SHEA Statement for Healthcare Settings Preparing for COVID-19 Vaccination

Current as of Dec 7, 2020

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Background

As we await Food and Drug Administration (FDA) authorization 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.

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 an HCP vaccination program. See the MMWR on vaccine allocation for Phase 1a 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 will be reviewed by FDA on December 10. FDA's December 8 trial data review and assessment is available here.
- The Moderna mRNA vaccine will be reviewed on December 17.
- If FDA authorizes either of these vaccines under an Emergency Use Agreement (EUA), ACIP will convene an emergency meeting to vote on a recommendation. ACIP has scheduled emergency meetings for December 11 and December 13.
- Shipping of each vaccine could begin within 24-hours of FDA EUA and ACIP's recommendations.

EUA Authorization

- FDA is expected to authorize the initial two COVID-19 vaccines (Pfizer/BioNTech and Moderna) under an EUA within the next month, and additional COVID-19 vaccine(s) within 6-12 months.
- Standards for efficacy are anticipated to be similar under an EUA, with a primary efficacy endpoint of ≥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.

Prioritization

ACIP voted on December 1 that Phase 1a. of prioritization will include:

- HCP in all settings, including inpatient, outpatient, long-term care (LTC), and community settings
- LTC residents.

Unknowns at the Time of Authorization

- Duration of protection
- Correlates of immunity
- Long-term safety
- Effectiveness and safety in certain population subgroups (children, pregnant women, lactating women, immunocompromised persons)
- Effectiveness and safety with simultaneous administration of other vaccines (e.g., influenza).

Planning

SHEA Recommendations

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

1. Infectious diseases
2. Infection prevention
3. Occupational health
4. Pharmacy
5. Local public health
6. Nursing and physician leadership
7. Informatics
8. Communication experts
9. Diversity/community engagement expert(s)
10. Ethicist(s)
11. Emergency Preparedness experts
12. Supply chain
13. HR/employee relations
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).
- 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. This fact sheet is similar to a Vaccine Information Statement (VIS), but also includes EUA information.
- 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 serious 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).
- 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.
- State/local health departments likely will receive initial vaccine allotments by mid- to late-December.

Vaccine Storage

- Significant storage 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., 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.
- Both vaccines have a short timeframe for administration (i.e., 6 hours) once reconstituted, or once the vial is entered for the first dose.
- 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.
    - The NHSN COVID-19 vaccine module for HCP vaccination is expected to be available in mid-December.

SHEA Recommendations

- To inform planning for this requirement, healthcare facilities should evaluate their current process for reporting administered vaccines.
- Facilities should ensure that internal tracking mechanisms are available to document employee 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 will be 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.
- Train staff members who will administer vaccines in:
    - Vaccine choice:
        - Choice of vaccine should rely on administration logistics.
        - At this time, the data about 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, spaced 21 or 28 days apart depending on the vaccine candidate.
        - Patients will need reminders for second doses. Consider providing a card, QR code, and/or other means for patients to track the type, lot, and date of their vaccine(s).
        - 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.
    - Safety tracking:
        - Provide patients with the *Emergency Use Authorization* fact sheet (takes the place of the VIS) in their primary language.
        - 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.

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 emphasizes the importance of health equity in vaccine allocation in each phase of distribution, given the significant disparities seen with COVID-19 disease.

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.

Phase 1a.

Includes HCP and long-term care residents.

- HCP are defined as paid or unpaid persons (including medical staff) serving in healthcare settings with potential for exposure to infectious patients or materials.
- Phase 1a includes HCP who do not perform direct patient care, but may be exposed at work.

Phase 1b./1c.

ACIP has not voted yet on prioritization, but proposed:

- 1b.: Essential personnel outside of healthcare
- 1c.: Adults with underlying medical conditions and adults 65 years and older.

The populations included in Phases 1a., 1b., and 1c. will 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.

Children and Pregnant Women

- Initially, vaccine(s) will not be FDA-authorized for use in children.
- Whether pregnant women will be included depends on the exact language of the EUA.
    - 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; however, “off-label” use is not allowed under an EUA. This may change as more data become available.

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 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. HCP 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.

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
- CDC Clinical Considerations
- ACIP Evidence Table