

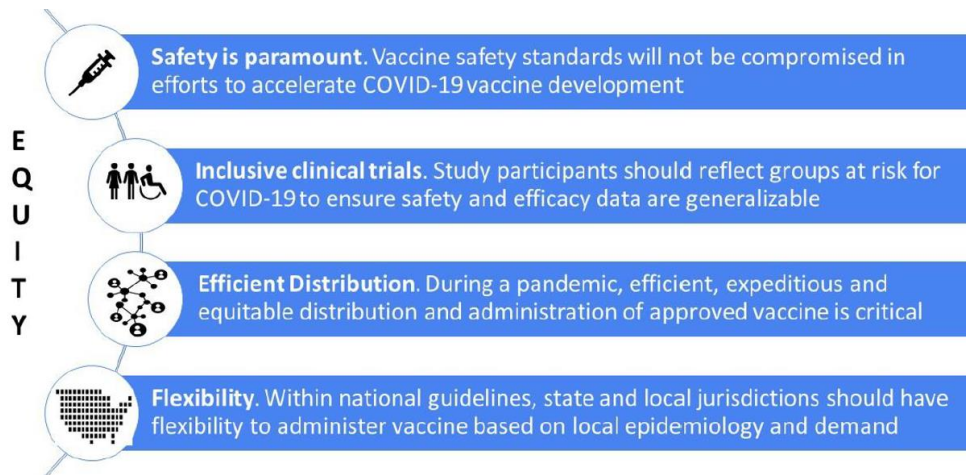


SHEA Statement for Healthcare Settings Preparing for COVID-19 Vaccination

Current as of Oct 14, 2020

As we await Food and Drug Administration (FDA) approval and the Centers for Disease Control and Prevention (CDC)'s Advisory Council on Immunization Practices (ACIP) recommendations for one or more vaccines to combat COVID-19, healthcare epidemiologists and infection preventionists (IPs), along with their Occupational Health, Pharmacy, and other colleagues, should prepare a plan to administer vaccine initially to high priority healthcare personnel (HCP) and eventually to additional HCP and patients. ACIP has convened a COVID-19 work group that is reviewing the epidemiology, immunology, sociology, and logistics, among other topics, of a national COVID-19 vaccination program, as well as both safety and efficacy data for specific vaccine candidates in Phase III clinical trials.

ACIP has adopted the following guiding principles for prioritization of initially limited numbers of doses of vaccine:



Intended Use

This document provides background and recommendations relevant to vaccination against COVID-19 for [healthcare personnel \(HCP\)](#), defined by CDC as “all paid and unpaid persons serving in healthcare settings, who have the potential for direct or indirect exposure to patients or infectious materials.”

COVID-19 Vaccine Presumptions

- One or more COVID-19 vaccine(s) will be FDA-approved within the next 6 months, with additional COVID-19 vaccine(s) likely to be approved within 12 months.
- mRNA vaccine(s) likely will be the first available.

- At the time of approval there will be insufficient supplies of the vaccine to provide to all persons desiring immunization. The highest priority group will be healthcare personnel (HCP).
- At the time of approval, the following will NOT be known:
 - Duration of protection
 - Correlates of immunity
 - Long-term safety
 - Effectiveness and safety in population subgroups (children, pregnant women, immunocompromised persons)
 - Effectiveness and safety with simultaneous administration of other vaccines (e.g., influenza).

Planning Considerations

SHEA recommendation:

Convene a local vaccine work group that includes:

- | | |
|-------------------------------------|---|
| 1. Infectious diseases | 8. Communication experts |
| 2. Infection prevention | 9. Diversity/community engagement expert(s) |
| 3. Occupational health | 10. Ethicist(s) |
| 4. Pharmacy | 11. Emergency Preparedness experts |
| 5. Local public health | 12. Supply chain |
| 6. Nursing and physician leadership | 13. HR/employee relations |
| 7. Informatics | |

Vaccine Approval

It is unknown at this time whether the first vaccines available will be approved under FDA's Emergency Use Authorization (EUA) process, or FDA's standard licensing process. Standards for efficacy are anticipated to be similar under an EUA or licensure, with a primary efficacy endpoint of $\geq 50\%$ with a lower bound $>30\%$ for a placebo-controlled trial. Because COVID-19 vaccines are anticipated to be given to millions of healthy individuals, standards for safety also will need to be similar under either mechanism of approval.

Vaccination Policies for HCP

- If approved under an EUA, a COVID-19 vaccine should not be mandatory or a condition of HCP employment ([FDA, page 24](#)).
- If approved under full licensure, healthcare facilities may consider whether to require the COVID-19 vaccine as a condition of employment.

SHEA recommendations:

- Include an informed consent process as part of all vaccination programs. The requirements for an informed consent process may differ based on FDA approval mechanism (EUA vs. full licensure), but under either mechanism HCP should have sufficient opportunity to have their questions and concerns addressed.

- SHEA generally supports vaccine requirements for HCP but does NOT recommend that a COVID-19 vaccine be required of HCP at this time, due to the limited information that will be available at the time of approval on long-term safety and effectiveness.
- SHEA does recommend that any adverse event related to a COVID-19 vaccine administered by the employer be covered under worker's compensation. While not required for non-mandatory vaccines, coverage under worker's compensation can be applied voluntarily. Because, at least initially, most people would not receive the vaccine were they not HCP, SHEA believes it is appropriate for healthcare employers to offer this coverage, in addition to assistance by any state/federal programs (e.g., the Vaccine Injury Compensation Program).

Vaccine Distribution & Storage

- Centralized distribution will occur for all available vaccine products, via state and local health departments.
- CDC has tasked state/local health departments to develop distribution plans by mid-October. They should be reaching out to local healthcare partners, if they have not already.
- Some of the initial vaccine candidates have significant storage requirements, including maintenance of a cold chain (frozen storage at -70°C or -20°C, or use of dry ice) and limited shelf-life once thawed. CDC is collaborating with state/local health departments to work through the logistics of these storage requirements.
- These requirements probably will limit the locations in which vaccine may be administered to those that can:
 - Manage the cold chain storage and handling requirements
 - Have high enough throughput to avoid vaccine wastage (e.g. 1,000 doses per box as a minimum for some vaccines).
- As additional data become available, storage requirements may lessen, and/or new vaccine candidates without such requirements may become available.

Vaccine Administration Tracking

- Healthcare systems will be required to report all vaccines administered to patients (including vaccine type, dose number, etc.) to state or local authorities, via state immunization registries or other tools.
- Healthcare facilities, including nursing homes, will be asked to report all vaccines administered to HCP via the National Healthcare Safety Network (NHSN) in aggregate, similar to current HCP influenza vaccination reporting. The frequency has not been finalized, but may be weekly.

SHEA recommendations:

- To inform planning for how to handle this requirement, healthcare facilities should evaluate their current process for reporting administered vaccines. Facilities should ensure internal tracking mechanisms available to document employee vaccination status.
- If possible, we recommend that registries be designed to allow automatic electronic data transfer.

Vaccine Administration Logistics

- Administration of initial COVID-19 vaccines is expected to be more complicated than for other vaccination programs like influenza. A centralized process may be needed initially to maximize throughput and avoid vaccine wastage, while maintaining physical distancing requirements and ensuring use of proper PPE by vaccinators.

SHEA recommendations:

Train staff members who will administer vaccines on details, including:

- 2 doses may be required for certain vaccines, spaced 21 or 28 days apart (depending on the vaccine candidate):
 - Reminders for second doses
 - Making sure that that a second dose will be available for those who have received their first dose
 - The second dose must be from the same manufacturer as the first dose.
- Thawing and reconstitution processes
- Safe handling of multidose vials
- Providing the *Vaccine Information Statement*
- Counseling individuals to anticipate local and systemic reactions after vaccination
- Providing a card and/or QR code or other means for vaccines to be able to remember and track the type, lot, and date of their vaccine(s)
- Internal data entry/collection process

Vaccine Safety Monitoring

- Post-approval vaccine safety monitoring for COVID-19 vaccines will occur via several large passive and active safety surveillance systems, such as the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), the National Healthcare Safety Network (NHSN), and the Centers for Medicare and Medicaid Services (CMS).
- Some of these safety surveillance systems may ask early vaccine recipients to enroll in a text- or email-based active monitoring programs with daily contact for 7 days after receiving the vaccine, and weekly for up to 6 weeks.
- VAERS will be used to identify safety signals rapidly.

SHEA recommendations:

- Report all potential vaccine adverse events in HCP or patients to [VAERS](#).
- Also report serious vaccine adverse events in HCP in aggregate via NHSN.

Vaccine Prioritization

- ACIP is finalizing its recommendations for vaccine allocation, pending available Phase III clinical trial data. Its goal is to target populations:
 - At higher risk of acquiring COVID-19
 - At higher risk of severe COVID-19

- Or, if feasible, both.
- ACIP will emphasize the importance of health equity in vaccine allocation in each phase, given the significant disparities seen with COVID-19 disease.
- **Phase 1a:** HCP will be one of the earliest groups recommended for vaccination.
 - HCP are defined as paid or unpaid persons (including medical staff) serving in healthcare settings with potential for exposure to infectious patients or materials
 - This includes HCP who do not perform direct patient care, but may be exposed at work.
- **Phase 1b:**
 - Other essential personnel
 - Adults with underlying medical conditions
 - Adults 65 years and older.
- Initially, vaccine(s) will not be FDA-approved for use in children or pregnant women because they were not enrolled in the initial studies. This may change as more data become available.

SHEA recommendations:

With the likelihood for initially insufficient doses of vaccine for all HCP, healthcare systems should consider these factors in planning distribution:

- Prioritize HCP who interact directly with patients (or family members of patients), and are not able to work remotely to perform their job function. The 3 categories below are considered to be of equal priority:
 - HCP who provide direct patient care to suspected or confirmed COVID-19 patients (e.g., COVID-designated units, Emergency Departments, first responders, testing centers, urgent care clinics). HCP in these roles may have the highest amount of contact with COVID-19 patients.
 - HCP who provide direct patient care to patients NOT suspected of having COVID-19 (e.g. non-COVID units, staff performing aerosol-generating procedures, radiology staff, ambulatory care, phlebotomy, long-term care facilities, nursing homes).
 - Other HCP providing essential services throughout the healthcare delivery system:
 - HCP who provide services to patients or patients' family members (e.g. food services, medical assistants, front desk staff, transport, etc.)
 - HCP who handle infectious materials (e.g. environmental services, laboratory workers, autopsy staff, etc.)
- Healthcare facilities and systems should ensure *equity* is included in all stages of planning and implementation when delivering COVID-19 vaccines in the workplace. The HCP workforce reflects the diversity of the country as a whole; therefore:
 - Lower wage workers within healthcare delivery systems may have higher rates of COVID-19 infection due to inability to work remotely, the need take public transportation to work, and exposures in households, high-risk communities, and the workplace.
 - Until vaccine supply is sufficient, local data on COVID-positive HCP can help healthcare facilities guide phased vaccination of the workforce.
- Within the above categories, if supply is insufficient, consider prioritizing HCP who are at high risk for severe disease, including HCP with certain medical conditions or older adults as defined by CDC [here](#), if feasible.

- If vaccine supply is sufficient, *also* consider vaccinating HCP who are at high risk for severe disease, even if able to work remotely to perform their job function, including HCP with certain medical conditions or older adults as defined by CDC [here](#).

Vaccine Hesitancy

- HCP at all levels may hesitate to seek COVID-19 vaccinations when they first are available. Studies have shown significant levels of potential vaccine hesitancy – an individual or their caregiver’s decision to delay acceptance or to refuse vaccines despite availability of vaccine services – specific to COVID-19 vaccine(s) due to:
 - Concerns about their rapid development
 - The use of new vaccination platforms
 - Limited data on short-term and no long-term safety data at the time of approval.

SHEA recommendations:

Healthcare facilities and systems should work to build vaccine confidence broadly, and especially among groups anticipated to receive early vaccination, through transparency, clear and frequent communication, and active advocacy.

- By publicly being vaccinated themselves, leaders at the local and healthcare system levels may help promote vaccination.
- Healthcare facilities should develop a communications plan to:
 - Provide HCP with information about their vaccination plans ahead of vaccine availability
 - Maintain maximum transparency about what is and is not known about each specific vaccine candidate’s safety and efficacy
 - Dispel vaccine misinformation

Vaccination in the Setting of a COVID-19 Infection Prevention Program

SHEA recommendations:

Make sure that HCP are aware that, given our current state of understanding, vaccination against COVID-19 does not change or negate other policies or practices to prevention transmission of COVID-19, including but not limited to:

- Proper use of PPE
- Routine masking and wearing of eye protection
- Physical distancing
- Quarantine or furlough after an exposure
- Daily assessment of symptoms of COVID-19. If symptoms are present, HCP should not report to work and should immediately contact Occupational Health.

Additional Details and Planning Assistance

Please see [CDC’s COVID-19 Vaccination Administration Interim Playbook for Jurisdictional Operations](#). While primarily intended for state/local health departments, CDC’s Playbook contains information that can be applied to planning on the healthcare facility or system-level as well.