



ASSOCIATION OF UNIVERSITY CENTERS ON DISABILITIES
THE LEADERSHIP, EDUCATION, ADVOCACY & RESEARCH NETWORK

Frequently Asked Questions (FAQ): COVID-19 Vaccine Distribution Considerations for the Disability Community

Pre-Distribution Considerations

I. What is the federal approval process for a COVID-19 vaccine?

The federal approval process for a COVID-19 vaccine is the same as the federal approval process for any vaccine product. The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) is responsible for approving and regulating vaccines. The FDA is a part of the U.S. Department of Health and Human Services (HHS), which is a federal agency led by Presidential appointees.

All COVID-19 vaccines developed in the United States will go through the same steps of development, testing, and safety checks as any other vaccine. These steps include three phases of clinical trials of increasing size, and safety and efficacy standards. When Phase 3 of a clinical trial is complete, the vaccine developer can then apply to the FDA for approval and use.

In certain types of emergencies, the FDA can issue an Emergency Use Authorization (EUA) to provide more timely access to critical medical products, such as vaccines, medications, and supplies, that may help during the emergency.

The Centers for Disease Control and Prevention (CDC) does not have a role in developing COVID-19 vaccines but will support local and state health departments and partners in planning dissemination efforts and monitoring for vaccine safety and effectiveness.

Resources:

- [FDA: COVID-19 Frequently Asked Questions](#)
- [FDA: Vaccine Product Approval Process](#)
- [FDA: Emergency Use Authorization](#)
- [CDC: How is CDC Making COVID-19 Vaccine Recommendations](#)

II. What is Operation Warp Speed and how does it impact the federal approval process for a COVID-19 vaccine?

Operation Warp Speed (OWS) is a partnership among the Department of Health and Human Services (HHS) and the U.S. Department of Defense (DoD) to help develop, make, and distribute 300 million doses of COVID-19 vaccines in the United States by mid-2021. The role of OWS is to invest in and coordinate vaccine development between the public and private partners in order to accelerate the development and distribution of a safe and effective vaccine.

Resources:

- [HHS Fact Sheet: Explaining Operation Warp Speed](#)
- [Developing Safe and Effective Covid Vaccines – Operation Warp Speed’s Strategy and Approach](#)

III. What current vaccine developments are under way?

Over 100 vaccine candidates are currently in development. OWS has invested in 14 of the candidates deemed most likely to succeed. Currently, four COVID-19 vaccine candidates are in Phase 3 clinical trials in the United States*:

1. [Pfizer/BioNTech](#): BNT162b2 (2 dose)
 - Pfizer/BioNTech [submitted a request](#) to the FDA for an Emergency Use Authorization on November 18, 2020.
2. [AstraZeneca/Oxford University](#): AZD 12222 (2 dose)
3. [Moderna/NIH](#): mRNA-1273 (2 dose)
4. [Janssen Pharmaceutical Companies of Johnson & Johnson](#): AD.26.COVS.1 (1 dose)

Several other companies also currently have vaccine candidates in clinical trials. The [Novavax](#) vaccine candidate (NVX-CoV2373, 2 doses) is expected to enter Phase 3 of clinical trials soon.

**Note: last updated November 20, 2020. Check the [HHS website](#) for updates.*

IV. I know a COVID-19 vaccine has not yet been approved for use, but has manufacturing started?

Yes, through OWS, the federal government has announced the start of several manufacturing partnerships. The goal is to have millions of vaccine doses available so that distribution can begin within 48 hours of a vaccine candidate earning FDA approval. Currently, the federal government is financially supporting the large-scale manufacturing of vaccine candidates from Pfizer/BioNTech, Novavax, Sanofi and GlaxoSmithKline, Janssen Pharmaceutical, Moderna, and AstraZeneca. The government’s manufacturing contracts secure over 300 million doses of potential COVID-19 vaccines. It is important to note, however, that most of the vaccine candidates require two doses for effectiveness. Additionally, at least two of the vaccines must be stored at an unusually cold temperature, which will require storage and transport procedures that may delay the timeline for getting a vaccine from manufacturer to patients.

Resources:

- [HHS Fact sheet: Explaining Operation Warp Speed](#)
- [Temperature concerns could slow the rollout of new coronavirus vaccines](#)

Distribution Guidance

V. Has AUCD provided any guidance for COVID-19 vaccine distribution to federal and/or state governments?

Yes, AUCD has provided [comments](#) to the National Academies of Sciences, Engineering, and Medicine's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus. AUCD has also signed the [COVID-19 Vaccine Allocation Principles](#) along with other member organizations of the Consortium for Citizens with Disabilities.

VI. Have other organizations in the disability community provided any guidance for COVID-19 vaccine distribution to federal and/or state governments?

Yes, several other organizations in the disability community have filed comments to the National Academies, including, but not limited to:

1. [Consortium for Citizens with Disabilities](#)
2. [Disability Rights Education and Defense Fund](#)
3. [National Council on Disability](#)
4. [American Association of People with Disabilities](#)

VII. What guidance has the federal government provided for COVID-19 vaccine distribution?

Following the public comment period, the National Academies published the '[Framework for Equitable Allocation of COVID-19 Vaccine](#)'. This consensus study was commissioned by the CDC and the National Institutes of Health (NIH) to guide the U.S. Department of Health and Human Services and state, tribal, local, and territorial authorities on equitable COVID-19 vaccine allocation planning. The Framework recommends a four-phased allocation plan to provide a COVID-19 vaccine and the necessary ancillary resources to ensure equitable allocation, distribution, and administration of a COVID-19 vaccine in the United States. It also provides guidance for launching a COVID-19 vaccine promotion, risk communication, and engagement campaign, and recommendations for supporting equitable allocation globally.

The final Framework explicitly mentions individuals with disabilities in both Phase 1 and Phase 2 allocations. Phase 1 includes people of all ages with comorbid and underlying conditions that put them at significantly higher risk of COVID-19, as well as all older adults in congregate care settings. Phase 2 includes people with disabilities in group homes and staff who work in a congregate care or group home setting.

Resources:

- The full report: '[Framework for Equitable Allocation of COVID-19 Vaccine](#)'.
 - [Report at a glance](#).

- [Recommendations within the report.](#)
- [CDC: COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#)

VIII. What guidance has my state provided for COVID-19 vaccine distribution?

All states and territories had to submit draft plans to the CDC for how they would distribute the vaccine by October 16, 2020. CDC will review the plans and provide technical assistance. The CDC also published the [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#) describing what the plans should cover. The key parts of the plans include: public health preparedness planning, phased approaches to vaccination, identification of critical populations, provider recruitment and enrollment, capacity to administer, program monitoring, and vaccine storage and handling.

IX. Where do I find my state's plan?

[The Council of State Governments has created a webpage with each state and territory's current draft vaccination plan.](#) Additionally, the CDC has the [Executive Summaries of every state and territory's plan](#) on their website. Some large municipalities are developing their own plans. For those, you should search for the city directly. In most cases, the state Department of Health is the primary author of the plan. There may also be a special COVID Task Force that is working on the plan. Each plan says who developed and submitted it. Thus far only the first drafts of the plans have been sent to CDC. The plans are likely to continue to be developed and changed even as distribution occurs.

X. My state has county and local health departments. Do they have separate plans?

In some states, public health authority is not only at the state level, but also at the county or local level. To find plans at the county or local level, reach out to your county or local public health officials. They may be developing their own plans either separately or in conjunction with the state plan. Your COVID vaccination state plan may give you the outline of how public health is organized in your state and a place to start. Responsibilities within states may vary – is your state public health department in charge of the counties and locals? Or is each level in charge separately? We recommend you contact your state and/or local health departments to learn more details. Use the resources below to find contact information and websites for state, local, and tribal departments.

Resources:

- Links to the [Health Department Directories](#) for States and Territories, Cities and Counties, and Tribes.
- Learn more about the [Health Department Governance](#) in your state or territory from the CDC.

XI. How will the vaccine be distributed at the local level?

There will be differences in how the vaccine will be distributed to community members. For example, some national pharmacies have announced that vaccines will be given at their stores. In some places, doctors' offices or hospitals will provide them to patients and/or the public. Local public health departments are also likely going to distribute the vaccines by setting-up local dispensing sites, within a community building and/or via a drive thru site. When reviewing the local (city, town, county) vaccine distribution plan, look for the words "Emergency

Dispensing Site” (EDS), “Point of Distribution” (POD), or distribution of “medical countermeasures” (MCM) for opportunities to provide input on accessibility needs.

Resources:

- [States are Getting Ready to Distribute COVID-19 Vaccines. What Do Their Plans Tell Us So Far?](#)
- [HHS: From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine](#)

Considerations for state and local disability leaders

XII. How can the AUCD network and your AUCD network center be poised to provide guidance to both the disability community and to state and local governments?

The AUCD network is uniquely positioned to advocate to state and local governments for the rights and needs of the disability community for a COVID-19 vaccine due to our wealth of knowledge and expertise on the disability community. Potential points of feedback to state and local governments could include:

- How COVID-19 has impacted the physical and mental health, livelihood, housing, education, and social wellbeing of individuals with disabilities, their families, and Direct Support Professionals (DSPs);
- How and why to prioritize individuals with disabilities, their families, and DSPs in allocation plans;
- State- or local-specific considerations for reaching those impacted most in the disability community;
- Facilitation of conversation between state and local public health officials and other stakeholders in the disability community; and
- Advocating for accessible formatting and options in any vaccine education and distribution plans (e.g. providing information in ASL or braille, plain language versions).

Additionally, AUCD network centers have established, trusted relationships with disability communities and partners in their states that can be utilized in COVID-19 vaccine distribution.

Potential points of guidance to the disability community could include:

- Relaying information from the state or local health department to the community in accessible language and formatting;
- Addressing vaccine hesitancy concerns through vaccine education initiatives;
- Providing information on when and how to receive a COVID-19 vaccine per state and local distribution guidance, as well as any follow-up information for vaccines requiring two doses;
- Connecting with state and local partners to reach a greater portion of the disability community;

- Liaising with related medical and healthcare professionals (e.g. primary care clinicians) on best practices in providing vaccine education and administration to individuals with disabilities, their families, and DSPs.

XIII. What should I be looking for in my review of the state COVID Vaccine plan?

1. Look to see who is *not* covered in your state plan for vaccines. You can advocate for those people, such as:
 - Are DSPs included in the sections on people who should receive early vaccinations?
 - Are unpaid caregivers of people with disabilities or seniors included?
 - Are non-prison non-elderly congregate care settings such as group homes, mental health facilities included?
 - Are young (under 65) people with disabilities in nursing homes included?
2. How does the definition of risk status due to identified health conditions impact people with disabilities? What health conditions are included? Are they expansive?
3. Does the plan consider environmental and social factors that impact what people with disabilities can do, where they can go, and whether and how they can participate in their communities?
4. Are considerations for distribution for people with disabilities specifically included (or are people included by age and limited disease type but not disability)?
5. How will information be made accessible? Are they including plain language? ASL? CART? Other languages?
6. How will distribution be made accessible? Are the sites accessible? Are there plans for people who may need to be accompanied to get their vaccine?
7. If you are in a rural state, how should distribution look different in order to be accessible? What might have to be put into place in terms of transportation or other access?
8. Is there any recognition/addressing of racial and ethnic disparities and/or mistrust of the medical system based on previous vaccines or care? How can we help address that?
9. Is there a recognition that disability civil rights (ADA) continue to apply? Any judgment based on “quality of life” should not apply.

XIV. After I have reviewed my state or local plan, how should I share my feedback and with whom?

We recommend contacting your [state or local public health departments](#) and [local Boards of Health](#) to find the correct person with whom to share your feedback. Your [state Developmental Disability Council](#) may also have recommendations for who within the state public health department to contact. When sharing your feedback, you may also be able to participate in the vaccine dissemination planning process by:

- Offering your disability expertise;

- Offering your expertise in COVID and the disability community specifically;
- Offering your evaluation/data tracking expertise;
- Offering your accessibility and plain language expertise;
- Offering to take a role in educating the disability community and systems about vaccine distribution and vaccine safety;
- Sharing AUCD materials (see below) on Flu Vaccines and offer similar materials on COVID vaccines;
- Asking if there is there a role that your LEND trainees might have in the process.

XV. Final thoughts to remember.

This is another instance where states are being forced to develop plans without the necessary information with which to do it. There is no common understanding of what is being asked, who is paying for it, what it will look like, what requirements must be met for the vaccine, or when they will be needed. There is no common understanding of what roles the federal, state or local entities will or should play. There is likely to be confusion and jurisdictional problems. They will be looking for partners to help. They will also be unclear about what they need, what they know or what they don't know.

AUCD Network Vaccine Tools and Resources

1. ***Synopsis of Vaccine Reluctance Work in the AUCD Network:*** A document that includes the myriad projects and products in the AUCD network to address vaccine reluctance in the disability community.
2. ***#FightFlu Social Media Mini-Toolkit:*** A social media messaging toolkit for use by AUCD network centers and individual leaders in the disability community with the purpose of sharing information and resources on the flu vaccine in an accessible format. This mini toolkit was created as a reflection of collaboration efforts with the CDC, other federal partners and disability organizations. While tailored to the flu, the messaging can be modified for a future COVID-19 vaccine.
3. ***Fight the Flu: It's Important to the Disability Community:*** A fact sheet in accessible language on why getting the flu shot is important to the disability community, with recommendations and resources from the CDC. While tailored to the flu, the messaging can be modified for a future COVID-19 vaccine. Developed by the Boggs Center on Developmental Disabilities at Rutgers University.
4. ***Getting a Flu Shot: A Social Story for People with Intellectual and Developmental Disabilities:*** A social story to help readers understand why it's important to get a flu shot and what to expect when getting the shot. DSPs, family members, and others can use this social story to prepare people with intellectual and developmental disabilities for getting the flu shot by printing or sharing with the person on a computer, tablet, or smart phone. While tailored to the flu, the messaging can be modified for a future

COVID-19 vaccine. Developed by the Boggs Center on Developmental Disabilities at Rutgers University.

5. **Plain Language: The Flu Shot:** A fact sheet on the flu shot in plain language to answer common questions and address flu vaccine hesitancy for individuals with intellectual and/or developmental disabilities. Developed with the intention of being easily modifiable for a future COVID-19 vaccine.

Last updated November 22, 2020

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