

COVID-19 Vaccine Planning Healthcare Call #7



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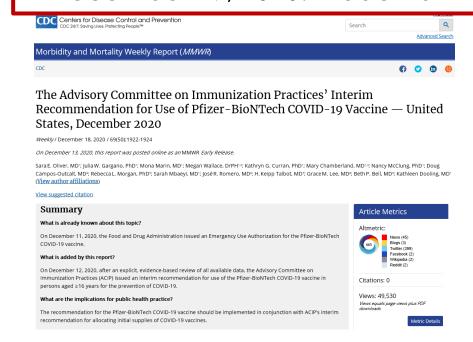
Agenda

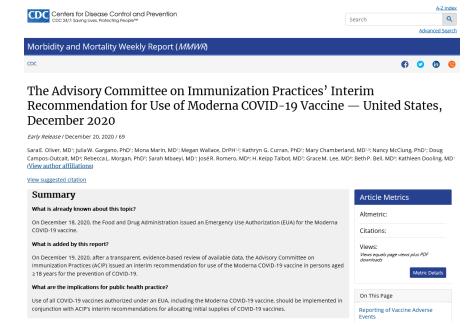
- Vaccine Recommendations
 - Pfizer-BioNTech
 - Moderna
- Clinical consideration FAQs
- Anaphylaxis
- Allocation/Prioritization
- Considerations for implementation
- Data and Reporting
 - I-CARE
 - Vaccine Finder



ACIP recommendations for use of COVID-19 vaccines

- Use of mRNA COVID-19 vaccines under FDA's Emergency Use Authorization
 - December 12, 2020: Pfizer-BioNTech
 - December 19, 2020: Moderna





https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1

COVID-19 Vaccination Reporting

Data Systems

Content source: National Center for Immunization and Respiratory Diseases



Advanced Search Vaccines & Immunizations CDC > COVID-19 Vaccination ♠ COVID-19 Vaccination U.S. COVID-19 Vaccine Product Information Product Info by US Vaccine Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, Pfizer-BioNTech Vaccine storage and handling, safety, and reporting. Moderna Vaccine Pfizer-BioNTech Moderna Clinical Considerations Provider Requirements and Support Requirements, Trainings, and Resources Training and Education Vaccine Storage and Handling Toolkit **Provider Requirements and Support Recipient Education** Training and Education Planning & Partnerships Vaccination Toolkits Page last reviewed: December 20, 2020

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

mRNA COVID-19 vaccines

- Two mRNA COVID-19 vaccines authorized under Emergency Use
 - Pfizer-BioNTech
 - Moderna
- Both products demonstrate vaccine efficacy >90%
 - · Efficacy demonstrated across age groups, racial and ethnic groups
- Vaccine safety profile of both products acceptable
 - Local and systemic reactogenicity, particularly after second dose



Dosing and administration

- Authorized age groups:
 - Pfizer-BioNTech: ≥ 16 years
 - Moderna: ≥ 18 years
- Administration: two-dose series administered intramuscularly
 - Pfizer-BioNTech: three weeks apart (21 days)
 - Moderna: four weeks apart (28 days)
- mRNA vaccines are not interchangeable with each other or other COVID-19 vaccines
 - Either vaccine series may be used; ACIP does not state a product preference
- mRNA vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines



Cosing and administration

- Persons should not be prospectively scheduled to receive the second dose earlier than recommended (Pfizer-BioNTech= 3 weeks, Moderna=4 weeks)
 - Second doses administered within a "grace period" of ≤4 days from the recommended date are considered valid
 - There is no maximum interval between the first and second dose for either vaccine.
- If minimum intervals (between COVID-19 doses or between COVID-19 and other vaccines) are violated, still consider the COVID-19 dose VALID
 - COVID-19 vaccine supply is constrained
 - We don't have data on 3 doses of COVID-19 or doses given with shorter inter-dose intervals



Persons with a <u>history</u> of SARS-CoV-2 infection

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
 - Data from clinical trials suggest vaccination safe in these persons
- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making



Persons with known <u>current</u> SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) and <u>criteria</u> have been met to discontinue isolation
- No minimal interval between infection and vaccination
- However, <u>current evidence</u> suggests reinfection uncommon in the 90 days after initial infection, and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired



Persons with a <u>known</u> SARS-CoV-2 exposure

- Residing in the Community:
 - Defer vaccination until <u>quarantine period</u> has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit
- Residents of congregate healthcare settings (e.g., long-term care facilities):
 - May be vaccinated, as likely would not result in additional exposures. HCP are already in close contact with residents and should employ appropriate <u>infection</u> <u>prevention and control procedures</u>
- Residents of congregate settings (e.g., correctional facilities, homeless shelters)
 - May be vaccinated, in order to avoid delays and missed opportunities for vaccination
 - Where feasible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff



* Persons with underlying medical conditions

- Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination
- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities



- COVID-19 and pregnancy
 - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
 - Might be an increased risk of adverse pregnancy outcomes, such as preterm birth
- There are limited data on the safety of COVID-19 vaccines in pregnant women
 - Limited animal developmental and reproductive toxicity (DART) data
 - Studies in humans are ongoing and more planned
- If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated.

Pregnant women

- Considerations for vaccination:
 - Level of COVID-19 community transmission (risk of acquisition)
 - Personal risk of contracting COVID-19 (by occupation or other activities)
 - Risks of COVID-19 to her and potential risks to the fetus
 - Efficacy of the vaccine
 - Known side effects of the vaccine
 - Lack of data about the vaccine during pregnancy



X Post-Vaccination Symptoms-Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- Depending on vaccine product, age group, and dose:
 - 80-89% of clinical trial participants reported ≥1 local reaction (e.g., pain or swelling at injection site; swollen lymph nodes on same side as vaccinated arm)
 - 55-83% of clinical trial participants reported ≥1 systemic reaction (e.g., fever, fatigue, muscle aches, headache, chills)
 - Most are mild-moderate in severity, occur within first 3 days of vaccination, and resolve within 1-2 days of onset
 - More frequent and severe following the second dose and among younger age groups



Infection prevention and control recommendations for persons with post-vaccination symptoms

- Healthcare personnel
- Long-term care facility residents

Infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among healthcare personnel (HCP). The approach described in this document is intended to reduce the risks for disruptions in care and pathogen (e.g., SARS-CoV-2) transmission resulting from:

- unnecessarily excluding HCP with only post-vaccination signs and symptoms from work, and
- inadvertently allowing HCP with SARS-CoV-2 or another transmissible infection to work.

These considerations are based on the current understanding of signs and symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine accumulates.

Overview

Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination. Preliminary data from mRNA COVID-19 vaccine trials indicate that most systemic post-vaccination signs and symptoms are mild to moderate in severity, occur within the first three days of vaccination (the day of vaccination and following two days, with most occurring the day after vaccination), resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (>55 years). Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are **not** consistent with post-vaccination symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.

Because systemic post-vaccination signs and symptoms might be challenging to distinguish from signs and symptoms of COVID-19 or other infectious diseases, HCP with postvaccination signs and symptoms



Contraindications to vaccination

- Prescribing information for both Pfizer-BioNTech and Moderna COVID-19 vaccines:
 - Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination
 - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine

*

Ingredients* included in mRNA COVID-19 vaccines

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	nucleoside-modified mRNA encoding the viral spike (S)	nucleoside-modified mRNA encoding the viral spike
	glycoprotein of SARS-CoV-2	(S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-	1 monomethoxypolyethyleneglycol-2,3-
	ditetradecylacetamide	dimyristylglycerol with polyethylene glycol of
		average molecular weight 2000 (PEG2000-DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	cholesterol	cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-	heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-
	hexyldecanoate)	(undecyloxy) hexyl) amino) octanoate
Salts and	potassium chloride	Tris buffer containing sucrose and sodium acetate
Sugars	monobasic potassium phosphate	
	sodium chloride	
	dibasic sodium phosphate dihydrate	
	sucrose	

*As reported in the prescribing information



Precautions to vaccination: mRNA COVID-19 vaccines

- History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy(e.g., intramuscular, intravenous, or subcutaneous)
 - Risk assessment should be conducted in persons who report history of severe allergic reaction (e.g., whether reaction required use of epinephrine [EpiPen®, etc.], resulted in hospitalization)
- These persons may still receive vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination

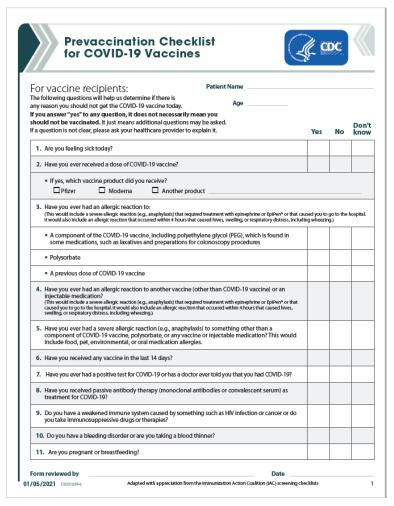


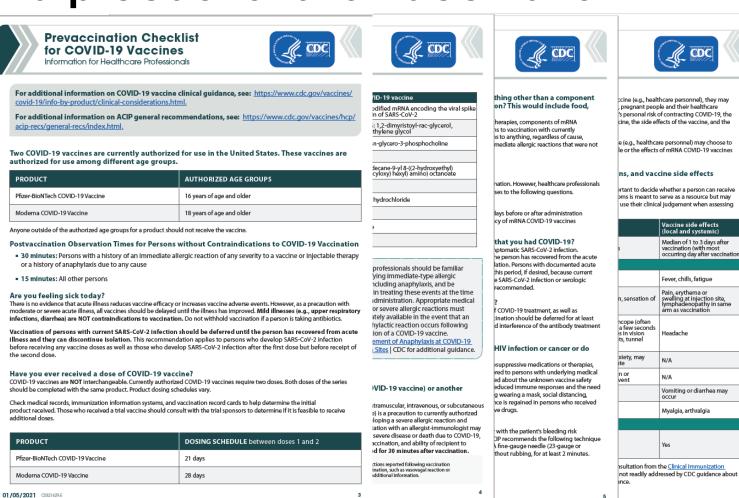
X Observation period following vaccination

- Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
- Persons with a history of anaphylaxis (due to any cause) = 30 minutes
- All other persons = 15 minutes



Additional tools to identify persons with contraindications and precautions to vaccination









ccine (e.g., healthcare personnel), they may , pregnant people and their healthcare 's personal risk of contracting COVID-19, the ring the side effects of the vaccine, and the

e (e.g., healthcare personnel) may choose to e or the effects of mRNA COVID-19 vaccines

ns, and vaccine side effects

rtant to decide whether a person can receive bms is meant to serve as a resource but may use their clinical judgement when assessing

	Vaccine side effects (local and systemic)
5	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
	Fever, chills, fatigue
n, sensation of	Pain, erythema or swelling at injection site, lymphadenopathy in same arm as vaccination
ncope (often a few seconds is in vision ts, tunnel	Headache
xiety, may ite	N/A
n or vent	N/A
	Vomiting or diarrhea may occur
	Myalgia, arthralgia
	Yes



Recent MMWR Publication on Allergic Reactions



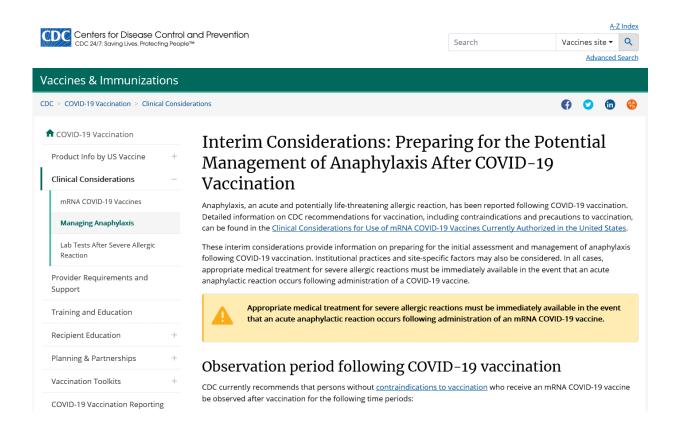


Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020

- As of December 23, 2020, an estimated 1,893,360 first doses
 - 4,393 adverse event reports on these vaccine recipients submitted to VAERS
 - 175 had been identified on initial review for rapid evaluation for potential anaphylaxis
 - 21 were determined to be anaphylaxis
 - 86 were non-anaphylaxis allergic reactions
 - 61 were non-allergic adverse events
 - 7 were under investigation.
- Post-event follow-up indicates that the patients experiencing anaphylaxis fully recovered following treatment.



Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites



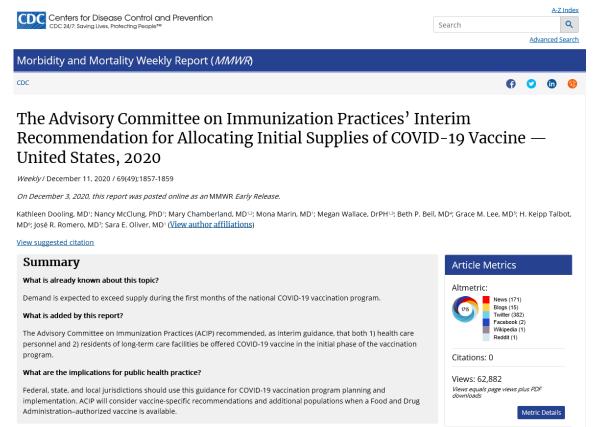
- Stay up to date on current recommendations
- Early recognition of anaphylaxis symptoms
- Prompt treatment with epinephrine
- Activation of emergency medical services

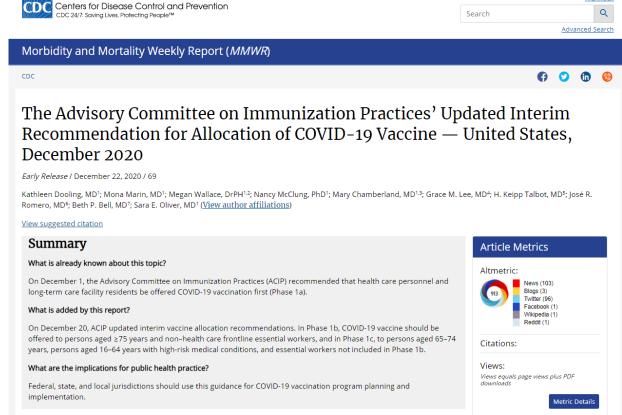
Remember

- Recognize, respond, and report anaphylaxis following COVID-19 vaccination to VAERS
- Report adverse events to VAERS in accordance with FDA EUA reporting requirements and CDC guidance
- Participate in CDC's v-safe program yourself when you get vaccinated and encourage patients to participate in v-safe
- Communicate with patients on vaccine safety



ACIP recommendations for use of COVID-19 vaccines

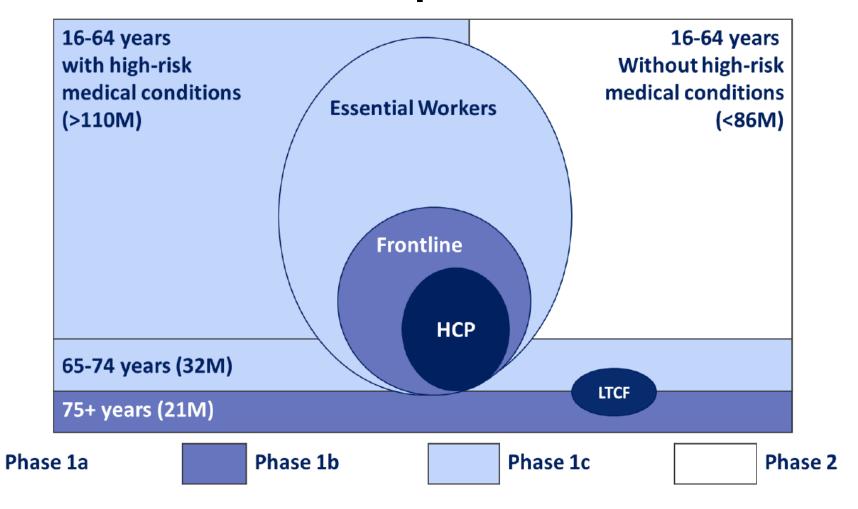




A-Z Index



COVID-19 vaccination phases





* Phased allocation: Balancing Goals

Prevention of			
Morbidity & Mortality			

Preservation of **Societal Functioning**

1a	LTCF residents	Health care personnel
1b	Persons 75 years and older	Frontline Essential Workers
1 c	Persons 65-74 years Persons 16-64 with high-risk medical conditions	Other Essential Workers

- Ensure safety and effectiveness of COVID-19 vaccines●
- Ensure equity in vaccine allocation and distribution



Frontline Essential Workers

- First Responders (Firefighters, Police)
- Education (teachers, support staff, daycare)
- Food & Agriculture
- Manufacturing
- Corrections workers
- U.S. Postal service workers
- Public transit workers
- Grocery store workers

Other Essential Workers

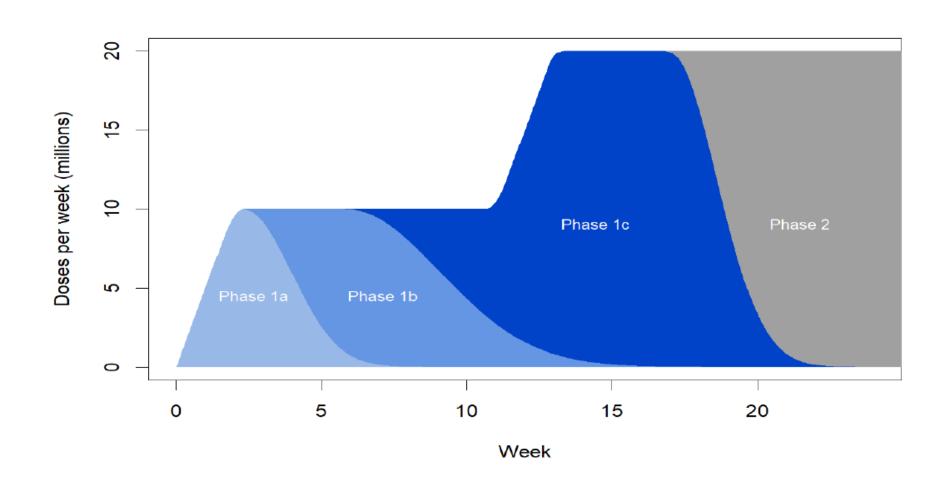
- Transportation and logistics
- Food Service
- Shelter & Housing (construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

Frontline Essential Workers: workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

Phase	Goal: Prevent Severe COVID Outcomes (Hospitalization and death; outbreaks)	Goal: Preserve Functioning of Society and Prevent COVID Infections
January- February*	Residents and Staff of Congregate Settings Long-Term Care Facilities Skilled Nursing Facilities Assisted Living Facilities Other Health Care Congregate Settings Behavioral health residential Developmentally disabled residential Non-Health Care Congregate Settings* Correctional settings Homeless shelters Other residential settings with local outbreaks (e.g. convents)	Health Care Workers—prioritize by COVID exposure risk Hospital-based Non-hospital-based Protect Chicago outreach workers, testers, vaccinating teams
1b February*- March- April?	Older Chicagoans People age 75 and older (155,000) People age 65-74 (207,000)	Front Line Essential Workers Correctional workers* and detainees First responders* Grocery store workers Education (teachers, support staff, daycare) Public transit workers Manufacturing Agriculture
*1a/1b depending on vaccine availability		Agriculture



Example of Phase 1 & Phase 2 COVID-19 vaccine roll-out





Considerations for transitioning between phases

- When demand in the current phase appears to have been met (e.g., appointments for vaccination are < 80% filled for several days)
- When supply of authorized vaccine increases substantially (e.g., more vaccine doses are available than are necessary to complete vaccination of persons in the current phase)
- When most people in the current phase are vaccinated (e.g., when approximately 60-70% of the target population in a phase has been vaccinated)
- When vaccine supply within a certain location is in danger of going unused unless vaccination is expanded to persons in the next phase



Public health recommendations for vaccinated persons

- Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated
- No vaccine is 100% effective
- Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all current guidance to protect themselves and others, including:
 - Wearing a mask
 - Staying at least 6 feet away from others
 - Avoiding crowds
 - Washing hands often
 - Following CDC and CDPH travel guidance
 - Following quarantine guidance after an exposure to someone with COVID-19
 - Following any applicable workplace or school guidance

Overall US COVID-19 Vaccine Distribution and Administration

Total Doses Distributed

21,419,800

Total Number of People Initiating Vaccination (1st Dose Received)

5,919,418

CDC | Updated: Jan 07 2021 As of 9:00am ET

Federal Pharmacy Partnership for Long-Term Care Program (Subset of Overall Numbers)

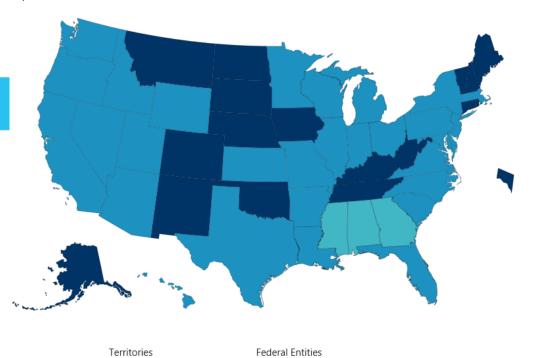
Doses Distributed for Use in Long-Term Care Facilities

3,770,425

Number of People Initiating Vaccination (1st Dose Received) in Long-Term Care Facilities

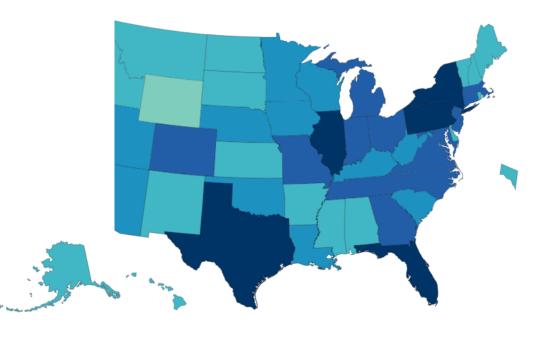
603,313

CDC | Updated: Jan 07 2021 As of 9:00am ET





le Initiating Vaccination (1st Dose Received) Reported to the CDC by State/Territory and for Selected Federal Entities



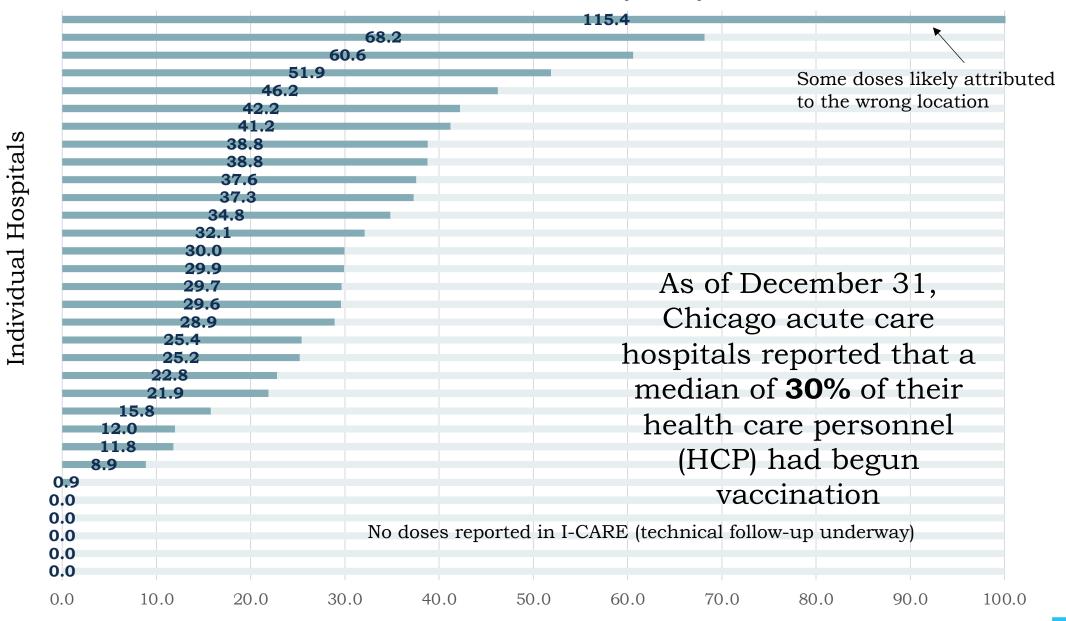


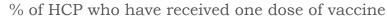
Total Number of People Initiating Vaccination



Estimated Acute Care Hospital Uptake









Vaccine Data Reporting

- Ensure data reported is complete and accurate
- Common data issues
 - Address: ensure the employees address is reported in I-CARE and not the hospital address
 - Missing race/ethnicity data
 - No data reported
- VaccineFinder
 - **Inventory reporting** (required for all providers): COVID-19 vaccination providers will report on-hand COVID-19 vaccine inventory each day.



Logistics and Security

Christopher Shields



"If you see something, say something"

December 21, 2020

Federal Agencies Warn of Emerging Fraud Schemes Related to COVID-19 Vaccines

The Federal Bureau of Investigation (FBI), Department of Health and Human Services Office of Inspector General (HHS-OIG), and Centers for Medicare & Medicaid Services (CMS) are warning the public about several emerging fraud schemes related to COVID-19 vaccines.

The FBI, HHS-OIG, and CMS have received complaints of scammers using the public's interest in COVID-19 vaccines to obtain personally identifiable information (PII) and money through various schemes. We continue to work diligently with law enforcement partners and the private sector to identify cyber threats and fraud in all forms.

The public should be aware of the following potential indicators of fraudulent activity:

Un-Affiliated Medical Closed PODs



City of Chicago initiated our closed POD network to align with your institutions implementing the vaccination campaign

We are starting to expand our daily operations to match the available vaccine associated to this component of the Tier 1a group

There have been over 4000 private providers who have registered to participate in this component of the vaccination campaign

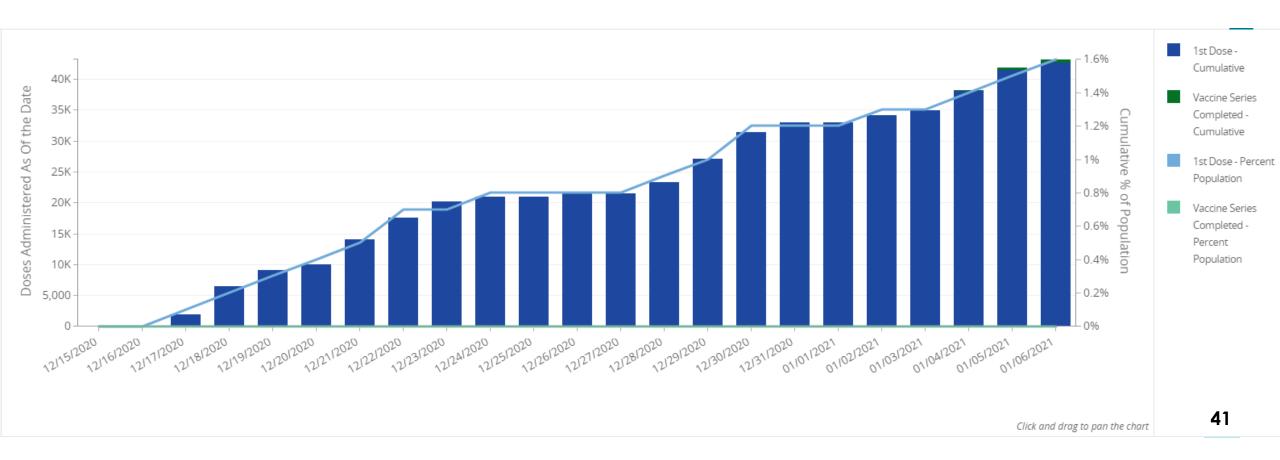
There are over 400,000 clinical providers within the Chicago Healthcare Enterprise, so further coordination between our Hospital partners and community providers is essential to move us on to the Tier 1b group.

Vaccine Allocation and Distribution Vaccination record and reports



https://www.chicago.gov/city/en/sites/covid-19/home.html

Total doses: 43,029 – this number includes provider and City vaccinations 1/6

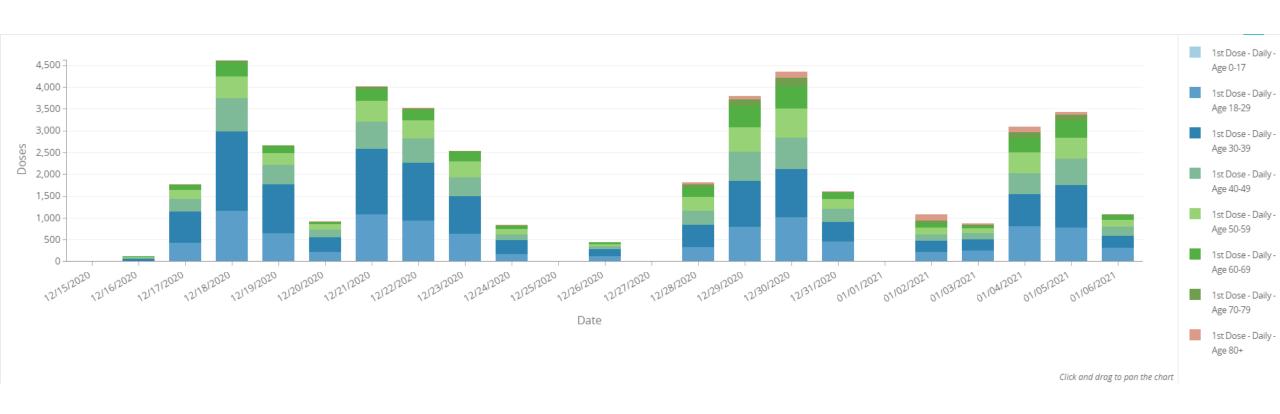


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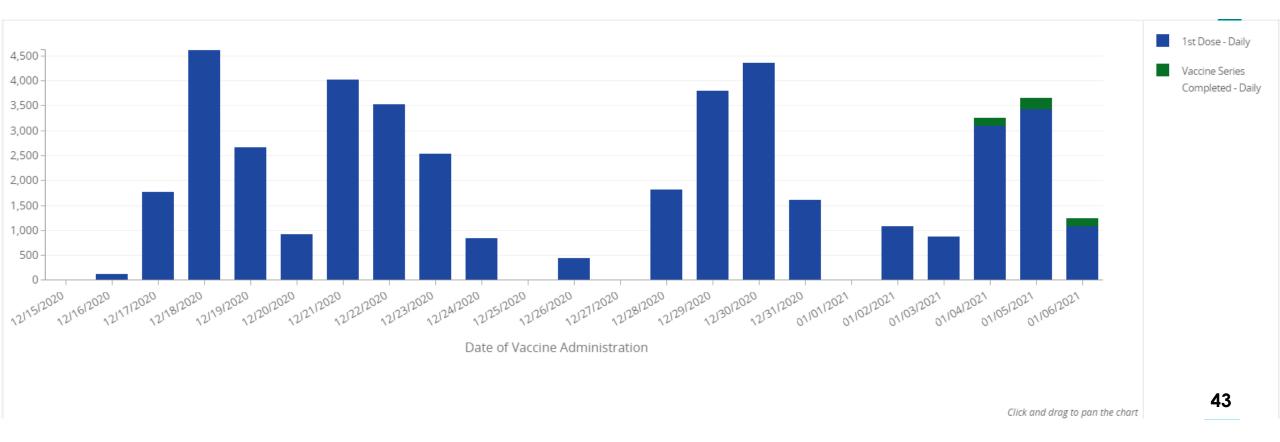


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Chicago (IL Region 11) Hospital Capacity COVID-19 Update

January 7, 2021

Data updated: Jan 6, 2021 at 11:59pm

Chicago Hospital Capacity Summary: Key Findings



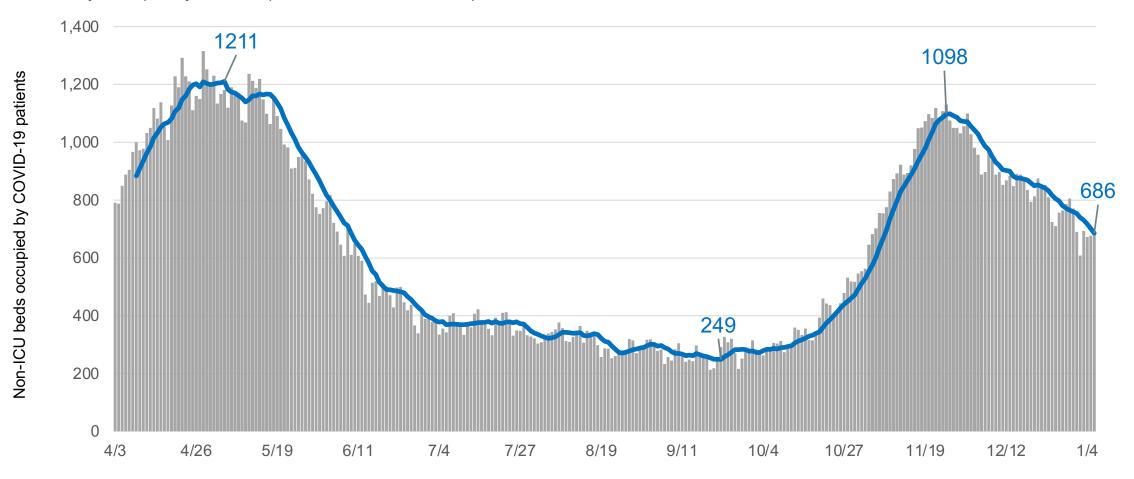
- Non-ICU bed, ICU bed and ventilator availability remains well above the 20% threshold
- Occupancy of non-ICU beds by COVID-19 patients has been declining since 11/26
 - Current 7-day average at 686
- Occupancy of ICU beds by COVID-19 patients has been declining since 12/15
 - Current 7-day average at 234
- Utilization of ventilators by COVID-19 patients has been declining since 12/13
 - Current 7-day average at 144

Non-ICU Bed Occupancy from COVID-19

Peak 7-day rolling average	1211 avg. occupied non-ICU beds 5/4/2020
Current	22%
Availability	01/06/2021



COVID-19 acute/non-ICU beds occupied, daily counts and 7 day average, daily occupancy census (04/03/2020-01/06/2021)

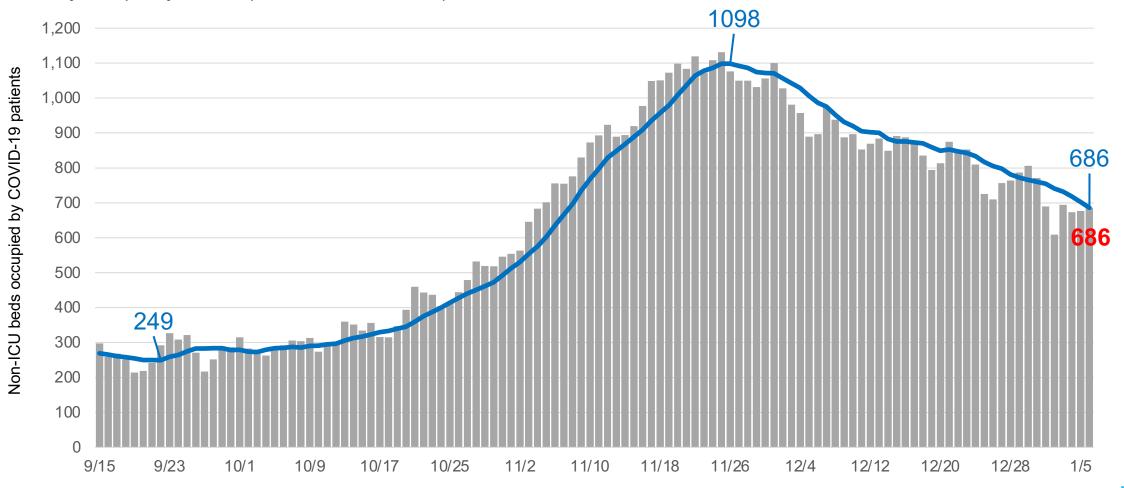


Non-ICU Bed Occupancy from COVID-19

	1211 avg. occupied non-ICU beds 5/4/2020
Current	22%
Availability	01/06/2021



COVID-19 acute non-ICU beds occupied, daily counts and 7 day average, daily occupancy census (9/15/2020-01/06/2021)



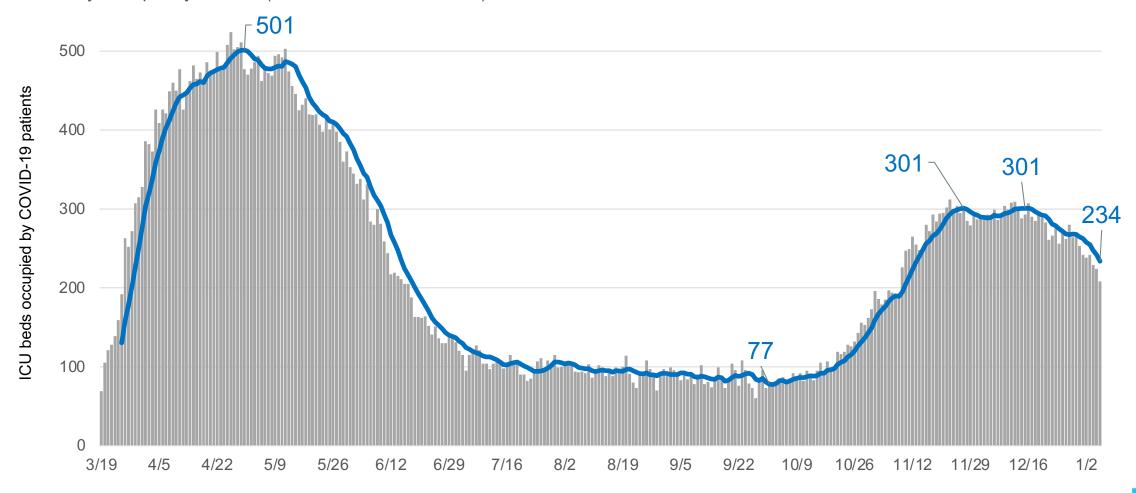
Includes all Chicago hospitals. Hospitals report daily to CDPH via EMResource, beginning April 3 (acute non-ICU occupancy). Acute non-ICU bed counts include burn, emergency department, med/surg, other, pediatrics and psychiatry beds in Chicago hospitals. Includes Chicago and non-Chicago residents. Includes confirmed and suspected COVID-19 cases.

ICU Occupancy from COVID-19

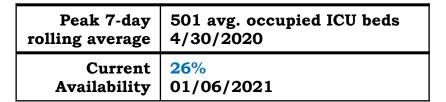




COVID-19 ICU beds occupied, daily counts and 7 day average, daily occupancy census (03/13/2020 - 01/06/2021)

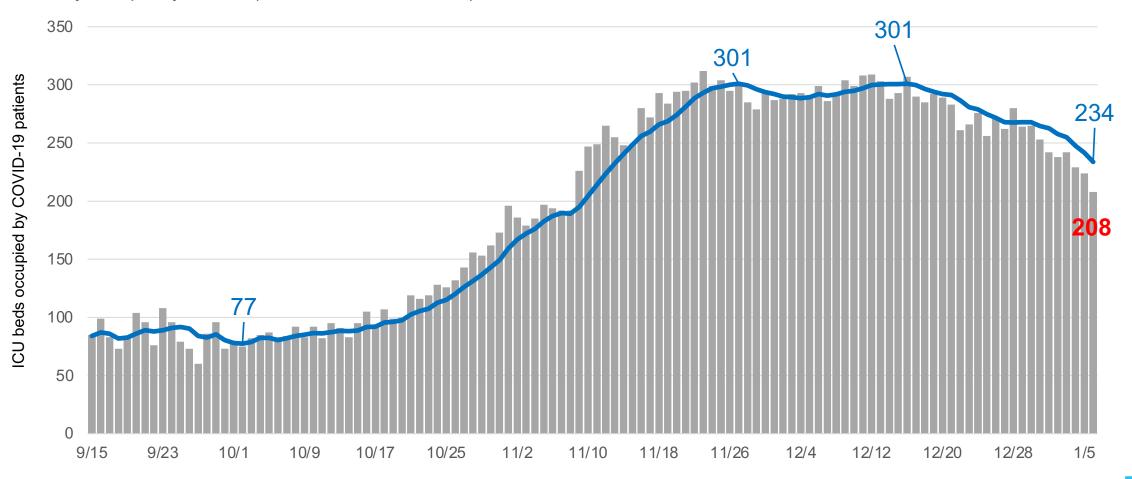


ICU Occupancy from COVID-19





COVID-19 ICU beds occupied, daily counts and 7 day average, daily occupancy census (09/15/2020 - 01/06/2021)



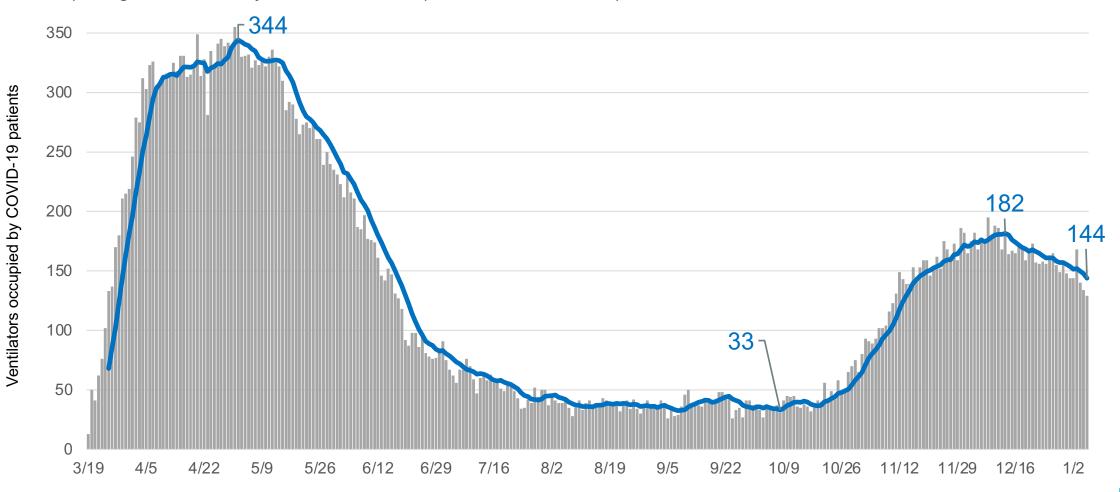
Includes all Chicago hospitals. Hospitals report daily to CDPH via EMResource, beginning March 19. ICU bed count includes all adult and pediatric ICU beds in Chicago hospitals. Includes Chicago and non-Chicago residents. Includes confirmed and suspected COVID-19 cases. Beginning 4/24/2020, the definition of ICU status changed as requested by HHS.

Ventilator Utilization from COVID-19

Peak 7-day rolling average	344 avg. ventilators in use 5/2/2020
Current	70%
Availability	01/06/2021



COVID-19 ventilators in use, daily counts, 7 day average and reopening threshold, daily utilization census (3/19/2020-01/06/2021)



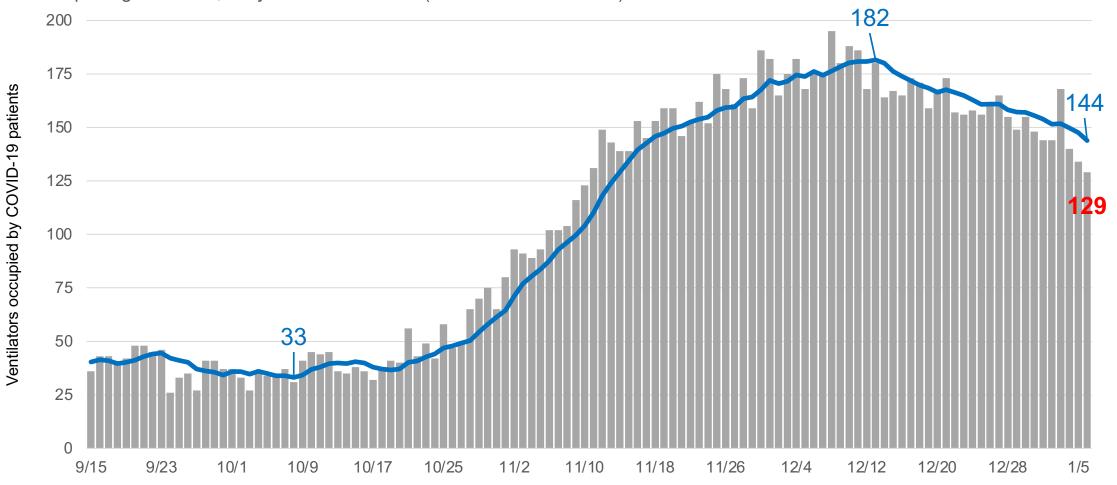
Includes all Chicago hospitals. Hospitals report daily to CDPH via EMResource, beginning March 19. Includes Chicago and non-Chicago residents. Includes confirmed and suspected COVID-19 cases. Beginning 4/24/2020, ventilator counts include all full-functioning mechanical ventilators, BiPAP, anesthesia machines and portable/transport ventilators.

Ventilator Utilization from COVID-19

Peak 7-day rolling average	344 avg. ventilators in use 5/2/2020
Current	70%
Availability	01/06/2021



COVID-19 ventilators in use, daily counts, 7 day average and reopening threshold, daily utilization census (9/15/2020-01/06/2021)



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Questions?



Chicago.gov/Health



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