COVID-19 Vaccine
Disclaimers

Background and assumptions are from the CDC document:

“COVID-19 Vaccination Program Program Interim Playbook for Jurisdiction Operations,” September 16, 2020

This document is for planning purposes and subject to change.
Background

- There are many vaccine candidates currently in the pipeline.
- Cold chain storage and handling requirements will vary by product.
- Some vaccines may require reconstitution or an adjuvant.
- Multiple vaccines from different manufacturers are likely to be available and in use at the same time.
The Vaccine Life Cycle

safety at every phase

GUIDE
ACIP
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
BLA
BIOLOGICS LICENSE APPLICATION
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
FDA
FOOD AND DRUG ADMINISTRATION
IND
INVESTIGATIONAL NEW DRUG APPLICATION

VACCINE
DEVELOPMENT

safety is a priority during vaccine development + approval

PHASE 1
safety

PHASE 2
effectiveness

PHASE 3
safety + effectiveness

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FDA REVIEW
ACIP REVIEW

PHASE 4
safety monitoring for serious, unexpected adverse events

FDA APPROVAL OF NEW VACCINE
ACIP RECOMMENDATION
POST-APPROVAL MONITORING + RESEARCH

LEARN MORE
FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd
CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe
Background

- Initial doses of COVID-19 vaccine may either be approved as licensed vaccines or authorized for use under an Emergency Use Authorization (EUA) issued by the FDA.
- Two doses of pandemic vaccine, separated by at least 21 or 28 days, may be needed for immunity.
- The second dose will likely need to match with the same kind received for the first dose.
Initial Vaccination – Priority Populations

- COVID-19 vaccine will first be available in limited quantities, with supply anticipated to increase substantially in 2021.

- Guidance will be forthcoming from the federal government regarding the groups to prioritize – the Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine (NASCEM).
Initial COVID-19 vaccination efforts will likely target those in the critical workforce who provide health care and maintain essential functions of society, and staff and residents in long-term care and assisted living facilities.

Recommendations on groups to target will likely change throughout the response, depending on vaccine supply and disease epidemiology.
Vaccine will be distributed through existing infrastructure used for publically funded routine vaccines (i.e., Vaccines for Children program).

Enrolled vaccination providers will order COVID-19 vaccine from their state immunization program’s allocation.
Assumptions – Allocation

COVID-19 vaccine will be allocated to jurisdictions based on multiple factors, including:

• Populations recommended by the Advisory Committee on Immunization Practices (ACIP), with input from the National Academy of Medicine.
• Current local spread/prevalence of COVID-19
• COVID-19 vaccine production and availability.
Vaccine Allocation

- When vaccine first becomes available, the number of individuals in a targeted group will greatly outnumber the doses available to Wisconsin at that time.

- The Division of Public Health (DPH) will need a clear, transparent method to determine how pandemic vaccine is allocated to jurisdictions/vaccinating entities when it is a scarce resource.
It may be necessary to sub-prioritize tiered groups.

For example, hospital-based “front-line” health care providers who are essential for maintaining emergency departments and ICUs may be vaccinated earlier than other health care providers.
Decisions

The Wisconsin State Disaster Medical Advisory Committee, comprised of individuals from across the state and representing different communities, has two workgroups that are addressing the ethics and logistical issues associated with the allocation of scarce resources, like COVID-19 vaccine.
General Population — Allocation

- Once priority groups have been vaccinated and vaccine is widely available:
  - Vaccine will be administered primarily in traditional health care settings, such as primary care clinics, pharmacies, and local public health clinics.
  - Outreach and different approaches will be needed for certain segments of the population where coverage is low.
Assumptions — Cost

COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled pandemic vaccination providers and their patients.
Assumptions — Technology

- The Wisconsin Immunization Registry (WIR) is a web-based, all ages repository of immunizations for Wisconsin residents, in use since 1999 and used broadly by immunizers across the state.

- The WIR will be a key component in vaccine ordering, allocation, recording of administered doses, and real-time analyses of these efforts.
Vaccine Safety

- Safety is of utmost importance and there are several ways it will be monitored:
  - Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
  - Adverse events will also be monitored through electronic health record (EHR)- and claims-based systems (e.g., Vaccine Safety Datalink).
Vaccine Safety (cont.)

Additional vaccine safety monitoring may be required under the EUA.
Influenza Vaccine
Why is seasonal influenza vaccination important every year?

- Keeps you from getting sick with flu
- Reduces the risk of flu-associated hospitalization
- Protects people with chronic health conditions
- Keeps the community healthy
Why is influenza vaccination extra important this year?

SARS-CoV-2 and influenza will be circulating at the same time

Avoid people getting COVID-19 and flu at the same time

More healthy people and a less overwhelmed health care system

Similar symptoms

Flu vaccination

Avoid possible misdiagnosis and number of COVID-19 tests
Cumulative percentage of Wisconsin residents who received 1 or more doses of influenza vaccine, 2019-2020 influenza season

Healthy People 2020 Goal: 70%

2018-2019 Total Vaccinated: 40%

2019-2020 as of 03/19/2020: 42%

As of 02/01/2020, the cumulative percent of Wisconsin residents vaccinated has surpassed the total from the 2018-2019 season.

Data source: All influenza vaccination rates presented were calculated using data from the Wisconsin Immunization Registry (numerator) and Wisconsin population estimates (denominator).
SEASONAL INFLUENZA VACCINATION

Percentage of Wisconsin residents who received one or more doses of influenza vaccine, by age group and influenza season

Each season includes doses administered during the same time period (August 1 through May 3).
Vaccine Strain Composition

- Three strains have been changed since last year.
  - A(H1N1) component
  - A(H3N2) component
  - B Victoria component
- B Yamagata lineage is the same as last year.
- All but one vaccine (Fluad, aIIV3) are quadrivalent.
Influenza Vaccine Recommendations

Recommended for everyone over the age of 6 months
Pharmacy Partnership
Pharmacy Partnership

- CVS and Walgreens will be offering on-site COVID-19 vaccination for nursing home and assisted living facility residents.
- Staff may also be vaccinated as part of the program though are likely to be part of an earlier priority group.
- There is no cost to participate. The deadline to sign-up is November 6.
Pharmacies Bring These Components to Our Partnership

- Procurement of vaccine and associated supplies (e.g., syringes, needles, PPE)
- Vaccine cold chain management
- Scheduling and coordination of on-site vaccination
- Safe vaccination of patient population while reducing burden on facilities and local health departments
- Fulfillment of reporting requirements
Other Options for Vaccination

- A facility may partner with a different vaccination provider (e.g., other pharmacy).

- The facility/partner vaccination provider is responsible for:
  - Completing provider registration.
  - Ensuring appropriate vaccine storage and handling.
  - Maintaining vaccine cold chain.
  - Vaccine administration.
  - Meeting reporting requirements including entry into WIR within 24 hours.
How do I sign up?

- Skilled nursing facilities should make their selection through the National Healthcare Safety Network.

- Assisted living facilities should make their selection via an online REDCap sign-up form.
  - [https://redcap.link/LTCF](https://redcap.link/LTCF)
What if I miss the deadline?

- Send an email to eocevent494@cdc.gov
Questions?