MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

NOVEMBER 23, 2020

SUMMARY MINUTES

The Centers for Disease Control and Prevention (CDC) convened an emergency meeting of its Advisory Committee on Immunization Practices (ACIP) on November 23, 2020. These summary minutes provide an overview of the meeting, which was devoted solely to the topic of coronavirus disease 2019 (COVID-19) vaccines. **Dr. Robert Redfield** (CDC Director) delivered the opening remarks. **Dr. José R. Romero** (ACIP Chair) then announced the publication of The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020 in the Morbidity and Mortality Weekly Report (MMWR).

Dr. Beth Bell (ACIP WG Chair) opened the COVID-19 Vaccines session. Dr. Bell reviewed the COVID-19 vaccines currently under development and provided information on the vaccines in phase I/II or phase III clinical trials in the United States. The available phase III clinical trial results for the two mRNA vaccines from Pfizer/BioNTech and Moderna were summarized.

EVIDENCE TO RECOMMENDATIONS FRAMEWORK

Dr. Sara Oliver (CDC ACIP WG Co-Lead) presented the "EtR Framework: Public Health Problem, Resource Use and Equity Domains." The ACIP's Evidence to Recommendations (EtR) framework uses an explicit and transparent method for assessing the quality of the evidence related to benefits and harms as well as consideration of additional factors ("domains") when considering a recommendation. The first presentation of the afternoon focused on three of the EtR domains, 'Public Health Problem,' 'Resource Use,' and 'Equity.' The information presented focused on the current evidence and Work Group discussions to date. Areas where EtR domain judgements would vary by individual vaccine characteristics were highlighted.

Dr. Oliver walked through the available data supporting each of these domains and provided the Work Group's judgments.

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 disease of public health importance?	Yes
Resource Use	Is COVID-19 vaccine 'X' a reasonable and efficient allocation of resources?	Yes
Equity	What would be the impact of COVID-19 vaccine 'X' on health equity?	Probably reduced/Probably increased*

*Impact probably reduced for vaccines with challenging handling and storage requirements (e.g., need for storage at ultra-cold temperatures); impact probably increased for vaccines whose characteristics would allow for use across a range of settings or require only one dose.

Summary of Discussion

Public Health Problem: There was a strong consensus from the committee that the data presented clearly demonstrates that COVID-19 disease is a serious public health problem and additional data/information on the public health problem is not needed before a vote.

Resource Use: There was also strong consensus from the committee that sufficient information has been presented to date on resource use. The committee agreed that cost-effectiveness may not be a primary driver for decision-making in the setting of a pandemic. However, as additional vaccines become available for use analysis of cost-effectiveness and economic impact may be necessary.

Equity: The following feedback was provided from the ACIP committee members on the equity domain:

- Local considerations about implementation will have a large impact on equity and the populations that are reached with vaccine.
    - Equity and implementation are intertwined. Local and state health authorities require adequate resources to get COVID-19 vaccines to the most affected communities and ensure equitable access.
    - Local decisions about selection of initial administration venues and potential recipients will be critical for maximizing equity.
    - Although some vaccines pose challenging handling and administration requirements, it may be necessary to potentially set aside what is easiest to help ensure equitable access.
- Importance of focused outreach and education
    - Providers are a trusted source of information.
    - Information needs to be tailored to specific groups. Low perceived acceptance should not result in reduced allocation to areas and populations, but rather in increased efforts and resources for focused outreach and education to improve vaccine acceptance.
    - Willingness to receive vaccine is modifiable, especially in the setting of a pandemic. Early experience with vaccine will be very important to increase interest and demand. Transparency is essential to improve trust and acceptability.

Dr. Sara Oliver (CDC ACIP WG Co-Lead) then presented the "EtR Framework: Values, Acceptability and Feasibility Domains." Similar to the previous presentation, Dr. Oliver walked through the available data supporting each of these domains and provided the Work Group's judgments.

EtR Domain	Question	Work Group Judgments
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Probably yes; Varies

	Is there important variability in how patients value the outcomes?	Important/probably important uncertainty or variability
Acceptability	Is COVID-19 vaccine 'X' acceptable to key stakeholders?	Probably yes; Varies
Feasibility	Is COVID-19 vaccine 'X' feasible to implement?	Probably yes

Summary of Discussion

Values: The following feedback was provided from the ACIP committee members on the values domain:

- Declines in vaccine intent are relatively recent, and therefore likely modifiable.
    - Concerns were predominantly about safety and vaccine characteristics.
    - As more data become available about these factors, it may be possible to modify intent.
    - Agreement with strategies to overcome barriers, and that barriers are modifiable.
- Patients need to know what to expect (e.g. reactogenicity reflects immune response to the vaccine) which can improve the likelihood of completing a 2-dose series.
- People who seek vaccine (and value getting vaccine early) will be important for messaging and increasing vaccine uptake by subsequent groups of recipients.

Acceptability: The following feedback was provided from the ACIP committee members on the acceptability domain:

- As we think about equity, we may need to reconsider expanding the definition of "stakeholders" to include businesses/employers other than healthcare.

Feasibility: The following feedback was provided from the ACIP committee members on the feasibility domain:

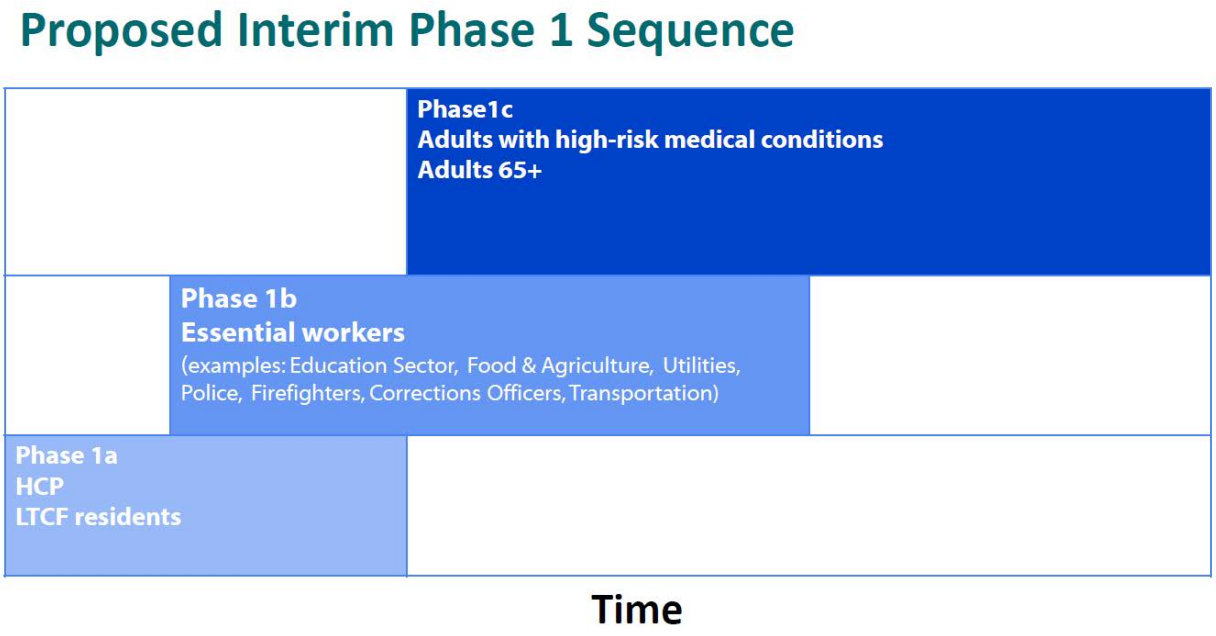
- Although COVID-19 vaccine will be provided at no cost, personal investments in time and travel (e.g., time off from work to be vaccinated or vaccine-associated side effects) may be a barrier for some (particularly for hourly workers who are not paid if they do not work).
- Work is underway to address potential administrative costs associated with vaccine receipt which can be a deterrent; e.g., for uninsured patients, Prep ACT funding will allow for providers to be reimbursed for administrative costs.
- While the focus should be on targeting people susceptible to COVID-19, screening of individuals for prior infection (i.e., presence of antibodies) should not be done. Delaying vaccination for people with documented prior infection could be considered, although information on the duration of protection following natural infection is limited.
- The committee emphasized that adequate funding must be available to deliver a vaccination program that is feasible to implement, values equity, and addresses issues of accessibility and acceptability; otherwise, investments in vaccine research and development may not be realized.
- Communication between healthcare providers/healthcare systems and local public health authorities is essential throughout the vaccination program.

- The need for provider and patient educational materials/guidance was stressed. CDC noted that a health care provider tool kit and other materials will be available in the near future.

PHASED ALLOCATION OF COVID-19 VACCINES

Dr. Kathleen Dooling (CDC ACIP WG Co-Lead) then presented the 'Phased Allocation of COVID-19 Vaccines.' The objective of this session was to help ACIP select the groups for COVID-19 vaccine allocation in Phase 1a, Phase 1b, and Phase 1c.

A summary of the Work Group's considerations and the data considered for each population were presented. The proposed interim phase 1 sequence that was presented for discussion was as follows.



Summary of Discussion

Phase 1a

Long term care facility residents

- Because LTCR residents were not enrolled in COVID-19 vaccine trials, safety and efficacy data are not available to assess the benefits and harms of COVID-19 vaccines in this group.
- Influenza vaccine effectiveness (VE) is known to be reduced in older compared with younger adults and could be reduced for COVID-19 vaccines as well. Even reduced VE, however, could result in benefits to some individuals; reduce COVID-19-related hospitalizations in this group; and ease the burden on strained healthcare systems.
- Reactogenicity following receipt of COVID-19 vaccine could lead to medical evaluation and treatment in this group and the potential for unnecessary harm.
- Baseline mortality among LTCF residents is high; deaths temporally associated with receipt of COVID-19 vaccine during the early phases of vaccine distribution will be difficult to evaluate and could reduce overall public confidence in the safety of COVID-19 vaccines. Similar issues may arise following vaccination of people with high-risk medical conditions in phase 1c.

- Vaccinating both LTCF residents and staff on-site would offer efficiency in operations; likely result in increased vaccine coverage; and decrease intra-facility transmission between staff and residents.
- If consideration is given to delaying vaccination for previously infected individuals, some LTCF residents and staff have been previously infected with SARS-CoV-2.
- It was stated that 30% of LTCF residents turn over every 30 days. However, a subsequent written communication to the committee noted that "…many nursing homes have both short-stay residents that are there for post-acute care rehab, and longer-stay residents that reside there. Both populations would not be difficult to track in terms of 2nd COVID-19 vaccine dose. …hospitals in some states are still using nursing home post-acute care for COVID-19 convalescent care."
- Many LTCF staff (as well as other health care personnel [HCP]) live in higher-risk communities; vaccinating them can help to protect the health of others in their community.
- Some committee members indicated that provision of information to LTCF staff as well as residents and their family members about COVID-19 vaccines, including available safety data and the lack of vaccine trial data for LTCF residents, would help to address their concerns if it was accompanied by consent for vaccination.

Health care personnel

- Given the limited amount of vaccine that will be available in the first few weeks, all HCP cannot be vaccinated initially. Subsets of HCP will need to be targeted, possible examples noted by committee members included frontline HCP; HCP who cannot work remotely or who have inadequate PPE; older HCPs and those with high-risk medical conditions.
- The need for clear guidance on prioritization of subsets of HCP was emphasized. The initial shipments of vaccine will likely go to tertiary care facilities due to the requirement for storage at ultra-cold temperatures. The risk for acquiring SARS-CoV-2 is higher, however, for HCP working in the community at LTCFs.
- Among state health officials there is strong support for vaccinating HCP due to increased opportunities for exposure and the important role they play in the response.

Phase 1b

- Strong agreement with essential workers (non-healthcare) in Phase 1b
    - Racial and ethnic minority groups are disproportionally represented in many essential industries and live in communities that are disproportionally affected; offers an opportunity to really impact equity.
    - By nature of their jobs, many essential workers are at increased risk and should be given the opportunity to be vaccinated early on.

Gating criteria

- This will be a dynamic process. As demand is saturated in one group, need to be ready to move onto the next group before 100% coverage is attained to ensure that vaccine is used as effectively as possible. Guidance on gating criteria needed.

SUMMARY

- Of the 14 ACIP voting members, 12 expressed that they support phase 1a, 1b, and 1c as presented.
    - Overall, there was general agreement among the ACIP members with the proposed interim phase 1 sequence, with 2 members expressing a desire for better data to inform recommendations about including LTCF residents in phase 1a
- All 14 ACIP voting members indicated agreement with essential workers as phase 1b.
- Multiple stakeholders also agreed with the proposed interim phase 1 allocation sequence.

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José R. Romero, MD, FAAP, FIDSA, FPIDS, FAAAS
Chair, Advisory Committee on Immunization Practices

Certification

I hereby certify that, to the best of my knowledge, the summary of the November 23, 2020 ACIP Meeting is accurate.

11/25/2020
Date

José R. Romero, M.D., Chair
Advisory Committee on Immunization Practices (ACIP)