

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases




Next Steps for the COVID-19 Vaccine Program

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ACIP Meeting

February 28, 2024

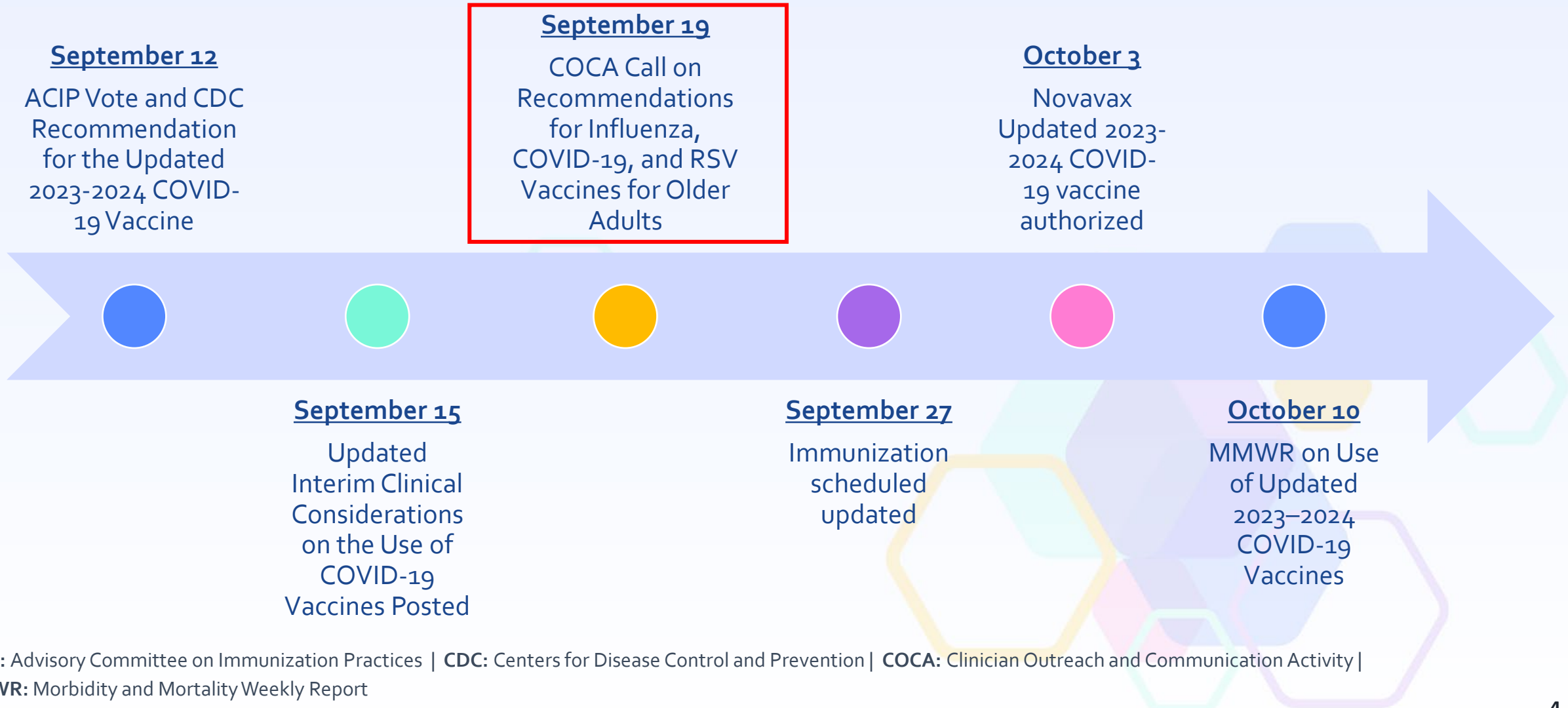
**Can we improve the current COVID-19
vaccine policy timeline?**



COVID-19 Vaccine Policy Decision – Fall 2023

- mRNA updated (2023–2024 Formula) vaccines were authorized or approved on September 11, 2023
- ACIP met September 12, 2023 to review the available evidence for updated COVID-19 vaccines (monovalent, XBB.1.5 component)
- ACIP recommended updated COVID-19 vaccines as authorized under EUA or approved by BLA in persons aged ≥ 6 months:
 - Moderna COVID-19 vaccine in persons ≥ 6 months
 - Pfizer-BioNTech COVID-19 vaccine in persons ≥ 6 months
 - Novavax COVID-19 vaccine in persons ≥ 12 years*

Timeline: Fall 2023 COVID-19 Vaccine Recommendation

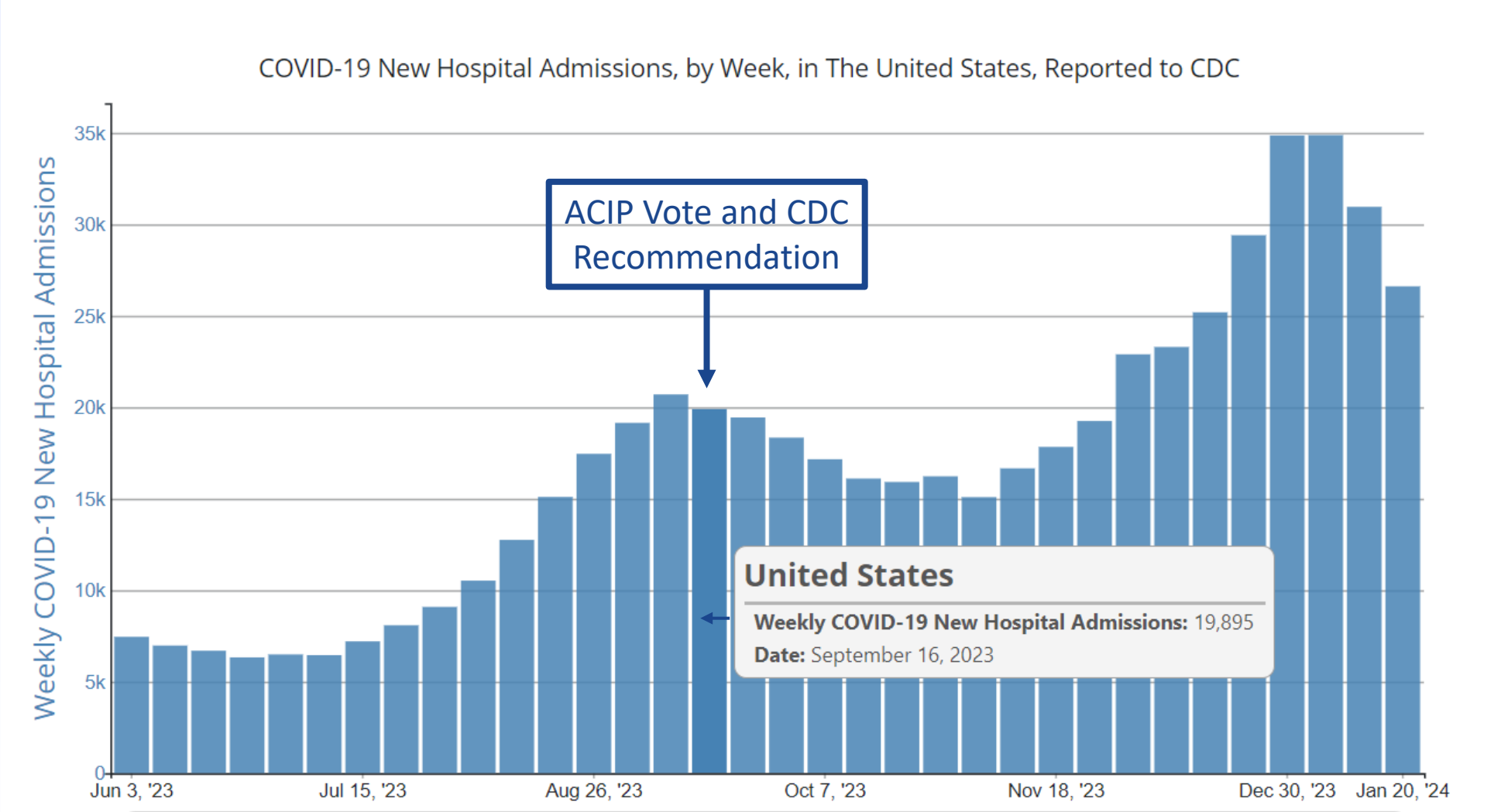


ACIP: Advisory Committee on Immunization Practices | **CDC:** Centers for Disease Control and Prevention | **COCA:** Clinician Outreach and Communication Activity |

MMWR: Morbidity and Mortality Weekly Report

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html> | <https://www.cdc.gov/mmwr/volumes/72/wr/mm7242e1.htm>

COVID-19 related hospitalizations had already begun to increase before the ACIP vote on use of the updated (2023-2024) COVID-19 vaccine



Weekly COVID-19 new hospital admissions – National Healthcare Safety Network (NHSN), United States, June 2023 – January 2024
https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_oo

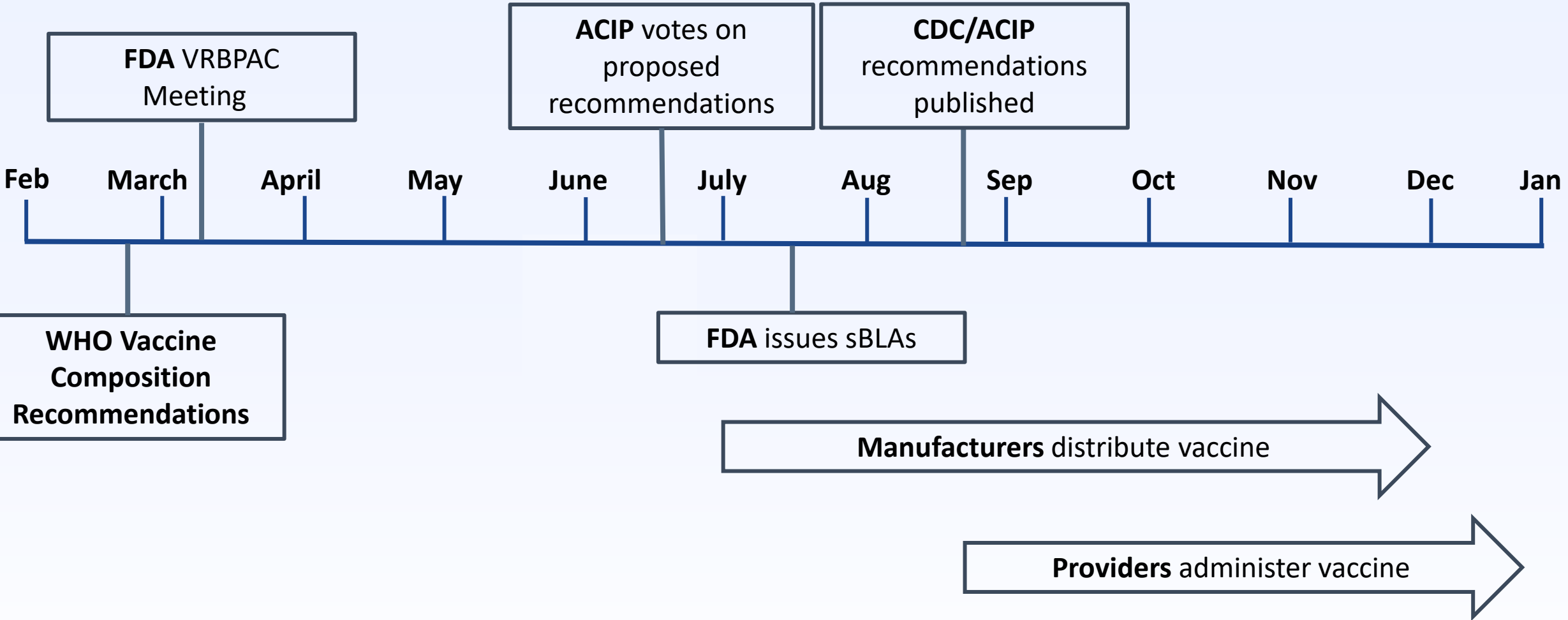
What happened after the Fall updated (2023-2024) COVID-19 vaccine policy vote?

- Uncertainty around recommendations made planning for state and local vaccine programs challenging
- Vaccine orders had to be placed prior to knowing groups for whom vaccine would be recommended
- Stakeholder presentations, provider toolkits, and webpages all had to be updated after recommendation was made, limiting available window for communication of recommendation prior to the respiratory virus season
- There were reports of issues with vaccine access, including among those at highest risk of severe illness

Potential impacts of continuing with a Fall vote for the 2024-2025 COVID-19 vaccine

- Less lead time for planning (e.g., staffing, scheduling, EHR prompts)
- A new recommendation may occur during a surge in COVID-19 associated hospitalizations and may not provide enough time for distribution, partner engagement, preparation of healthcare providers and facilities, and uptake to mitigate the rise in disease
- May limit ability to coordinate messaging surrounding the fall/winter respiratory virus season and promote importance of COVID-19 vaccination in communications
- Likely limit ability to plan vaccination clinics with COVID-19, flu, and/or RSV vaccine in settings such as long-term care facilities, communities, workplaces, and schools

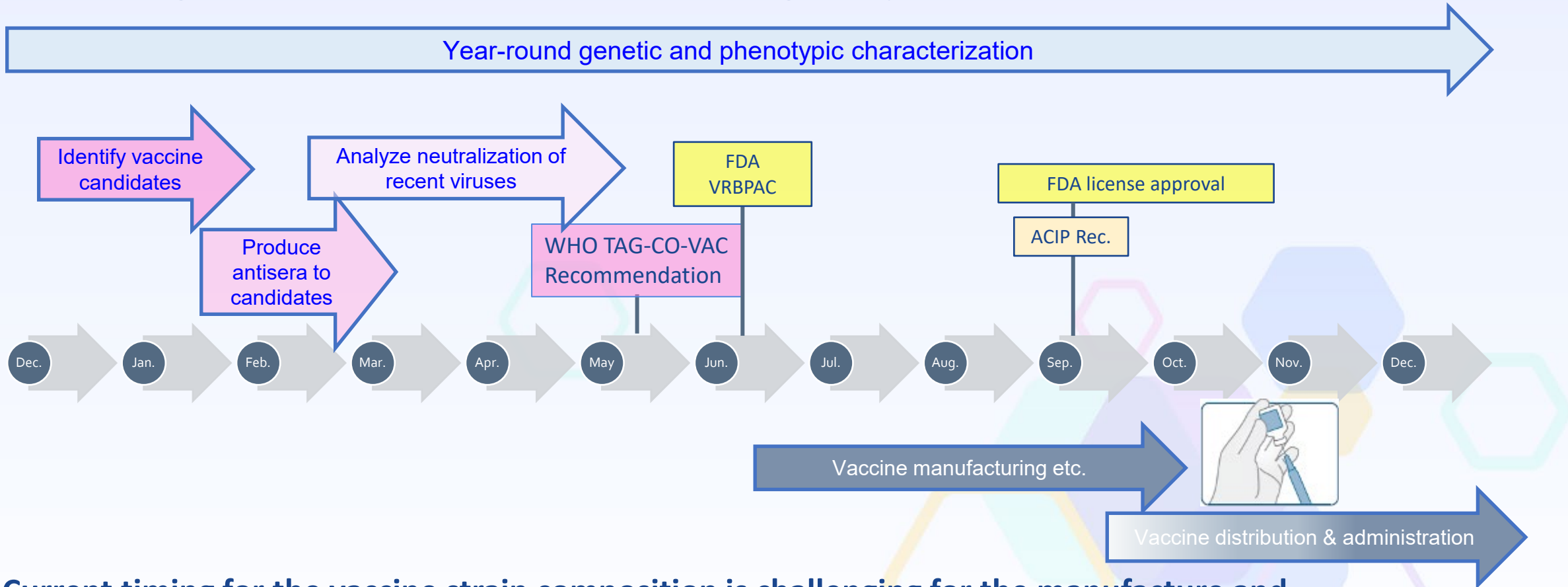
Annual seasonal influenza vaccine timeline



WHO: World Health Organization | FDA: Food and Drug Administration | VRBPAC: Vaccines and Related Biologic Products Advisory Committee | ACIP: Advisory Committee on Immunization Practices | CDC: Centers for Disease Control and Prevention | sBLAs: Supplemental Biologics License Applications

Current Time Frame for Updated COVID-19 Vaccine Availability

- Timing of TAG-CO-VAC recommendations and regulatory review for 2022 and 2023 shown

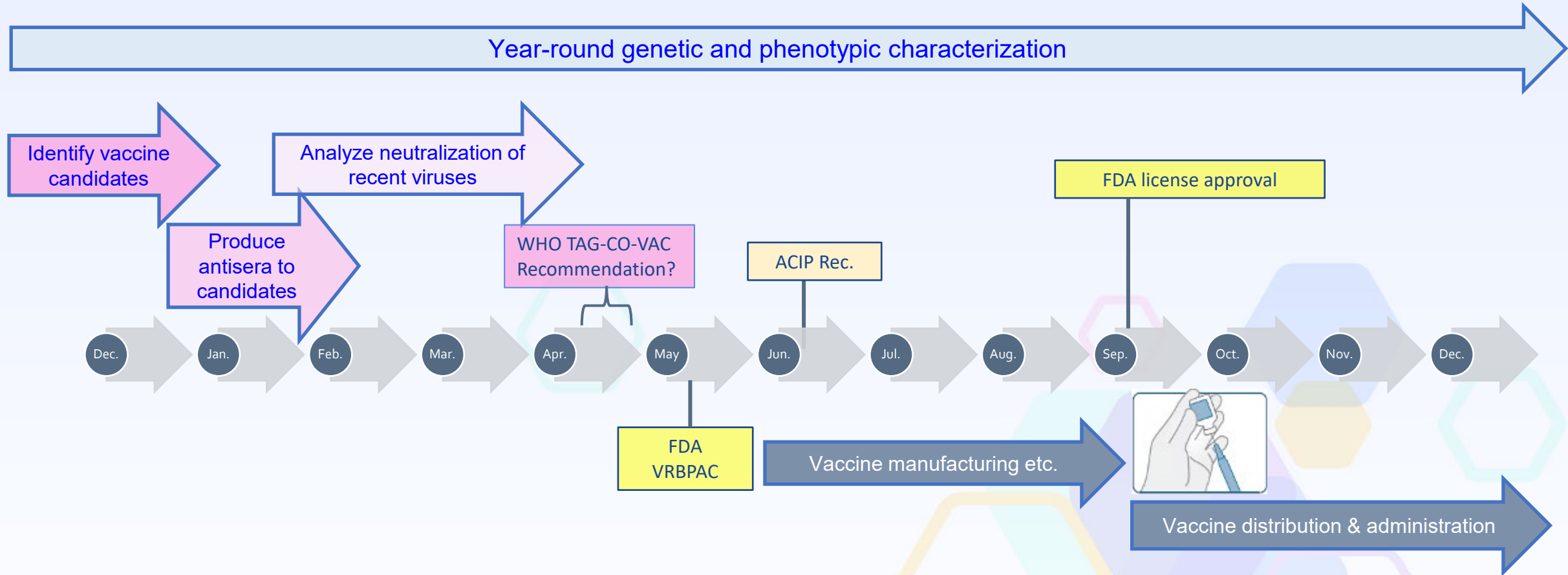


Current timing for the vaccine strain composition is challenging for the manufacture and distribution of vaccine early in the Fall

Slide for discussion purposes. Information is approximated and exact timelines for manufacturing are inferred.

WHO: World Health Organization | TAG-CO-VAC: Technical Advisory Group on Covid-19 Vaccine Composition | FDA: Food and Drug Administration | VRBPAC: Vaccines and Related Biologic Products Advisory Committee | ACIP: Advisory Committee on Immunization Practices

Revised Time Frame for 2024-2025 COVID-19 Vaccine Availability



Proposed changes: WHO-TAG-CO-VAC mid-late April (exact date to be determined), FDA VRBPAC in May, ACIP in June

Slide for discussion purposes. Information is approximated and exact timelines for manufacturing are inferred.


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[Vaccines and Related Biological Products Advisory Committee May 16, 2024 Meeting Announcement - 05/16/2024 | FDA](#)

Proposed COVID-19 Vaccine Policy plan - 2024

- ACIP meeting in June to review evidence for 2024-2025 COVID-19 vaccine recommendations, including:
 - WHO and FDA antigen selections
 - Manufacturer studies and immunogenicity data
 - Cumulative effectiveness and safety data
 - Epidemiology from current and prior years
 - Uptake from current and prior years
 - Cost effectiveness
- ACIP vote on 2024-2025 COVID-19 vaccine recommendations in June
- 2024-2025 Formula will become available as regulatory actions are taken by FDA and vaccines are distributed by manufacturers

Pros and Cons of a June COVID-19 vaccine policy decision



Pros of a June COVID-19 vaccine policy decision

- Enables early planning across entirety of healthcare delivery system
 - National, state and local public health departments
 - Large and small practices, other venues for vaccine delivery (e.g., pharmacies)
- Allows time for clear communication of recommendations
- Provides vaccine sites with earlier information on which to base ordering decisions
- Vaccines potentially available immediately following FDA authorization or approval
- Alignment with influenza vaccine recommendations
- Decrease number of emergency ACIP meetings

Potential cons of a June COVID-19 policy decision

- Epidemiology and strain changes
 - Minor changes: unlikely to impact recommendation
 - Major changes: may require subsequent emergency action
- Updated vaccine antigen changes do not require new human data
 - Manufacturers provide pre-clinical immunogenicity for VRBPAC antigen selection
 - Additional clinical trial data beyond that presented at VRBPAC may not be available before ACIP votes (both for June and September)
 - Reliance on large body of cumulative effectiveness and safety data
- Consistent temporal patterns of COVID-19 not yet established
 - While this is true, we have four years worth of epidemiologic data to predict a peak in the winter 2024-2025

Takeaways

- We have more than four years worth of data on COVID-19 and three years worth of data on COVID-19 vaccines
- We have a well-established precedent from influenza vaccine recommendations
 - Virus evolves rapidly and updates to vaccine antigens are needed
- It is unlikely there will be more data between June and September to influence updated COVID-19 vaccine policy decision
- Increased lead time will ease implementation challenges for vaccine providers
- Increased lead time can also allow for clearer messaging in provider and patient educational materials



Work Group Interpretation

- Important to separate **policy question/decision** from **timing of decision**
- Work group members were in favor of moving decision to June, and discussed many ways that this could **ease implementation challenges**, including **clearer communication** of vaccine policy and **increase lead time** for clinicians
- Work group members emphasized that **communication** surrounding a recommendation prior to updated vaccine availability, as done routinely for influenza vaccine, will be important

Acknowledgements

- Megan Wallace
- Mary Chamberland
- Kevin Chatham-Stephens
- Matthew Daley
- Katherine Fleming-Dutra
- Monica Godfrey
- Susan Goldstein
- Lisa Grohskopf
- Aron Hall
- Elisha Hall
- Sarah Meyer
- Danielle Moulia
- Evelyn Twentyman
- David Wentworth
- JoEllen Wolicki
- ACIP COVID-19 Work Group
- Immunization Services Division
- Immunization Safety Office
- Coronavirus and Other Respiratory Viruses Division
- National Center for Immunization and Respiratory Diseases

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