

COVID-19 Vaccine Planning Healthcare Call #11

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Candice Robinson, MD, MPH Medical Director, Immunizations

Chicago Department of Public Health



Janssen/Johnson & Johnson COVID-19 vaccine

• Public facing VaccineFinder launch

• Vaccine data

Hospital capacity



Received Emergency Use Authorization (EUA) and ACIP/CDC recommendation

X Janssen Vaccine Key Efficacy Findings

85% vaccine efficacy* against severe COVID-19 globally, including the United States

- Consistent vaccine efficacy against severe disease across all regions
- Equally high protection in South Africa (n> 6,500) where B.1.351 is highly prevalent (> 95%)
- Complete protections against COVID-19 related hospitalizations as of day 28 and no COVID-19 related deaths in the Ad26 group compared to 5 in the placebo group

72% vaccine efficacy* against moderate to severe/critical COVID-19 in the United States

Participants reflected diversity of the US populations (n > 19,000)

66% vaccine efficacy* against moderate to severe/critical COVID-19 across all countries

• Protection as of 2 weeks after vaccination

Similar vaccine efficacy demonstrated by age, comorbidities status, sex, race, and ethnicity

Summary of the Available Evidence: Vaccine Efficacy

- Higher efficacy against severe outcomes than for any symptomatic COVID-19*
 - VE against deaths due to COVID-19: 100%
- Efficacy estimates for severe outcomes assessed ≥ 28 days post vaccination were higher: 83.5% for severe disease**, 100% for hospitalization
- Efficacy against severe disease** remained high across world regions (73-82%*), suggesting protection against severe illness with variant strains

**Definition: Respiratory Rate ≥ 30, Heart Rate ≥125, SpO2≤ 93% on room air at sea level or PaO2/FIO2< 300 mm Hg; OR respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure <90mmHg, diastolic BP<60mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death



- ACIP states no preference for any of the three authorized vaccines
- Results of Janssen Phase III trials not comparable with mRNA vaccines
 - Different circulating variants, Higher background incidence
 - Different calendar time
 - Different geography
- Strong protection against severe COVID-19
 - 93% VE against hospitalizations (2 cases in vaccinated vs. 29 in placebo)
 - No COVID-associated deaths in vaccinated vs. 7 in placebo

Summary of Available Evidence: Safety and Reactogenicity

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.4% vs 0.4%).
- Severe reactions were more common in vaccine recipients; any grade ≥3 reaction was reported by 2.5% of vaccinated versus 0.7% of placebo group.
- Local reactions within 7 days occurred in ~50% vaccine recipients
 - Pain at the injection site most common
- Systemic reactions within 7 days occurred in ~55% vaccine recipients
 - Headache, fatigue, and myalgia most common
- Most symptoms resolved after 1-2 days

X Janssen COVID-19 vaccine implementation

• What?

- 1 dose
- Intramuscular injection (0.5 ml)
- Transport and storage (3 months) at 2-8°C.
- Long term freezer storage at standard freezer temperatures (-20°C)
- No diluent/reconstitution necessary

X Janssen COVID-19 vaccine implementation

• Where?

- Mobile/pop-up clinics
- Newly established vaccine administration sites
- Sites that do not have freezer (e.g adult HCP offices)

• Who?

- Patients aged 18+
- People who want to be fully vaccinated quickly
- People who don't want to return or can't return for a second dose
- Mobile populations or homebound populations

x Interchangeability of COVID-19 vax products

• Any COVID-19 vaccine can be used when indicated; no product preference

COVID-19 vaccines are NOT interchangeable

- Safety and efficacy of a mixed series has not been evaluated
- If first dose of mRNA COVID-19 vaccine was received but patient unable to complete series with same or different mRNA vaccine
 - Single dose of Janssen COVID-19 vaccine may be administered at a minimum interval of 28 days from mRNA dose*
 - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector)

*Persons with a contraindiction to mRNA COVD-19 vaccines have a precaution to Janssen COVID-19 vaccine. In these patients, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

K Coadministration of COVID-19 vaccines with other vaccines

- Currently authorized COVID-19 vaccines are all inactivated vaccines
- COVID-19 vaccine should be administrated alone with minimum interval of 14 days before or after administration of other vaccines
- A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g. tetanus toxoid vaccine for wound management, etc.) or to avoid barriers or delays to vaccination

Clinical Considerations

- CDC clinical considerations for mRNA COVID-19 vaccines:
 - <u>https://www.cdc.gov/vaccines/covi</u> <u>d-19/info-by-product/clinical-</u> <u>considerations.html</u>
- Clinical considerations are being updated to include Janssen COVID-19 vaccine
 - Viral vector COVID-19 vaccine

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Summary of recent changes (last updated March 3, 2021):

- Clinical considerations added for use of Janssen (Johnson & Johnson) COVID-19 vaccine.
- Updated recommendations for fully vaccinated people who subsequently develop COVID-19.
- Updated recommendations related to COVID-19 vaccination timing for immunocompromised people.
- Updated contraindications and precautions to mRNA COVID-19 vaccines.
- Updated information on interpretation of SARS-CoV-2 antibody test results after vaccination.

Key points

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of <u>Pfizer-BioNTech</u>, <u>Moderna</u>, and <u>Janssen (Johnson & Johnson)</u> COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

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Considerations for vaccination of people with certain underlying medical conditions



- Clinical considerations remain the same as with mRNA vaccines
 - Underlying medical conditions
 - Immunocompromised persons
 - Pregnant individuals

Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
 History of the following: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine[†] Immediate allergic reaction[*] of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine[†] 	 Among persons without a contraindication, a history of: Any immediate allergic reaction* to other vaccines or injectable therapies[‡] 	 Among persons without a contraindication or precaution, a history of: Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative. ⁺	Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	 30-minute observation period: persons with history of anaphylaxis (due to any cause) 15-minute observation period: all other persons

*See Appendix C for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

¹Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction. [#]Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccine. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Soft Launch: VaccineFinder

- Launched 2/25/2021
- Initial launch included:
 - Active COVID 19 vaccinating providers in participating jurisdictions
 - Select pharmacy locations participating in the Federal Retail Pharmacy Program (FRPP)
 - Other providers that have activated their locations to be visible on VaccineFinder.org



https://VaccineFinder.org

Public Display



*VaccineFinder will only display vaccine availability as shown here. Inventory quantities will never display on the website.

- Location name, display address, and phone number: from partner enrollment files submitted to IZDL. Phone numbers can also be updated via the provider portal.
- Screener/Scheduler URL: Link for action; pulled from Pre Screen Web Address field. If <u>not</u> populated, directs consumers to call the location. (*public display file or log manually page*)
- COVID-19 stock availability*: pulled from the In Stock value for each NDC (inventory file or log manually page)
- 4. Hours: pulled from the 7 columns Sun Hours – Sat Hours (*public display file or log manually page*)
- Notes: Text provided in Notes field (public display file or log manually page)
- 6. Web Address: Provider location web URL from Web Address Field (*public display file or log manually page*)

Public Display – Supporting Mass Vaccination Sites



- Location name, display address, and phone number: Update provider enrollment file with the correct site address (loc_admin_street1, loc_admin_street2) and submit to IZDL.
- Screener/Scheduler URL: Add an appointment link for the site. If <u>not</u> populated, ensure the phone number to make an appointment is correct. (provider portal)
- COVID-19 stock availability*: Update with vaccines offered at this clinic; pulled from the In Stock value for each NDC (provider portal)
- Hours: Populate clinic hours of operation; pulled from the 7 columns Sun Hours – Sat Hours (provider portal)
- Notes: Add dates and details for the clinic. E.g., This clinic will run from March 1-March 31. Make an appointment by clicking 'Check Appointment Availability'. (provider portal)
- 6. Web Address: Provider location web URL from Web Address Field (*provider portal*)

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*VaccineFinder will only display vaccine availability as shown here. Inventory quantities will never display on the website.

Vpdating public display fields

- Display to the Public: Only activate locations that will be receiving vaccine that you wish to display to the public. All locations default to <u>not</u> display to the public.
 - Log Manually : Use the toggle for each site to activate a location to display to the public
 - File Upload : Accepted values for the "Display to the Public" field are Yes and No
- "In Stock": Let consumers know that your site has COVID 19 vaccines available. Inventory quantities will never display to the public.
- Screener/Scheduler Link: Link for action to point consumers to the next step to confirm eligibility to get a vaccine in their area or make a vaccination appointment
 - May be the same URL as the location's website
 - If left blank, i.e., NOT populated , consumers will be directed to call the location for more information
- Phone number (required): Can be updated directly in the provider portal
- Hours of operation
- Notes : Include important information for consumers about a site (e.g., appointments are required,



Updates to provider details submitted before 7am EST will display on VaccineFinder the same day

- Ensure closed sites are set to NOT display to the public
- The "next action step" for all sites should lead to an appointment scheduler or phone number as appropriate
- Include extra messaging in the notes field for sites as needed
 - E.g., This clinic will run from March 1 March 31. Appointments are required.



Report your inventory and keep vaccine availability current in the same step!

ABC Rx	#123	
123 Main St Main City, MA	02108	
Find out if yo	u can get a COVID-1	19 vaccine at this location
TAKE THE	NEXT STEP 🗗	
	123)456-7890	☑ Website

Moderna	0	In Stock
Pfizer-BioNTech	0	Call to Confirm

Last updated: 2 hours ago

Update Vaccine Inventory				
	Upload File Log N	fanually		
In preparation of the public search on vaccinefinder.org, new fields have been added for you to update. More information about when this will become publicly available will be provided shortly.				
			Last updated 2	/18/21, 2:11 PM
sophialoc-goldenloc-70387 ADDRESS_879866 City QA		O Displ	ay to the Public	
VACCINES	DOSES (PUBLIC DI	PUBLIC DISPLAY ()	
The second se		IN STOCK	SUPPLY LEVEL	Luit
Moderna, COVID-19 Vaccine, 100mcg/0.5mL 80777-0273-XX	100	✓ Yes		٥
Pfizer-BioNTech, COVID-19 Vaccine, 30 mcg/0.3mL 59267-1000-XX	1000	× No		٥

LEGEND: No Supply Low (<24 hours) Hedium (24-48 hours)

- Update vaccine availability for each location regularly using the same step for reporting inventory quantities in the provider portal (via batch upload or manually)
- Vaccine availability will display as "out of stock" if this information is not updated within 72 hours
- Ensure additional details are up to date on the Public Display page

Updates to provider details submitted before 7am EST will display on VaccineFinder the same day



- The VaccineFinder COVID Locating Health provider portal is updated to include the Janssen COVID 19 Vaccine
- Add the Janssen vaccine for each location as relevant on the Update Vaccine Inventory > Log Manually tab
 - The portal will display the Janssen vaccine as: Janssen, COVID 19 Vaccine, 0.5 mL, 59676 0580 XX
 - The downloadable file template also includes the Janssen NDC
 - Both unit of use NDC and unit of sale NDCs are accepted in the file upload

*		Total Doses	First Dose	Fully Vaccinated (second dose given)
	Administered at Chicago Sites	683,955 240,802 doses given to non-Chicagoans (35%)	476,890	207,065
	Administered to Chicago Residents	562,911 119,701 doses given outside Chicago (21%)	376,036	186,875

1 in 8 Chicagoans have received a first dose of vaccine

1 in 6 Chicagoans **18+** have received a first dose of vaccine

1 in 3 Chicagoans **65+** have received a first dose of vaccine

Webinar: An Update on Johnson & Johnson's Janssen Vaccine EUA and New Federal Vaccination Programs

 On March 8, the weekly CDC partner call will share updates on CDC's COVID-19 response. Questions should be submitted to <u>eocevent337@cdc.gov</u> with "Partner Call 3/8" in the subject line

•The webinar will be from 2-3 p.m. CST and registration is <u>available here</u>.



Molly Gabaldo, BSN, RN, DNP (c) Rush University College of Nursing Intern, Emergency Preparedness

Elisabeth K. Weber, MA, RN, NHDP-BC Projects Administrator, Hospital Preparedness Program

Chicago Department of Public Health



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

March 2, 2021 Data updated: March 1, 2021 at 11:59pm

Chicago COVID-19 Community Metrics, Phase IV

		Very high risk	High risk	Moderate risk	Lower risk	Controlled transmission
*	COVID cases diagnosed per day Chicago residents 7-day rolling daily average	-or- 7+ consecutive days more than 15% higher than daily average one week prior	400 - 799 -or- 5+ consecutive days more than 10% higher than daily average one week prior	200 - 399 -and- decreasing or stable compared to daily average one week prior	20 – 199 -and- decreasing or stable compared to daily average one week prior	<20
	COVID test positivity Chicago residents 7-day rolling daily average	10%+ -or- 7+ consecutive days more than 15% higher than daily average one week prior	6.6 - 9.9% -or- 5+ consecutive days more than 10% higher than daily average one week prior	5.0 - 6.5% -and- decreasing or stable compared to daily average one week prior	2 - 4.9% -and- decreasing or stable compared to daily average one week prior	<2%
	Emergency dept visits for COVID-like illness Chicago hospitals 7-day rolling daily average	90+ -or- 7+ consecutive days more than 15% higher than daily average one week prior	-or- 5+ consecutive days more than 10% higher than daily average one week prior	60 - 79 -and- decreasing or stable compared to daily average one week prior	20 - 59 -and- decreasing or stable compared to daily average one week prior	<20
	ICU beds occupied by COVID patients	-or- <20% overall ICU bed availability	300 - 399 -or- <22% overall ICU bed availability	100 - 299	20 - 99	<20

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 is <u>declining</u> and is now at its lowest point since collecting data (!)
 - Current 7-day average 243
- Occupancy of **ICU beds** by COVID-19 patients is <u>declining</u>
 - Current 7-day average at 100, putting us at the threshold of "lower risk"
 - ICU bed availability = 28%
- Utilization of **ventilators** by COVID-19 patients is <u>declining</u>
 - Current 7-day average at 56



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.

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ICU Occupancy from COVID-19

×

ICU beds available and occupied by COVID-19 patients, daily counts and 7 day average, daily occupancy census (09/15/2020 - 03/01/2021)

Peak 7-day rolling average	501 avg. occupied ICU beds 4/30/2020
Current Availability (7DRA)	28% 03/01/2021





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.

Vpdate: Chicago MRC

- Over 1588 hours/ 198 shifts of volunteer medical vaccinators have been working in the Chicago PODs since February 21, 2021
- Week of March 1: Started scheduling non-medical, nonvaccinators in select Protect Chicago Plus programs
- Mass Care Vaccination Sites transition- planning
 ongoing with Federal and Regional Partners and
 information will be provided when confirmed

MRC Volunteer Hours Worked

WEEKLY REPORT OF MRC HOURS WORKED					
WK#	WEEK	TOTAL MRC'S ASSIGNED	TOTAL HOURS WORKED	COMMENTS	
1	2/21/21 TO 2/6/21	28	216		
2	2/9/21 TO 2/13/21	52	408		
3	2/13/21 & 2/14/21	12	96	Special Assignment with Oak Street Provider (Sat & Sun) @ Steinmetz HS	
4	2/16/21 TO 2/23/21	7	52	*Severe Weather/ Vaccine arrival delayed	
5	2/23/21 TO 2/27/21	46	360		
6	3/2/21 TO 3/6/21	58	456		
7	3/9/21 TO 3/13/21	0	0	Currently rostering	
	TOTALS	<mark>203</mark>	<mark>1588**</mark>	** 198 shifts	



Questions?



Chicago.gov/Health



HealthyChicago@cityofchicago.org



*@***ChicagoPublicHealth**



@ChiPublicHealth