine distribution and administration
- Political and regulatory environment

2235

2236 An ideal COVID-19 vaccine would be a one-dose vaccine that produces high levels of
 2237 neutralizing antibodies in all age groups, prevents moderate-to-severe disease as well as
 2238 infection, prevents transmission from infected individuals to other susceptible persons,²⁷ has very

²⁷ Current clinical trials are focused on clinical endpoints related to infection or mild-moderate symptomatic COVID syndrome and do not explicitly address the issue of transmission blocking.

2239 mild adverse reactions, has no severe adverse effects, and provides long-term protection. This is
2240 the “best” scenario because such a product profile would be most compatible with widespread
2241 use of the vaccine, both for personal protection and outbreak interruption. It would also be the
2242 scenario that produces the greatest demand for the vaccine. Few vaccines will have such an ideal
2243 product profile, with each shortcoming reducing demand (e.g., lack of efficacy in some age
2244 groups, complex administration, adverse reactions), as will vaccine hesitancy.

2245 While major efforts are being made by the federal government through Operation Warp
2246 Speed (OWS) to have a significant supply of vaccine as soon as possible, the committee has been
2247 tasked with considering the tough choices that will need to be made with the tightly constrained
2248 initial supplies (e.g., 10–15 million doses, enough to vaccinate 3–5 percent of the U.S.
2249 population). In the initial period when demand exceeds supply, the committee, in Chapter 2,
2250 recommended a phased approach, guided by evidence to maximize societal benefit by reducing
2251 morbidity and mortality caused by the transmission of novel coronavirus. As highlighted above,
2252 a range of uncertain factors related to the available vaccine(s) may affect the implementation of
2253 the framework. Table 3 at the end of this chapter summarizes how the framework could be
2254 affected in various scenarios.

2255 **Number and Timing of Available Vaccine Doses**

2256 OWS estimates that it will begin delivery of COVID-19 vaccines by January 2021.
2257 However, given the uncertainty regarding how many doses will actually be available by January
2258 2021, available vaccines should initially be allocated to individuals according to the phases
2259 described in Chapter 2.

2260 It is possible that the vaccine will require two doses instead of one to ensure adequate
2261 protection (IOM, 2013). In this case, two doses will be allocated to each person so that, in effect,
2262 half as many people could be vaccinated. Vaccination would still follow the proposed allocation
2263 framework, but some individuals would receive vaccination later. If the vaccine requires two
2264 doses, strategies and systems (e.g., use of established providers or use of federally qualified
2265 health centers) are necessary to help ensure continuity of care between the first and second dose.
2266 This is important because if efficacy with only one dose is low, individuals who receive only one
2267 dose are effectively unvaccinated and that vaccine dose was in essence wasted.

2268 A related issue is durability of protection. It may be that duration of protection is short
 2269 enough that people vaccinated in an early phase must receive a booster dose before some
 2270 individuals in later phases receive vaccination. Again, vaccination would still follow the
 2271 proposed allocation framework, but some individuals in subsequent phases would receive
 2272 vaccination later.

2273 **Vaccine Efficacy**

2274 Trials of a number of candidate vaccines are currently underway, but at this time the
 2275 likely efficacy of each COVID-19 vaccine in preventing infection or in preventing severe disease
 2276 is unknown. The level of efficacy in preventing infection will affect transmission of the infection
 2277 in the population, and the level of efficacy in preventing severe disease will affect demand for
 2278 acute and intensive hospital care—key factors relating to future management of COVID-19.
 2279 Vaccine efficacy may also differ in different population groups (e.g., it might be less efficacious
 2280 in older adults). Moderate to low efficacy may lead people to reject the vaccine, believing their
 2281 risk of side effects or the “unknown” outweigh the benefit of vaccination (Smith, 2017).²⁸
 2282 Epidemic modeling—once a vaccine becomes available—could be useful to determine whether
 2283 individuals in the priority groups identified in the committee’s framework should still be offered
 2284 vaccination if the vaccine is determined to be less efficacious for their group. Once widespread
 2285 vaccination commences, presumed efficacy may be influenced by how adherent people are to
 2286 other basic protective measures such as masks and social distancing (CDC, 2020). Additional
 2287 public messaging about maintaining such behaviors may be called for, particularly if people who
 2288 are vaccinated erroneously believe they are no longer at risk of infection or transmission.

2289 **Vaccine Safety**

2290 Significant numbers of individuals must be vaccinated before vaccine safety is fully
 2291 understood. When a vaccine becomes available, the knowledge concerning vaccine safety will be
 2292 based on existing clinical trials which, of necessity, are limited. If it is found that certain
 2293 population groups (e.g., children or older adults) experience significant side effects from the

²⁸ To ensure that a widely deployed COVID-19 vaccine is effective, FDA stated the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50 percent, and the statistical success criterion should be that the lower bound of the appropriately alpha-adjusted confidence interval around the primary efficacy endpoint point estimate is >30 percent. <https://www.fda.gov/media/139638/download> (accessed August 18, 2020).

2294 vaccine, it may be advisable to allocate the vaccine with caution to such population groups or to
2295 reallocate it to a different group that is less vulnerable to those particular side effects. As the
2296 vaccine starts to be allocated broadly in the U.S., monitoring of side effects and possible
2297 adjustment of the allocation framework are essential to minimize possible side effects in the
2298 population, while maximizing benefit by preventing deaths and severe disease. Effective
2299 collection and communication of evidence regarding population effects, both efficacy and
2300 adverse effects, are also essential to securing and maintaining public trust. Additionally,
2301 vaccinated individuals should be assured of compensation (especially for health care costs) for
2302 vaccine-related injuries. If the Department of Health and Human Services issues a Public
2303 Readiness and Emergency Preparedness (PREP) Act declaration, preempting state tort remedies,
2304 the government must then fully fund and make accessible PREP Act compensation. Failing to do
2305 so will lead to distrust and anger if and when adverse events arise.

2306

Vaccine Uptake

2307 Vaccine hesitancy has been well documented among numerous population groups in the
2308 United States. The COVID-19 vaccine is no exception: Many individuals will be hesitant to
2309 receive a new COVID-19 vaccine, particularly if there are perceived safety concerns or if
2310 vaccine efficacy is thought to be relatively low. Vaccine hesitancy will also be greater if there is
2311 any suspicion that political or economic considerations have influenced the vaccine safety
2312 assessments made by government regulatory or advisory bodies, such as the Food and Drug
2313 Administration and the Advisory Committee on Immunization Practices (ACIP). It may be that
2314 some people are “COVID-vaccine hesitant” and do not want to be vaccinated when it is offered
2315 to them—despite their individual risk—but would be willing to be vaccinated later when more
2316 evidence about vaccine safety has accrued. Thus, although an individual may be prioritized in
2317 our allocation framework, that person may refuse to be vaccinated when vaccination is offered to
2318 them, in which case the vaccine should be offered to another individual within that priority
2319 group. Of course, if enough individuals refuse to accept the vaccine, the resulting population
2320 protection (reduction in deaths and COVID-19 transmission) due to the vaccine may not be high.

2321 Messages about vaccine safety and efficacy are essential for all people and at all phases.
2322 Direct-to-consumer advertising may influence public perceptions and preferences. It is critical
2323 that the communication campaign accompanying the vaccine outline the risks and benefits of the

2324 vaccine in a way that members of the population can understand (Malik et al., 2020). Health care
2325 providers can also play an important role in communicating vaccine risks and benefits to their
2326 patients. Additionally, if vaccine uptake is low, the idea of adhering to an allocation framework
2327 could lead some providers to shift to lower priority groups or be left with excess vaccine stock.
2328 Programs should do everything possible to reach all individuals in one priority group, before
2329 proceeding to the next one. That will include making special efforts to address issues related to
2330 health inequities that may reduce trust in some groups or make health care less accessible to
2331 them.

2332 **Number and Timing of Available Vaccine Types**

2333 It is possible that multiple vaccine types, and not just a single vaccine, will be made
2334 available in early 2021. If this happens, the available vaccines might be rated on a spectrum by
2335 ACIP with recommendations about which groups should receive which vaccines. The available
2336 vaccines may have major differences in important features (e.g., safety and efficacy, overall and
2337 in different populations; duration of protection; robustness of immune response; etc.) and it is
2338 important to determine which vaccine is best for different groups, based on all the information
2339 available when a vaccine is released. Vaccines would still be allocated to the different phases,
2340 with the rate of allocation to different groups determined by availability of the vaccine(s) for that
2341 group. For example, if Vaccine A is determined to be best for individuals in Phases 1 and 4, and
2342 Vaccine B is determined to be best for individuals in Phases 2 and 3, then vaccination with
2343 Vaccine A would proceed for individuals in Phase 1 followed by Phase 4, while vaccination with
2344 Vaccine B would proceed for individuals in Phase 2 followed by Phase 3. It is also possible that,
2345 after an initial vaccine is made available, a safer or more effective vaccine may be released. In
2346 this case, vaccine allocation must take into account the benefits and harms of the vaccine for
2347 each particular population group. To the extent possible, vaccines would continue to be made
2348 available in the same phases as outlined in the framework. However, if a particular vaccine is
2349 inappropriate for use by a particular group, that group would need to wait for a new form of a
2350 vaccine, and the existing vaccine might be provided to those who otherwise are slated for a later
2351 phase. With multiple available vaccines, it is particularly important to monitor safety and
2352 efficacy as immunization efforts progress so as to ensure that different population groups receive
2353 an appropriate vaccine.

2354 **Epidemic Conditions and Immune Status**

2355 At the time of writing, COVID-19 is spreading widely in the U.S., across many states and
2356 jurisdictions, with 50,000–70,000 newly identified cases each day and 1,000–2,000 deaths daily.
2357 Increasing numbers of cases are occurring among younger people, who are also thought to be
2358 key agents in transmitting the disease. It is currently not known how long immunity from
2359 COVID-19 infection lasts, nor the extent to which transmission may be reduced in different
2360 populations due to more people acquiring immunity from having been infected. If sufficient
2361 numbers of individuals in a population group are immune due to previous infection, then it may
2362 be that scarce vaccine doses should be allocated to individuals in other prioritized population
2363 groups. Conversely, if the infection is found to be spreading particularly rapidly in a particular
2364 geographic region or population group, it may be reasonable to prioritize allocating vaccines to
2365 that region or group. This could be done by holding back a certain fraction of vaccine doses (e.g.,
2366 10 percent) for use in vaccinating individuals in COVID-19 “hot spots” who are at high risk of
2367 infection and who cannot protect themselves.

2368 Personal protective behavior—such as sheltering in place, social distancing, and wearing
2369 face masks—also affects the spread of COVID-19 (CDC, 2020). It is essential that vaccinated
2370 individuals be encouraged to engage in personal protective behavior to the extent that they are
2371 able to.

2372 **Vaccine Distribution and Administration**

2373 Specific details of how the COVID-19 vaccine will be distributed and administered have
2374 not been fully determined at this time. The vaccine is being developed through the federal OWS
2375 initiative, and presumably the federal government will issue guidelines for allocation,
2376 distribution, and administration of the vaccine. The extent to which states will be obligated to
2377 follow such guidelines is not known. Such state-level decisions will affect the implementation of
2378 the vaccine allocation framework. As an example, a state may make a commitment to set aside a
2379 certain fraction of vaccine doses for tribal governments in that state (this would be a supplement
2380 to what would be allocated by the federal government through the Indian Health Service).

2381 **Social, Economic, and Legal Contexts**

2382 The social, economic, and legal contexts will affect vaccine distribution and uptake. For
2383 example, if some health insurers, care providers, or employers fail to cover the full vaccine
2384 administration cost, the allocation framework is unchanged, but the federal government or states
2385 should make efforts to provide funds to cover the cost of vaccine administration (and other
2386 vaccination costs) for low-income individuals.

2387 Once vaccine availability has increased sufficiently and vaccine safety in younger groups
2388 has been assessed, children will be offered a COVID-19 vaccine (Mello et al., 2020).
2389 Historically, the most effective way to ensure broad uptake of vaccine in children is through
2390 mandates that condition school attendance on evidence of vaccination or an accepted reason for
2391 exemption, such as a medical contraindication. There will certainly be wide variation among
2392 states and even within states regarding such mandates, particularly with respect to whether non-
2393 medical exemptions will be allowed. To ensure an orderly return to schools, states may benefit
2394 from having their mandates clarified by attorneys general issuing interpretations of existing
2395 authorities and their departments and agencies issue interpretative guidance, or by considering
2396 ways to tighten existing law regarding exemptions. Despite the allocation framework, it is
2397 possible that some school districts may be tempted to mandate vaccination of schoolchildren
2398 immediately, as a means of moving more quickly toward re-opening schools. At a state level,
2399 this would allocate the vaccine in a manner different from the committee's proposed allocation
2400 framework (i.e., by prioritizing schoolchildren).

2401 Another possibility is that some employers would require employees to be vaccinated or
2402 to have some evidence of prior infection (on the employer's assumption that this confers
2403 immunity) (Phelan, 2020). If a state is not allocating vaccine supplies in accordance with the
2404 recommended phases, this would divert vaccine supplies toward many who are not in the higher
2405 risk categories described in Phases 1 and 2. If large employers acquire doses of the vaccine, as
2406 has happened in the past with 2009 H1N1 vaccines, this could limit supplies available to state
2407 and local health departments. Although there is precedent for employers requiring vaccination,
2408 subject to some limitations based on union agreements or religious exemptions, (e.g., many
2409 hospitals and nursing homes require employees to be vaccinated against the flu) a number of
2410 concerns arise when vaccine supply is limited, as it will be with COVID-19 vaccine(s). If
2411 employers require vaccination, the allocation framework would be unchanged, but pressure

2412 would certainly be brought to bear on health care providers by people needing to maintain their
2413 employment, regardless of whether they are at high risk of infection. Such a requirement could
2414 change rates of vaccine uptake, and would pose a dilemma for those individuals for whom the
2415 vaccine is medically contraindicated—either take the vaccine or lose employment—and would
2416 be a possible violation of the Americans with Disabilities Act (Yang et al., 2020). Mandated
2417 vaccination could also violate Title VII of the Civil Rights Act of 1964 if there is a religious
2418 exemption or could violate collective bargaining rights (in unionized workplaces). Additionally,
2419 it is important to note that the equitable allocation scheme will fail if a separate private vaccine
2420 market emerges for those who can pay the most. SLTT authorities should not waiver from their
2421 adherence to the proposed equitable allocation scheme to satisfy the demands of private
2422 employers or institutions that are seeking or requiring vaccination of all workers.

2423 As a final example, if states do not provide free vaccine access to people without
2424 documentation of legal status, then the allocation framework is unchanged, but other sources of
2425 financial support (e.g., philanthropy, health systems, pharmaceutical companies) will be needed
2426 to assure access to vaccination for those individuals.

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2428 **DRAFT TABLE 3** Summary Table of the Application of the Committee’s Framework in Various Scenarios

Scenario	Change in Allocation Framework
Number and Timing of Vaccine Doses	
Fewer vaccine courses available than expected by Operation Warp Speed	Allocation framework is unchanged. Some individuals receive vaccination later than they would otherwise.
Vaccine requires two doses, rather than one	Allocation framework is unchanged, but some individuals receive vaccination later. Vaccination should use strategies and systems (e.g., use of established providers or use of federally qualified health centers) to ensure continuity of care between the first and second dose.
Number of Vaccine Types	
More than one vaccine type available	Allocation framework is unchanged, but which vaccines are allocated to which population groups must take into account the benefits and harms of the vaccine for each population group.
Vaccine Efficacy	
Low vaccine efficacy among older adults or other population subgroup	Only allocate to this population subgroup if vaccine benefits outweigh the risks.
Vaccine Safety	
Unanticipated vaccine side effects	Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to individuals for whom vaccine benefits outweigh the risks
Significant vaccine side effects among older adults or other population subgroup	Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to this population subgroup if vaccine benefits outweigh the risks.
Vaccine Uptake	
Vaccine uptake is lower than expected	Allocation framework is unchanged. The communication campaign accompanying the vaccine must outline the risks and benefits of the vaccine in a factual way that members of the population can understand.
Epidemic Conditions and Immune Status	
Epidemic spread is continuing across much of the U.S. when the vaccine becomes available	Allocation framework is unchanged. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing).
Epidemic is spreading most rapidly in particular hot spots when the vaccine becomes available	A certain fraction of vaccine courses (e.g., ten percent) is reserved for vaccinating individuals in hot spots. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing).
Vaccine Distribution and Administration	

States are required to follow federal guidelines for vaccine allocation	Allocation framework is unchanged.
States have some leeway in the extent to which they follow federal guidelines for vaccine allocation	States adapt the allocation framework to their needs (e.g., they may set aside a certain number of doses for particularly vulnerable populations in their state).
Social, Economic, and Legal Contexts	
Some health insurers do not cover full vaccine administration cost	Allocation framework is unchanged, but the federal government or states should make efforts to provide funds to cover the cost of vaccine administration (and other vaccination costs) for low-income individuals.
Some employers require proof of vaccination	Allocation framework is unchanged, but such requirements could change rates of vaccine uptake, and would pose hazards for those individuals for whom the vaccine is medically contraindicated and could raise issues around discrimination against those unable to obtain the vaccine and therefore unable to work
Some states mandate vaccination of schoolchildren	Allocation framework is unchanged, but states mandating vaccination of schoolchildren might allocate the vaccine in a manner different from the Committee's proposed allocation framework (i.e., prioritize schoolchildren)
Some states do not provide free vaccine access to people without documentation of legal status	Allocation framework is unchanged. Other sources of financial support (e.g., philanthropy, health systems, pharmaceutical companies) should be sought to provide vaccination for those individuals.

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