



SHEA Statement for Healthcare Settings Preparing for COVID-19 Vaccination

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Background

The Food and Drug Administration (FDA) authorized and the Centers for Disease Control and Prevention (CDC)'s Advisory Council on Immunization Practices (ACIP) recommended, the initial vaccines to combat the COVID-19 pandemic.

The ACIP COVID-19 work group has convened more than 25 times to review scientific, ethical, and implementation considerations for a national COVID-19 vaccination program, as well as vaccine-specific data for each of the Phase III clinical trial candidates.

Ethical Principles

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

- Maximize benefits and minimize harms
- Promote justice
- Mitigate health inequities
- Promote transparency

Facilities should consider each of the above principles when implementing a vaccination program for healthcare personnel (HCP). See the [MMWR](#) articles on vaccine allocation for more information on how to apply these principles during planning.

Intended Use

This document provides background and recommendations relevant to vaccination against COVID-19 for [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

Timing

- The Pfizer/BioNTech mRNA vaccine was reviewed by FDA on December 10 and the advisory panel recommended Emergency Use Authorization (EUA). FDA’s December 8 trial data review and assessment is available [here](#).
- The Moderna mRNA vaccine was reviewed on December 17 and the advisory panel recommended EUA. FDA’s trial data review and assessment if available [here](#).
- ACIP recommended the Pfizer/BioNTech vaccine on Dec 12, and the Moderna vaccine on Dec 19.
- Shipping of each vaccine could begin within 24-hours of FDA EUA and ACIP’s recommendations.
- As of Jan 14, 2021, more than 11 million people in the U.S. people have been vaccinated.

EUA Authorization

- FDA is expected to authorize additional COVID-19 vaccine(s) within 6 months.

- Standards for efficacy are anticipated to be similar under an EUA, with a primary efficacy endpoint of $\geq 50\%$ with a lower bound $>30\%$ for a placebo-controlled trial.
- Standards for safety will be similar under either mechanism of approval because COVID-19 vaccines are anticipated to be given to millions of healthy individuals.
- EUA allows for application after a median of 2 months of follow-up after the second dose; whereas, full licensure typically requires 6 months of follow-up. It is important to note that historically, nearly all vaccine adverse events occur within 6 weeks of administration.
- Vaccine manufacturers are expected to submit for full FDA licensure once 6 months of follow-up data are available. If approved, vaccine will likely be available for direct order/purchase from the manufacturers.

Prioritization

ACIP provided recommendations for prioritizing vaccine distribution. State and local governments are not obligated to prioritize vaccine distribution in the same way. Healthcare systems should plan to follow their state/local guidance. ACIP recommendations:

- [Phase 1a](#). should include HCP in all settings and LTC residents (voted Dec. 1)
- [Phase 1b](#). should include adults 75 years of age and older, and specific frontline essential workers (voted Dec. 20)
- [Phase 1c](#). of prioritization should include adults 65-74 years of age, persons 16-64 years of age with certain underlying health conditions, and other essential workers (voted Dec. 20)

Unknowns at the Time of Authorization

- Duration of protection
- Correlates of immunity
- Effectiveness and safety:
 - Long-term safety
 - Long-term effectiveness after single dose
 - Effectiveness and safety in certain population subgroups (children (<16 years of age), pregnant women, lactating women, immunocompromised persons)
 - Effectiveness and safety with simultaneous administration of other vaccines (e.g., influenza)
 - Effectiveness after symptomatic COVID-19 infection
 - Effectiveness after monoclonal antibody (mAb) therapy
 - Effectiveness after antibody containing products (e.g., whole blood, IgG; especially important as the number of infected and vaccinated persons increases)
- Appropriate timing:
 - After symptomatic COVID-19 infection
 - After monoclonal antibody (mAb) therapy
- Relatedness of possible rare side effects (e.g., Bell's palsy)

Planning

SHEA Recommendations

Convene a local COVID-19 vaccine work group that includes:

1. Infectious diseases
2. Infection prevention
3. Public health
4. Clinical medicine
5. Pharmacy
6. Behavioral science
7. Health equity
8. Communication experts
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 | 14. Legal |

Vaccination Policies for HCP

SHEA Recommendations

- COVID-19 vaccines authorized under an EUA should not be mandatory or a condition of HCP employment ([FDA, page 24](#)):
 - 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.
 - Once approved under full licensure, healthcare facilities may consider whether to require the COVID-19 vaccine as a condition of employment.
- Include an informed consent process in the person’s primary language as part of all vaccination programs:
 - The requirements for an informed consent process may differ based on FDA approval mechanism (EUA vs. full licensure). Under either mechanism, HCP should have sufficient opportunity to have their questions answered and concerns addressed.
 - Each authorized vaccine will have an EUA fact sheet that must be shared with the recipient in their preferred language. This fact sheet is similar to a Vaccine Information Statement (VIS), but also includes EUA information.
- SHEA does recommend that any serious adverse event related to a COVID-19 vaccine administered by the employer be covered under worker’s compensation if allowed under state laws/regulations.
 - While not required for non-mandatory vaccines, coverage under worker’s compensation may be allowable in some states.
 - Because, at least initially, most people would not receive the vaccine were they not HCP, SHEA supports states in allowing serious adverse events following administration of a COVID-19 vaccine to a healthcare employee to be covered under worker’s compensation.
- Prior to beginning the vaccination program, discuss and communicate to HCP human resources (HR) policies related to missed work due to non-serious adverse events (e.g., [a transient fever](#) post-vaccination).

Vaccine Distribution

Centralized distribution will occur for all available vaccine products via state and local health departments.

Vaccine Storage

- Significant storage requirements of current vaccines likely 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., approximately 1,000 doses per box as a minimum for the Pfizer/BioNTech vaccine).
- The Pfizer/BioNTech vaccine requires:
 - Maintenance of a cold chain (frozen storage at -70°C , or use of dry ice)
 - Limited shelf-life (5 days) once thawed.
- The Moderna vaccine requires:
 - Long-term storage at -20°C
 - Can be kept at refrigeration temperature for 2 weeks.
 - Once thawed, can be kept at room temperature for 12 hours.
- Both vaccines have a short timeframe for administration (6 hours) once reconstituted (Pfizer/BioNTech), or once the vial is entered for the first dose (Moderna).
- 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 on a weekly basis via the National Healthcare Safety Network (NHSN) the aggregate vaccines administered to HCP.
- This process will be similar to current HCP influenza vaccination reporting.
- Information about the NHSN COVID-19 vaccine module for HCP vaccination is available [here](#) for acute care facilities and [here](#) for long-term care facilities.

SHEA Recommendations

- To inform planning for this requirement, healthcare facilities should:
 - Evaluate their current process for reporting administered vaccines.
 - Ensure that internal tracking mechanisms are available to document HCP vaccination status.
- COVID-19 vaccine reporting requirements may include additional information that is not usually part of vaccination reporting, such as race/ethnicity, occupation, and/or other risk factors for COVID-19.
- If possible, we recommend the design of registries to allow automatic electronic data transfer.

Logistics and Training

Administration of initial COVID-19 vaccines is more complicated than other vaccination programs (e.g., influenza).

SHEA Recommendations

- Utilize a centralized process, at least initially, in order to:
 - Maximize throughput
 - Avoid vaccine wastage
 - Ensure adherence to physical distancing requirements
 - Ensure use of proper PPE by vaccinators.
- Have a mechanism in place to use all appointments and vaccine each day.
- Coordinate with the information technology (IT) department to develop a strategy to:
 - Optimize the appointment notification, sign-up, and reminder processes.

- Prevent against security breaches, e.g. phishing emails disguised as vaccine appointment alerts.
- Train staff members who will administer vaccines in:
 - Vaccine choice:
 - Choice of vaccine should rely on administration logistics.
 - At this time, data suggest that the Pfizer/BioNTech and Moderna vaccines are very similar in terms of efficacy, safety, and reactogenicity; therefore, there does not appear to be any reason to allow HCP to choose which vaccine they prefer to get.
 - Multiple doses:
 - 2 doses will be required for certain vaccines:
 - Ideal timing is 21-25 days for Pfizer/BioNTech, and 28-32 days for Moderna.
 - While there is a 4-day “grace” period related to appropriate interval, and vaccines given at day 17-20 (for Pfizer/BioNTech) or at days 24-27 (for Moderna) are acceptable, this should be the exception rather than the rule.
 - Vaccines given after the ideal interval are acceptable. There is no maximum interval at which the vaccine series must be restarted.
 - Vaccines given before day 17 for Pfizer/BioNTech or before day 24 for Moderna should be reported as a vaccine administration errors in NHSN, but no additional doses are recommended.
 - Patients will need reminders for second doses.
 - The vaccine administration cards that are shipped with vaccine provides a method for documenting administered doses (including lot numbers) as well as a date for the second dose.
 - Encourage recipients to keep the hard copy of this card as well as a photograph as proof of vaccination.
 - The second dose must be from the same manufacturer as the first dose and available for those who have received their first dose.
 - Thawing and reconstitution for multi-dose vials:
 - Given limited familiarity in the current era with multi-dose vials, consider including a second staff member (such as a pharmacy technician) to prepare vaccine doses for the nurse or other vaccinator to administer.
 - Safe handling of multidose vials is critical.
 - “Extra” doses available in multidose vials may be used if a full dose (0.3 mL for Pfizer/BioNTech, 0.5 mL for Moderna) can be withdrawn. Any partial doses cannot be combined between multiple vials, as they do not contain any preservatives.
 - Safety tracking:
 - Provide patients with the Emergency Use Authorization fact sheet (takes the place of the VIS) in their primary language.
 - EUA fact sheets in a variety of languages are available for [Pfizer/BioNTech](#) and for [Moderna](#).
 - Provide information and encourage use of [V-safe](#), the voluntary smartphone-based application. [V-safe](#) will provide active surveillance of vaccine recipients (see below).
 - Counseling individuals to anticipate local and systemic reactions after vaccination, especially after the second dose of the mRNA vaccines.
 - The process for internal data collection and entry.
 - Method for accounting for any vaccine wastage.

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:
 - [Vaccine Adverse Event Reporting System \(VAERS\)](#)
 - [Vaccine Safety Datalink \(VSD\)](#)
 - [National Healthcare Safety Network \(NHSN\)](#)
 - Centers for Medicare and Medicaid Services (CMS).
- [V-safe](#) is a new active surveillance system being stood up specifically for COVID-19:
 - Available for smartphone users via text message or QR code (no app download is required). At this time, this system will not be available to those who do not have a smartphone.
 - The system will:
 - Text recipients daily for 7 days post-vaccine, then weekly for 6 weeks, then periodically for up to 1 year.
 - Trigger telephone contact and [VAERS](#) reporting upon any reported serious adverse event.
- [VAERS](#) will be used to identify safety signals rapidly.
- [Clinical Immunization Safety Assessment \(CISA\) consultation](#) is also available to clinicians.

SHEA Recommendations

- Encourage recipients with smartphones to enroll in [V-safe](#).
- Report all potential vaccine adverse events in HCP to [VAERS](#).
- Report serious vaccine adverse events in HCP in aggregate via NHSN.

Vaccine Prioritization

ACIP Recommendations

- Emphasize the importance of health equity in vaccine allocation in each phase of distribution, given the significant disparities seen with COVID-19 disease.
- Aim to target populations:
 - At higher risk of acquiring COVID-19
 - At higher risk of severe COVID-19
 - Or, if feasible, both.
- The populations included in Phases [1a](#), [1b](#), and [1c](#) overlap:
 - Facilities are not expected to vaccinate all HCP before moving on to the next phase.
 - Facilities may decide to defer low-risk HCP (such as those who work entirely remotely) until after Phases 1b./1c.
- State and local governments are not obligated to prioritize vaccine in the same way as recommended by ACIP.
- Healthcare systems should plan to follow their state/local guidance.

Children and Pregnant Women

- Initially, vaccine(s) will not be FDA-authorized for use in children under 16 years of age.
- Pregnant women are not excluded from choosing to be vaccinated.
 - Pregnant women were not enrolled in the Phase III studies; thus, no safety data exist.

- The American College of Obstetricians and Gynecologists (ACOG) and others have stated that pregnancy should be a precaution rather than a contraindication for COVID-19 vaccine, given the increased risk of severe COVID-19 in this population.
- Facilities may anticipate information about pregnancy safety registries to be forthcoming.

SHEA Recommendations

- With the likelihood for initially insufficient doses to be able to vaccinate all HCP, healthcare systems should consider these factors in planning for 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.)
- Ensure equity is included in all stages of planning and implementation when delivering COVID-19 vaccines in the workplace. The healthcare 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 their 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.
- Stagger vaccine administration so that HCP in specific units/departments are not vaccinated at once in order to prevent staffing shortages:
 - Post-vaccine side effects may require HCP to call out from work.
 - Consider asking HCP to choose a vaccination date prior to planned time off. This may be particularly important for the second dose of the mRNA vaccines.
- If supply is insufficient, consider prioritizing HCP within the above 3 categories who are at high risk for severe disease, including HCP with certain medical conditions or older adults as defined by [CDC](#).
 - Be aware that HR records typically do not contain this information.
 - Asking to self-report age or underlying condition may inadvertently lead to greater inequity because lower-wage workers may be less likely to report such conditions.
 - Your facility's Legal/HR team should review plans to ask for HCP to self-report age or medical conditions.
- If vaccine supply is sufficient, also consider vaccinating HCP who are at high risk for severe disease, even if they are able to work remotely to perform their job function, including HCP with certain medical conditions or older adults as defined by [CDC](#).

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, defined as 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 short-term, and no long-term, safety data at the time of authorization.

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 facilities and healthcare system levels may help promote vaccination.
- Healthcare facilities should develop a communications plan with materials for HCP and patients in their preferred languages, to:
 - Provide HCP and patients 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 prevent transmission of COVID-19.
 - HCP and patients should continue to follow all infection prevention strategies and policies, 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.
- Have protocols in place to manage symptoms that may be due to COVID-19 vaccination or COVID-19 illness. This is important to reduce the risk for disruptions in care and SARS-CoV-2 transmission resulting from:
 - Unnecessarily excluding HCP with only post-vaccination signs and symptoms from work, and
 - Inadvertently allowing HCP with SARS-CoV-2 or another transmissible infection to work.
 - HCP presenting with symptoms shortly after vaccination can be grouped into 3 possible categories:

- Symptoms that are likely due to COVID-19 vaccination and NOT disease: local pain, redness, swelling at injection site, lymphadenopathy, immediate allergic reactions. *COVID-19 testing not indicated.*
- Symptoms that are likely due to COVID-19 disease and NOT vaccination: cough, shortness of breath, rhinorrhea, sore throat, loss of taste/smell. *COVID-19 testing and furlough until test results are available is indicated.*
- Symptoms that could be due to EITHER COVID-19 disease OR vaccination: fever, chills, fatigue, headache, myalgias, arthralgias. *Evaluate the HCP. COVID-19 testing with furlough until test results are available may be indicated.*
- For more information on this topic, see [here](#).

Additional Details and Planning Assistance

- [CDC COVID-19 Vaccination Program Interim Playbook](#), while primarily intended for state/local health departments, contains information that also can be applied to planning on the healthcare facility or system-level
- [CDC COVID-19 vaccine website](#)
- [MMWR](#) on Phase 1a. allocation
- [MMWR](#) on Phase 1b./1c. allocation
- [CDC Clinical Considerations](#)
- [ACIP Evidence Table](#)