MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

DECEMBER 1, 2020

SUMMARY MINUTES

The Centers for Disease Control and Prevention (CDC) convened an emergency meeting of its Advisory Committee on Immunization Practices (ACIP) on December 1, 2020. These summary minutes provide an overview of the meeting, which was devoted solely to the topic of coronavirus disease 2019 (COVID-19) vaccines.

The purpose of the meeting was for ACIP to vote on interim guidance for federal, state, and local jurisdictions on allocation of the initial doses of COVID-19 vaccine. **Dr. José R. Romero** (ACIP Chair) opened the COVID-19 vaccines session.

Dr. Beth Bell (ACIP Work Group Chair) reviewed the COVID-19 Vaccines Work Group's (WG) activities since the November 23, 2020 ACIP meeting. Dr. Bell noted that two applications for Emergency Use Authorization (EUA) for a candidate vaccine had been filed with the Food and Drug Administration (FDA): Pfizer/BioNTech announced their submission on November 20, 2020 and Moderna announced their submission on November 30, 2020.

ALLOCATION OF INITIAL SUPPLIES OF COVID-19 VACCINE: PHASE 1a

Dr. Kathleen Dooling (CDC ACIP WG Co-Lead) presented "Phased Allocation of COVID-19 Vaccines" to summarize the information available to inform the policy decision before ACIP, namely: "Should healthcare personnel and long-term care facility residents be offered COVID-19 vaccination in Phase 1a?"

Three areas of evidence were reviewed: 1) the science related to COVID-19 disease burden and the balance of benefits and harms of vaccine in each group; 2) implementation considerations, including the values and acceptability of each group, as well as feasibility; and 3) the ethical principles that apply to each group, namely maximize benefits and minimize harms, promote justice, mitigate health inequities, and the promotion of transparency throughout the policy deliberation process. A summary of the data for each population and the Work Group's considerations supporting vaccination of healthcare personnel (HCP) and long-term care facility (LTCF) residents in Phase 1a were presented.

SUMMARY OF DISCUSSION

Healthcare personnel

- The committee expressed concern that access to COVID-19 vaccine will be difficult for community-based HCP who are not employees of hospitals or health care systems. HCP who

practice in community settings are likely to provide care to patients early in the course of their infection when patients may be most infectious.

- There was strong agreement that healthcare systems and public health authorities must work together to ensure that HCP who are not affiliated with hospitals or health care systems have access to COVID-19 vaccines. Outreach into the wider community is critical to reach such HCP.

Long-term care facility residents

- There was strong consensus from the committee that LTCF residents are at high risk for infection with SARS-CoV-2 and severe disease and death from COVID-19. Prevention of infection in this population may reduce COVID-19 associated hospitalizations and reduce the burden on health care systems.
- The committee noted that the federal Pharmacy Partnership for Long-term Care Program offers efficiencies in implementation but expressed concern that high patient turnover among some residents may impede completion of a 2-dose vaccine series. Multiple visits to a facility and data tracking systems will help facilitate vaccine coverage in this population

CLINICAL CONSIDERATIONS FOR POPULATIONS INCLUDED IN PHASE 1a

Dr. Sara Oliver (CDC ACIP WG Co-Lead) then presented "Clinical Considerations for Populations Included in Phase 1a." Clinical considerations related to sub-prioritization, reactogenicity, and implementation were reviewed for HCP and LTCF residents.

Sub-prioritization of populations will be needed because the number of doses of COVID-19 vaccine will be limited during the first months of the national vaccination program. Considerations for sub-prioritization of HCP may include work that involves direct patient care or handling of infectious materials; an inability to telework; work in residential care or long-term care facilities; and known prior infection with SARS-CoV-2.

Reactogenicity, including systemic symptoms, may occur post-vaccination. Limited data regarding reactogenicity are available from Phase I/II vaccine clinical trials; there are no reactogenicity data for LTCF residents. Vaccination programs for HCP will need to plan for the possibility that some HCP may need time away from their duties if they experience systemic symptoms. Staggering vaccination of HCP who work in similar units or positions may be considered. CDC is developing guidance to assist with assessment of systemic symptoms in HCP following COVID-19 vaccination.

Guidance for use of COVID-19 vaccines in pregnant or breastfeeding women will be developed after Phase III clinical trial data and EUA Conditions of Use are available.

Vaccine-specific EUA fact sheets will be provided to vaccine providers and recipients. Fact sheets will be provided to family members or medical proxies of LTCF residents as applicable. Language clarifying the lack of data for LTCF residents will be included on CDC's website. Consent/assent will be obtained from LTCF residents or families/medical proxies as is standard practice for administration of other vaccines in this population.

SUMMARY OF DISCUSSION

Sub-prioritization

- Committee members concurred that sub-prioritization of HCP is challenging in the setting of a constrained vaccine supply. In addition to the risk of occupational exposure to SARS-CoV-2, it is unclear how to weigh other factors such as age, high-risk medical conditions, equity considerations, such as racial/ethnic disparities in COVID-19 morbidity and mortality, and risks associated with community transmission. Asking HCP to self-disclose medical conditions could result in unintended inequities.
- ACIP recommendations and CDC guidance must have adequate specificity to be helpful yet allow for flexibility to take local considerations into account. Committee members encouraged discussion and coordination among CDC and its partners and stakeholders in the development of guidance related to sub-prioritization and reactogenicity.
- It is anticipated that sub-prioritization will be needed for a limited period of time until vaccine availability increases.

Reactogenicity

- The committee emphasized that reactogenicity data currently available are limited, especially for older adults, and preclude generalizability to LTCF residents.

Implementation

- Partnerships between local and state public health authorities and hospitals can facilitate decision making around vaccine allocation to HCP and LTCF residents taking into account national guidance, the local situation, and considerations related to equitable distribution of vaccine.
- Although measures such as staggering of vaccination in similar units/professions may need to be considered for both inpatient and outpatient healthcare settings, the committee also noted that the storage, handling, and administration requirements for some vaccines will favor centralized, high throughput systems. This will make staggering challenging for both large healthcare systems and smaller hospitals.
- Detailed “gating criteria” will be needed to facilitate moving expeditiously from one Phase to the next.
- There was strong support for CDC’s efforts in the development of communication materials such as toolkits for vaccination of HCP and LTCF residents.

POST-AUTHORIZATION SAFETY MONITORING UPDATE

Dr. Tom Shimabukuro (CDC Vaccine Safety Team Co-Lead) presented “Post-Authorization Safety Monitoring Update.” Dr. Shimabukuro reviewed the multiple monitoring systems that will be in place for safety signal detection and assessment including several new systems to enhance routine vaccine safety surveillance. Early data on COVID-19 vaccine safety in HCP will be available primarily through v-safe (a

new smartphone based active surveillance system for people who receive COVID-19 vaccine) and VAERS. Early data for LTCF residents will be primarily available through VAERS. The National Healthcare Safety Network (NHSN) monitoring system will provide aggregated weekly data on the number of vaccine doses administered and the occurrence of clinically significant adverse events voluntarily reported by 17,000 enrolled LTC facilities. An ACIP COVID-19 Vaccine Safety Technical Sub-Group (VaST) has been established. Communication materials will be distributed to state health officials, healthcare providers, and healthcare systems to increase awareness of the critical importance of safety monitoring and the mechanisms for reporting adverse events.

SUMMARY OF DISCUSSION

- The committee underscored the importance of information materials and clear guidance to assist public health partners, stakeholders, and healthcare providers in promoting patient participation in v-safe, reporting of adverse events to VAERS, and communicating with partners about vaccine safety.
- Additional outreach and guidance will be needed to increase awareness of safety monitoring and reporting mechanisms among healthcare providers who may have limited experience with VAERS, as well as providers who serve LTCF resident populations. Rollout of COVID-19 vaccination programs must be accompanied by robust participation in safety monitoring systems, with particular attention to LTCF residents.
- Communication materials should be culturally and linguistically appropriate to enhance patient and provider participation in safety monitoring systems.

THE VOTE: ALLOCATION OF INITIAL SUPPLIES OF COVID-19 VACCINE FOR PHASE 1a

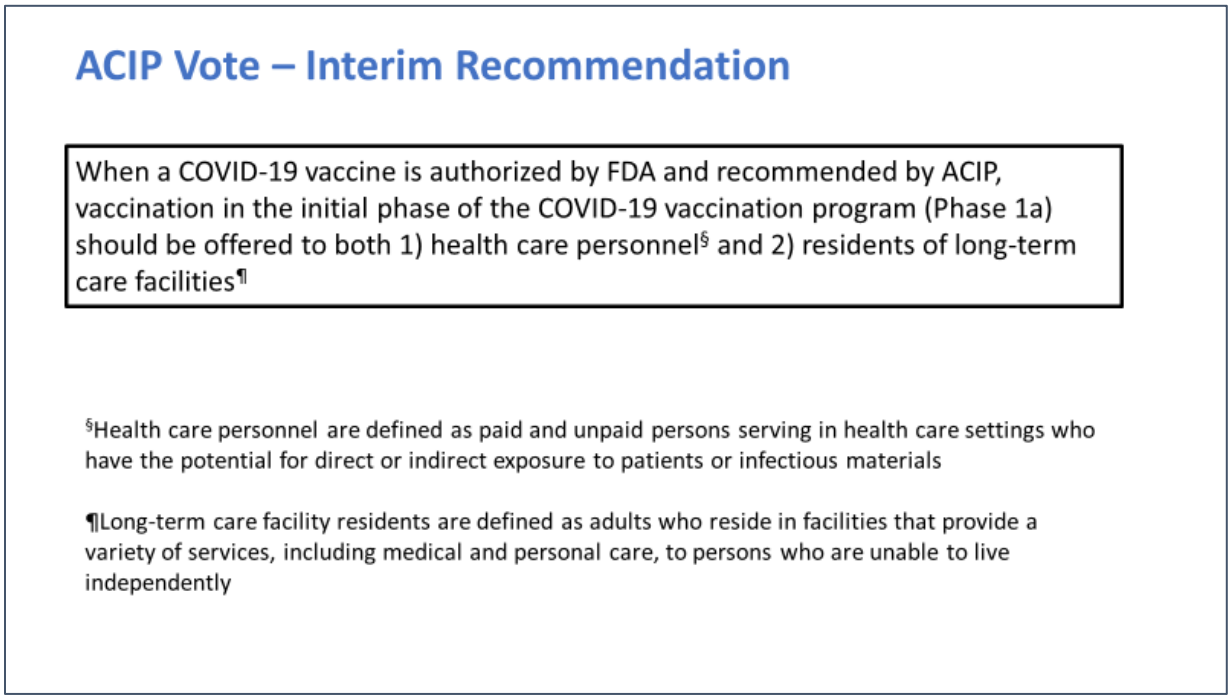
SUMMARY OF DISCUSSION PRIOR TO THE VOTE

- There was strong consensus for allocation of initial supplies of COVID-19 vaccine to HCP to maintain healthcare capacity for care of patients with COVID-19 and other medical conditions.
- Many committee members expressed support for vaccination of LTCF residents to reduce the high burden of morbidity and mortality in this population.
- Some committee members indicated that their initial hesitation about vaccination of LTCF residents had been lessened following the presentation of updated information about enhanced safety monitoring procedures and the transparency of consent/assent procedures. The insufficiency of non-pharmaceutical measures alone to mitigate transmission in LTCFs and the likely variability in LTCF staff uptake of vaccine were additional considerations.
- A few committee members expressed continued concern about vaccination of LTCF residents related to the unavailability of vaccine safety and efficacy data for this population, as well as what they viewed as an insufficient vaccine safety surveillance network for LTCF residents. To reduce transmission in LTCF, educational efforts and promotion of vaccine should be directed to LTCF staff.
- Other members noted that vaccination of LTCF residents may offset opportunities for transmission of SARS-CoV-2 if vaccine coverage among LTCF staff is low. Participation in the

Pharmacy Partnership for Long-term Care Program has the potential to improve uptake of vaccine in LTCF staff.

- Committee members re-iterated the importance of providing clear definitions for HCP and LTCFs, as well as clinical guidance related to sub-prioritization, reactogenicity, and implementation to accompany publication of the ACIP recommendation for Phase 1a allocation.
- Clarification was sought and the Work Group Co-Lead confirmed that the ordering of HCP and LTCF residents in the text of the interim recommendation does not imply any preferential ranking for vaccination implementation.

THE VOTE



ACIP voted 13-1 in favor of the Phase 1a allocation recommendation as interim guidance. The interim recommendation may be updated based on additional safety and efficacy data from Phase III clinical trials and the conditions of an FDA EAU.

SUMMARY OF DISCUSSION AFTER THE VOTE

Committee members cited the following considerations in support of their vote:

- Consideration of the three pillars of evidence related to science, implementation, and ethical principles.
- Alignment with the ethical principles of maximize benefits and minimize harms; promote justice; and mitigate health inequities.

- The risk of occupational exposure and the growing number of cases and deaths in HCP; inclusion of the full diversity of HCP which will help address health inequities; the importance of HCP to remain healthy to care for patients and maintain strained healthcare systems.
- The disproportionate burden of morbidity and mortality among LTCF residents and the need to protect a fragile population.
- The efficiency of vaccination of both LTCF residents and staff through the Pharmacy Partnership for Long-term Care Program.
- The implementation of routine and new systems of surveillance for adverse events and meticulous assessment of these systems for all populations in Phase 1a, but particularly in LTCF residents.
- The inclusion of the necessary and appropriate consent/assent procedures for LTCF residents.
- The one vote cast not in favor of the recommendation reflected concerns about the lack of safety and efficacy data for LTCF residents and the need to test and evaluate vaccines in this population; there were no reservations regarding allocation of COVID-19 vaccine to HCP.
- The importance of post-recommendation guidance to assist in implementation of the recommendation.

SUMMARY

- Of the 14 ACIP voting members, 13 voted in favor of the recommendation as interim guidance and one voted not in favor of the recommendation.
- ACIP will consider vaccine-specific recommendations and additional populations when an FDA authorized vaccine is available.

Certification

Upon reviewing the foregoing version of the December 1, 2020 ACIP meeting summary, Dr. Jose Romero certified that to the best of his knowledge, they are accurate and complete. His original, signed certification is on file with the Strategic Business Initiatives Unit (SBI) of CDC.

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José R. Romero, MD, FAAP, FIDSA, FPIDS, FAAAS

Chair, Advisory Committee on Immunization Practices