

ASPR TRACIE Technical Assistance Request

Request Receipt Date (by ASPR TRACIE): December 11, 2020

Response Date: December 16, 2020; Updated December 21, 2020, **December 31, 2020**

Type of TA Request: Complex

Request:

ASPR TRACIE received a request for information related to the approval, allocation, distribution, and administration of vaccines to prevent COVID-19 within healthcare facilities.

Response:

The ASPR TRACIE Team reviewed existing resources, including those in our [Mass Distribution and Dispensing of Medical Countermeasures](#), [Influenza Epidemic/Pandemic](#), [Ethics](#), and [Responder Safety and Health](#) Topic Collections and on our [COVID-19 Resources Page](#). We also conducted a search online for relevant materials. Information from these materials are gathered and provided as points for consideration in this document.

The information below is intended to provide high level considerations for vaccination administration and planning in healthcare facilities. **Additional information may be found in the [COVID-19 Vaccine Resources Collection](#). (updated December 31, 2020)**

Please refer to the Centers for Disease Control and Prevention's [Coronavirus Disease 2019 webpage](#) and the [NIH COVID-19 Treatment Guidelines](#) for the most up-to-date clinical guidance on COVID-19 outbreak management.

I. COVID-19 Vaccine Considerations

Vaccine Development and Approval: Development of a vaccine to prevent COVID-19 has proceeded at an unprecedented pace. Building on years of research on coronaviruses and with the support of purchase commitments from national governments, manufacturers focused on COVID-19 vaccine development and produced several vaccines authorized for use less than a year after the virus was first recognized.

- More than 200 vaccines are in development around the world using various technologies. Some of these technologies have been used in the past to prevent other illnesses, such as live attenuated vaccines for measles, inactivated vaccines for influenza, and protein sub-unit vaccines for pertussis. Some of the most promising COVID-19 vaccines use two newer technologies: viral vector-based vaccines (previously used for Ebola virus disease) and nucleic acid vaccines. The viral vector-based vaccines use well-established technology and elicit a strong immune response, but they are complex to manufacture and

there are concerns that previous exposure to the vector may affect effectiveness. Nucleic acid vaccines – including messenger RNA (mRNA) – are easier to manufacture and have no risk of triggering disease, but had previously only been approved for use in animals and some require ultra-cold storage.

- Each country has its own process for reviewing the safety and effectiveness of vaccine candidates and authorizing their use by the public.
- COVID-19 vaccines will not be administered in the U.S. until they are authorized by the Food and Drug Administration (FDA), likely via an Emergency Use Authorization (EUA). This does not constitute full approval or licensing for the vaccine but allows administration while an emergency declaration is in place when the current evidence favors the known benefit versus risk.
- China authorized the [Petrovax](#) vaccine for military use in June 2020 and authorized several other vaccines for emergency use in the months since. The [Sinopharm](#) vaccine authorized in China has also been approved by the United Arab Emirates and Bahrain. In August 2020, Russia authorized its [Sputnik V](#) vaccine for use. The [Pfizer/BioNTech](#) vaccine is the first mRNA vaccine to be authorized for human use for any disease and has been authorized or approved in the United Kingdom, Bahrain, Canada, the U.S., Mexico, Kuwait, Singapore, Jordan, Oman, Costa Rica, Ecuador, Panama, Chile, Switzerland, the European Union, and Saudi Arabia as of December 21, 2020. A second vaccine from [Moderna](#) was authorized in the U.S. on December 18, 2020. **On December 30, the United Kingdom authorized the AstraZeneca/Oxford University vaccine. (updated December 31, 2020)**
- Following its [emergency use authorization](#) in the U.S. by the FDA on December 11, the Advisory Committee on Immunization Practices (ACIP) issued an [interim recommendation](#) for the use of the Pfizer-BioNTech vaccine in those age 16 and older on December 13, 2020. Similarly, the FDA issued an [EUA](#) for the Moderna vaccine on December 18 followed by an [interim recommendation](#) from ACIP on December 19 for its use on those age 18 and older. (updated December 21, 2020)
- [Section II](#) includes information on the status of vaccines authorized for use in the U.S. and vaccine candidates with promising results in late stage trials for which manufacturers may seek approval in the U.S. in the coming months.

Vaccine Options: While experience developing other vaccines suggests that many of the current COVID-19 candidates will not be approved for use, it is expected based on vaccine trials data released so far that several vaccines to prevent COVID-19 will eventually be available ([see chart in Section II](#)).

- Neither facilities being shipped vaccines nor individuals who are being vaccinated may receive their preferred product, especially early in the vaccine distribution process when options are limited.
- The anticipated availability of multiple vaccines in 2021 will complicate decision-making for those ordering vaccines. Amounts of each vaccine available, booster dosing,

the setting in which vaccines are administered, and the populations needing to be vaccinated will be factors to consider.

- Some vaccines may be more efficacious in certain populations than others. As more data becomes available, those ordering vaccine should maintain awareness of any emerging differences in effectiveness in specific populations, such as older adults or children, and place orders appropriate to the population they serve.
- As additional options become available, it may be possible to select a product with characteristics more suitable for the setting in which it will be administered. For instance, supplies of vaccine requiring ultra-cold storage are expected to be directed to academic medical centers and large hospitals with the logistical capacity to manage them while vaccines that can be stored at refrigerator temperatures may be more suitable for physician offices or pharmacies.

Supply and Allocation: The initial supply of vaccine will be limited and will continue to grow as additional vaccines are approved and production increases.

- To encourage vaccine development, governments around the world made purchasing commitments that enabled manufacturers to begin producing vaccines prior to the completion of their clinical trials, thereby ensuring the availability of an initial, limited supply upon FDA authorization of each vaccine. Supplies will increase as production continues to ramp up and additional vaccines are authorized.
- Due to the initial limited supplies, a phased approach is necessary to prioritize which segments of the population are vaccinated first. Various governments and organizations have offered frameworks for the fair and ethical allocation of limited vaccine supplies, including the [National Academies of Sciences, Engineering, and Medicine](#), [ACIP](#), and the [World Health Organization](#). Most of these frameworks include considerations for healthcare and other essential workers, older adults, and communities of color that have been disproportionately affected by the COVID-19 pandemic.
- In the U.S., ACIP identified approximately 24 million [healthcare workers and residents of long-term care facilities](#) as the highest priority groups for the initial allocation of COVID-19 vaccine during Phase 1a. ACIP met on December 20 to [recommend](#) essential frontline workers and those age 75 and older as the next prioritized groups in Phase 1b and other essential workers, those age 65 and older, and those with high-risk medical conditions in Phase 1c. (updated December 21, 2020)
- Of the first [6.4 million vaccine doses](#) available in the U.S., the federal government is holding 500,000 doses in emergency reserve. 2.9 million doses were allocated to jurisdictions pro rata based on their population age 18 and older; the remaining 2.9 million doses will be shipped according to the same allocation for second doses. Shipment of ancillary supplies for the initial allocation to jurisdictions began on December 9, 2020.
- Because the initial supply is not sufficient to vaccinate all persons in ACIP's highest priority groups, additional sub-prioritization is needed at the state level as well as the sub-state level. For example, every hospital should prioritize the order in which all members

of their staff are eligible for vaccination relative to their risk of exposure and risk of severe complications from COVID-19 (e.g., front line staff over the age of 60 who work on the Emergency Department or Intensive Care Units).

- At the current time, there are no specific recommendations for whether individuals who have already had confirmed COVID-19 disease should wait and be vaccinated at a later time.
- Effective prioritization requires an accurate understanding of the total number of persons in each prioritized group in a community/coalition.
- In the U.S., five federal agencies – the Bureau of Prisons, Department of Defense, Department of State, Indian Health Services, and Veterans Health Administration – have been allocated their own supply of vaccine to prioritize among their staff and populations they serve. Additionally, federal agreements allow long-term care facilities to opt-in to having vaccine administered to their residents by CVS and Walgreens. Jurisdictions should consider these federal distribution efforts in their own prioritization decisions.

Transportation and Storage: Vaccines vary in their transportation and storage requirements, ranging from those that may be stored at normal refrigerator temperatures to those requiring ultra-cold storage. It is critical that those ordering vaccine understand the transportation and storage requirements associated with the ordered product and can support those requirements.

- Vaccine coordinators must be pre-identified at each shipping site to receive vaccine shipment and monitor its storage and supply.
- Due to its ultra-cold chain storage requirements, Pfizer developed [shipping containers](#) for its vaccine. Vaccine recipients should understand these shipping containers, including their size and weight, how long shipped vaccine can remain in the shipping container, how frequently the container may be opened, how to store vaccine once it is removed from the container, and plan for pelletized dry ice replenishment if required. Each shipment of this vaccine includes 975 doses in multi-dose vials.
- Orders for Moderna and other vaccines are expected to be a minimum of 100 doses per order. Health systems should consider central ordering for their affiliated hospitals, clinics, and other providers. Healthcare coalitions may have a role in coordinating orders and central shipping locations for participants, particularly in rural areas where facilities have limited staff and population served.
- Dry ice is a high demand product due to its use in vaccine shipments on top of its normal uses. Vaccine recipients should identify back-up sources of dry ice and train staff on the safe handling of dry ice. Have dry ice gloves in various sizes readily available.
- Emergency plans should account for the uninterrupted power supply needs of vaccine storage areas and identify generators or other back-up options to protect the vaccine supply in the event of a power outage.
- Many states require their boards of pharmacy to inspect freezers or mandate continuous monitoring of temperatures.

Logistics: In addition to the transportation and storage issues, vaccine distribution and administration involve numerous challenges.

- Vaccine providers must be pre-enrolled to be eligible for vaccine ordering and receipt. This requires outreach to recruit vaccine providers, completion of the enrollment process, and training on vaccine provider requirements, such as vaccine administration techniques and necessary reporting.
- Sites must be prepared to receive the vaccine itself and the [ancillary supplies](#) included in each kit. These kits do NOT include sharps containers, gloves, or bandages. Vaccine providers should understand what ancillary supplies will be provided and what additional supplies may be needed to support vaccine administration efforts.
- Security will be needed for both the vaccine storage site and the location where vaccine is administered.
- Each healthcare facility should have a plan that expands the vaccination of staff as supply increases. Various approaches may be used – including vaccinating on the unit/floor, operating a closed point of dispensing, scheduling appointments through occupational health services, or setting up a vaccine clinic – depending on the size of the facility, the number of staff, the amount of vaccine received, and other factors.
- Healthcare facilities should consider their full range of staffing needs. This includes not only vaccine providers, but also staff for planning, vaccine and related supply ordering, transport and storage, security, communications, finance, information technology, and administrative reporting. All staff should be trained on their expected roles.
- Healthcare facilities should review their workforce policies, including determining whether COVID-19 vaccination will be required.
- Use of multi-dose vials requires planning to avoid wastage.
- Vaccines administered under EUA will require the recipient review and provide consent. Ideally, these forms should be made available for review prior to the time of vaccination to speed the process.
- Include health care provider instructions for screening of patient’s eligibility for vaccine based on ACIP contraindications and precautions recommendations.
- Most of the vaccines will require two doses at a different number of days between doses depending on the vaccine. Tracking is needed to ensure that individuals receive both doses of the same vaccine at the correct interval.
- Like in all vaccines, some localized and systemic side effects are expected with vaccines to prevent COVID-19. Healthcare facilities should ensure staff know how to report adverse events, have strategies in place to minimize their impact on operations (e.g., do not vaccinate an entire unit staff at the same time), and have paid time off and return to work policies in place for staff who experience symptoms post-vaccination. Vaccine administration sites should have [medications and supplies](#) in place for the assessment and initial management of anaphylaxis, a potential rare adverse event following COVID-19 vaccination. (updated December 21, 2020)

- Extensive reporting requirements are in place to track both the vaccine and the vaccinated. Healthcare facilities and providers should understand reporting requirements and ensure systems are in place to support them.
- The success of the COVID-19 vaccination effort is dependent on accurate and effective communications among response partners and risk communication to the public. Healthcare coalitions may have a role in supporting information sharing among hospitals, clinics, physician offices, long-term care facilities, pharmacies, and other vaccine administration sites to ensure coordinated and equitable vaccine coverage in the community as supply increases. Additionally, consistent and coordinated risk communications can reduce confusion and build vaccine acceptance among the public as vaccine becomes available to other segments of the population.

Funding: Because the U.S. government is purchasing vaccines from the manufacturers, members of the public will not be charged for vaccines. However, there are costs associated with the mass vaccination effort.

- While individuals cannot be charged for the cost of the vaccine itself, they may be charged a vaccine administration fee. This administrative cost may be billed to the individual's [health insurer](#), [Medicare](#), [Medicaid](#), the [Children's Health Insurance Program](#), or the [COVID-19 Uninsured Program](#).
- The Centers for Disease Control and Prevention (CDC) [awarded](#) \$200 million to the 64 jurisdictions required to submit COVID-19 vaccination plans yet the CDC Director [estimated](#) that \$5.5-6 billion would be needed to distribute vaccine. The Adult Vaccine Access Coalition [requested](#) \$8.4 billion to modernize immunization information systems, recruit and train the immunization workforce, promote mass vaccination, remove financial access barriers, and compensate providers for various costs.
- In addition to billing payers for vaccine administration costs, healthcare facilities and providers should accurately document all expenses related to COVID-19 vaccination planning and response efforts. Reimbursement and cost recovery may be available through the various federal and state programs established with COVID-19 relief funding.

II. FDA Approved Vaccines and Most Promising Candidates

The vaccine development and approval processes are fluid and information updates frequently. The information in this table is current as of December 31, 2020.

Vaccine Sponsor	Technology	Dosing	Effectiveness	Storage	Supply Forecast	Status
Pfizer/ BioNTech ¹ (COMIRNATY®)	mRNA	2 doses 21 days apart	95% effective; common adverse reactions : injection site reactions, fatigue, headache, muscle pain, chills, joint pain, fever; and the second dose is associated with a higher incidence of side effects than the first; UK recommended against use in those with a history of anaphylaxis to a vaccine, food, or medicine	<ul style="list-style-type: none"> Transportation & long-term storage at -70° Celsius Developed shipping containers Conducted pilot delivery program in 4 states 	US purchased 100 million doses	<ul style="list-style-type: none"> Authorized for use in the United Kingdom on December 2, Bahrain on December 6, Canada on December 9, Saudi Arabia on December 10, Mexico on December 11, Kuwait on December 13, Singapore and Jordan on December 14, Costa Rica and Ecuador on December 15, Chile, Oman and Panama on December 16, Switzerland on December 19, and the European Union on December 21. As of December 31, the vaccine was authorized or approved by 26 regulatory bodies. The United Kingdom began administering the vaccine to prioritized healthcare workers and older adults on December 8. Submitted request for emergency use authorization (EUA) to the Food and Drug Administration (FDA) on November 20. FDA's Vaccines and Related Biological Products Advisory Committee met to

¹ [Pfizer-BioNTech COVID-19 Vaccine \(BNT162, PF-07302048\) Vaccines and Related Biological Products Advisory Committee Briefing Document](#)

						<p>discuss the request on December 10. FDA issued an EUA on December 11.</p> <ul style="list-style-type: none"> ACIP issued an interim recommendation for use of the vaccine on December 13 for those 16 and older.
Moderna ²	mRNA	2 doses 28 days apart	94.1% effective; common adverse reactions: injection site pain, fatigue, myalgia, arthralgia, headache, erythema/redness at injection site	<ul style="list-style-type: none"> Long-term storage at -20° Celsius 	US agreed to purchase 200 million doses if authorized; 20 million doses in U.S. by end of 2020; 85-100 million doses in U.S. plus 15-25 million doses outside the U.S. in the first quarter of 2021	<ul style="list-style-type: none"> Submitted request for EUA to the FDA on November 30. FDA's Vaccines and Related Biological Products Advisory Committee met to discuss the request on December 17. FDA issued EAU on December 18. ACIP issued an interim recommendation for use of the vaccine on December 19 for those 18 and older. Authorized in Canada on December 23.
AstraZeneca/Oxford University ³	Non-replicating viral vector	2 doses with an interval between 4 & 12 weeks	70.4% effective	<ul style="list-style-type: none"> Transportation and storage at 2-8° Celsius for up to 6 months 	US supported development of at least 300 million doses	<ul style="list-style-type: none"> Authorized for use in the United Kingdom on December 30.

² [Vaccines and Related Biological Products Advisory Committee Meeting Announcement](#)

³ [AZD1222 Oxford Phase III Trials Interim Analysis Results Published in the Lancet](#)

Johnson & Johnson/ Janssen ⁴	Non-replicating viral vector	Trials include 1 and 2 dose regimens		<ul style="list-style-type: none"> Transportation and storage at 2-8° Celsius 	US agreed to purchase 100 million doses if authorized, option for additional 200 million doses	Phase 3 trials
Novavax ⁵	Protein sub-unit	2 doses		<ul style="list-style-type: none"> Transportation and storage at 2-8° Celsius 	US agreed to purchase 100 million doses if authorized	Phase 2 and 3 trials

⁴ [Johnson & Johnson Initiates Second Global Phase 3 Clinical Trial of Its Janssen COVID-19 Vaccine Candidate](#)

⁵ [Novavax Announces COVID-19 Vaccine Clinical Development Progress](#)