

Executive Summary - October 26, 2020

The Wisconsin Department of Health Services (DHS) is working to establish the state's COVID-19 Vaccination Program as a critical component to Wisconsin's efforts to reduce disease and death related to the novel coronavirus. DHS staff are applying lessons learned during the H1N1 vaccination campaign, best practices from other immunization efforts, research into developing protocols, and insights from stakeholder groups to devise its approach and build critical systems.

Wisconsin's COVID-19 Vaccination Plan will be implemented in partnership with the state's 97 local health departments and tribal jurisdictions, collaborating with health care providers, pharmacies, community-based organizations, and other public agencies.

VACCINE AVAILABILITY

Many COVID-19 vaccines are in development. The U.S. Food and Drug Administration (FDA) will authorize or approve vaccines for use based upon the proven efficacy of vaccines coming out of Phase 3 FDA trials. The intent is to deliver safe and effective vaccines as a preventive measure to stop the spread of the virus and preserve greater health for the population.

Multiple vaccines from different manufacturers may be available and in use at the same time. Immunity is likely to require two doses of pandemic vaccine delivered either 21 days or 28 days apart, and the same vaccine must be administered for both doses (i.e., they must match each other).

Pending FDA authorization or licensing, limited COVID-19 vaccine doses may be available in late 2020 with supply expected to increase substantially through 2021. Allocation of the COVID-19 vaccine to Wisconsin will hinge on vaccine production and availability as well as current disease prevalence and/or local spread.

VACCINE ADMINISTRATION

States will administer the vaccine in three phases to account for limited availability at the outset. Phase 1 considers potentially limited doses being available; Phase 2 considers a large number of doses being available with supply likely to meet demand; and, Phase 3 considers a likely sufficient supply with slowing demand.

Priority Populations

Decisions about population priority rely on input from the National Academies of Sciences, Engineering, and Medicine through the Advisory Committee on Immunization Practices (ACIP) as well as from Wisconsin's State Disaster Medical Advisory Committee (SDMAC).

Phase 1 populations in Wisconsin are likely to include:

- Healthcare personnel exposed to or treating people with COVID-19
- People living in long-term care or assisted living facilities and people 65 years of age and older
- Other essential workers, based upon definitions recommended by ACIP and SDMAC

Phase 2 will include all people in Phase 1 and expand to other critical populations to be determined and eventually the general public when vaccine supply is sufficient.

VACCINE DELIVERY

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

Wisconsin plans to participate in the federal pharmacy partner program, which pairs long-term care and assisted living facilities with a vaccinating pharmacy, which will provide on-site vaccination to the residents. Local and tribal health departments and health care entities will also play significant roles in vaccinating critical populations. Wisconsin is exploring its ability to contract for mass vaccination capacity to supplement local resources and expand access to critical vaccination services.

As the COVID-19 vaccine becomes more broadly available, the range of vaccinators will broaden as well to include commercial pharmacies, health care systems, and individual providers. All vaccinators must enroll through the Wisconsin Immunization Registry (WIR), participate in trainings, actively manage inventories, and promote vaccine availability and access to the public.

Vaccinators will be responsible for reminding patients about their critical second dose.

VACCINE SAFETY

The development of a COVID-19 vaccine has been subject to rigorous standards set forth by the FDA. Should the FDA determine a vaccine to be safe and effective, it then goes before the American Committee on Immunization Practice (a federal advisory committee made up of medical and public health experts) for consideration and public review before delivering an ultimate recommendation to the CDC Director.

After the vaccine is approved for use, safety monitoring systems watch for side effects. Wisconsin is part of the Vaccine Adverse Event Reporting System (VAERS) that collects reports from healthcare professionals, vaccine manufacturers, and the public to monitor all adverse events and provide timely reports of any unusual patterns. Adverse events will also be monitored nationally through electronic health records and claims-based systems.

VACCINE SUPPLY AND STORAGE

Enrolled vaccination providers will order the COVID-19 vaccine from their state immunization program's allocation. The COVID-19 vaccine will ship from the CDC's distributor directly to the provider through existing infrastructure for publically funded routine vaccines.

The minimum order size for the COVID-19 vaccine will likely be 100 doses or possibly more (vaccine dependent) and will include ancillary supplies required to administer the vaccine such as needles, syringes, alcohol prep pads, vaccination record cards and limited PPE.

The COVID-19 vaccines in the FDA approval pipeline have three different cold chain parameters, including refrigerated (2-8°C), frozen (-20°C), and ultra-cold (-80°C). NOTE: Providers are not advised to purchase ultra-cold storage equipment at this time, as ultra-cold vaccine may be shipped from the manufacturer in coolers that are packaged with dry ice, can store vaccine for an extended period, and can be repackaged for longer use.

CONCLUSION

Vaccinations reduce risks of getting disease. The COVID-19 vaccine will be important for helping people of all ages in Wisconsin live healthier lives and helping our state find its way back to economic stability and overall vitality.

