





Disclosures

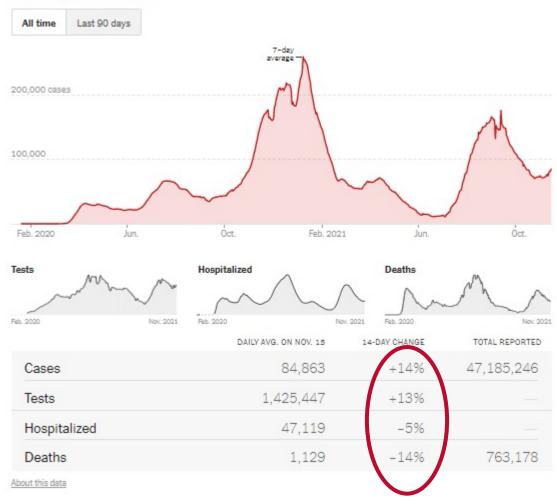
• We have no relevant financial interests to disclose.

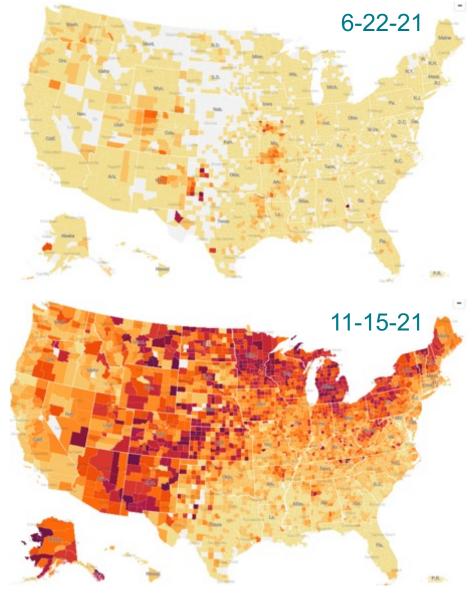




Coronavirus in the U.S.: Latest Map and Case Count

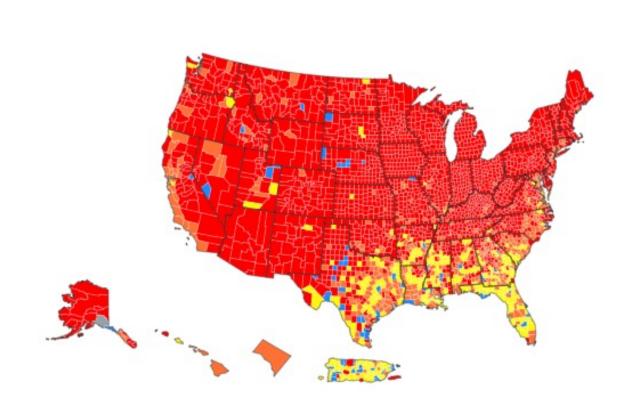
New reported cases





https://www.nytimes.com/interactive/2021/us/coronavirus-us-cases.html

Level of Community Transmission of All Counties in US



Community Transmission in US by County

21	Total	Percent	% Change
High	2301	71.42%	1.64%
Substantial	485	15.05%	-2.2%
Moderate	356	11.05%	0.34%
Low	77	2.39%	0.22%

How is community transmission calculated?

Jul 2021

Jan 2021

Data are updated M-F at 5:30 p.m., except for City holidays
All data are provisional and subject to change

CHICAGO I COVID-19 Summary

Jul 2021

Jan 2021

Apr 2021

Oct 2021

(?) Learn how to use this dashboard. CASES BY ZIP **VACCINES BY ZIP** SUMMARY CASES **TESTS VACCINES 盆 CASES W HOSPITALIZATIONS** DEATHS 445 403 (+10%) 16.4 30,967 0.5 333.793 14 V 23 (-41%) 3.14 2.00 (+57%) 6,138 0.1 Daily rate per 100,000 Daily rate per 100,000 Current daily avg Prior week Cumulative Current daily avg Prior week Cumulative Current daily avg Prior week Cumulative Daily rate per 100,000 Jan 2021 Jul 2021 Jul 2020 Jul 2020 Jan 2021 Jul 2021 Jul 2020 Jan 2021 Jul 2021 * VACCINATIONS ADMINISTERED TESTS PERFORMED POSITIVITY RATE 12,484 3,554,693 60.1% 66.7% 21,889 ▼ 23,123 (-5%) 6,722,249 2.5% 2.0% Current daily avg Current daily avg Cumulative Completed series At least one dose Current daily avg Prior week Cumulative Prior week 20K

Jan 2021

built by.

Jul 2020

0K

Jul 2020

Jul 2021

New Admissions of Patients with Confirmed COVID-19 per

=1

HHS Regions



3,320,189

Total Admissions Aug 01, 2020 - Nov 14, 2021

5,333

Current 7-Day Average Nov 08, 2021 - Nov 14, 2021

5,057

Prior 7-Day Average Nov 01, 2021 - Nov 07, 2021

16,478

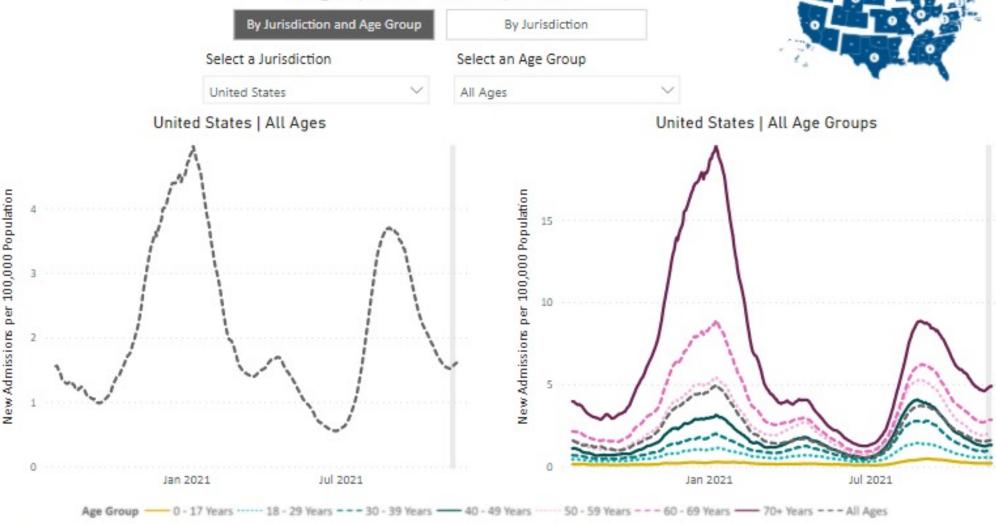
Peak 7-Day Average Jan 03, 2021 - Jan 09, 2021

+5.4%

Percent change from prior 7-day avg. of Nov 01, 2021 - Nov 07, 2021

-67.6%

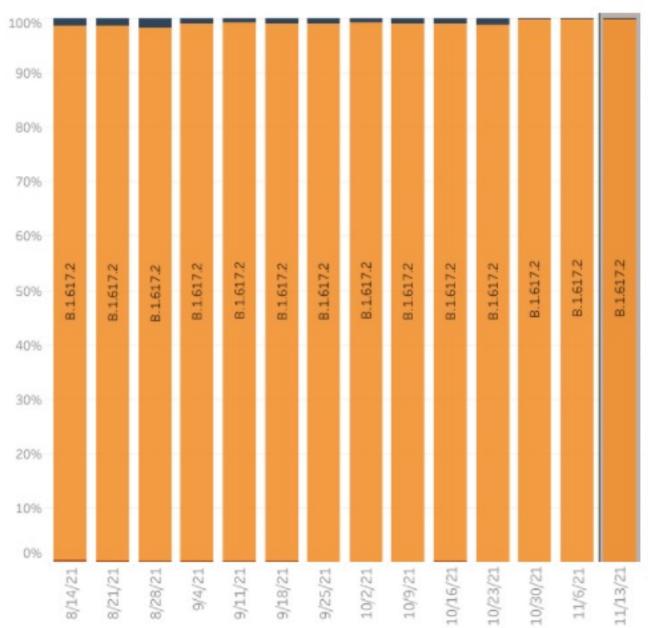
Percent change from peak 7-day avg. of Jan 03, 2021 - Jan 09, 2021 100,000 Population by Age Group, United States
Aug 01, 2020 - Nov 14, 2021



Based on reporting from all hospitals (N-5,259). Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution.

Small shifts in historic data may occur due to changes in the CMS Provider of Services file, which is used to identify the cohort of included hospitals. Data since December 1, 2020 have had error correction methodology applied. Data prior to this date may have anomalies that are still being





USA

WHO label	Lineage #	US Class	%Total	95%PI
Delta	B.1.617.2	VOC	99.9%	99.9-100.0%
	AY.1	VOC	0.1%	0.0-0.1%
	AY.2	VOC	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.1%

^{*} Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

^{**} These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

[#] AY.3-AY.47 and their sublineages are aggregated with B.1.617.2.

Total Vaccine Doses

Delivered 556,077,145

Administered 443,374,199

Learn more about the distribution of vaccines.

195.4M

People fully vaccinated

30.7M

People received a booster dose**

At Least One Dose	Fully Vaccinated	Booster Dose	
Fully Vaccinated* People	Count	Percent of US Population	
Total	195,435,688	58.9%	
Population ≥ 12 Years of Age	195,297,762	68.9%	
Population ≥ 18 Years of Age	182,447,095	70.6%	
Population ≥ 65 Years of Age	47,174,536	86.1%	

^{*}For surveillance purposes, COVID Data Tracker counts people as being "fully vaccinated" if they received two doses on different days (regardless of time interval) of the two-dose mRNA series or received one dose of a single-dose vaccine.

^{**}The count of people who received a booster dose includes anyone who is fully vaccinated and has received another dose of COVID-19 vaccine since August 13, 2021. This includes people who received booster doses and people who received additional doses.

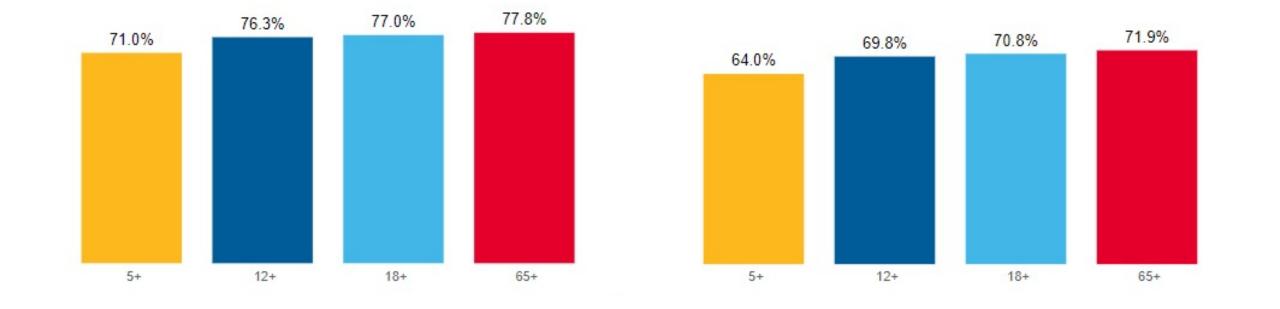
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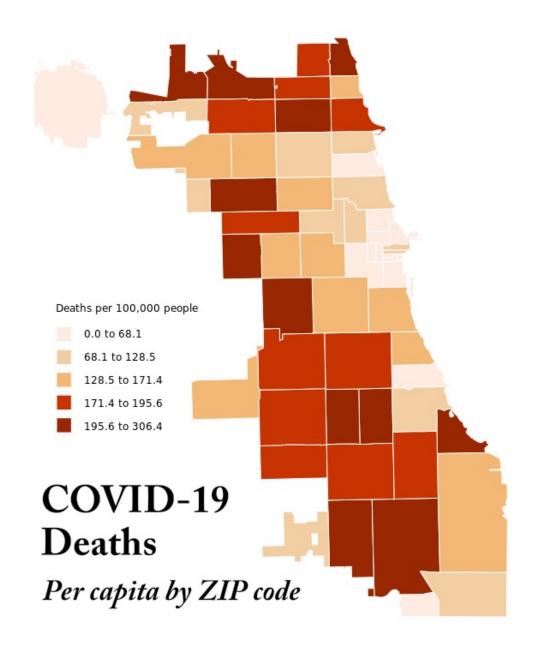


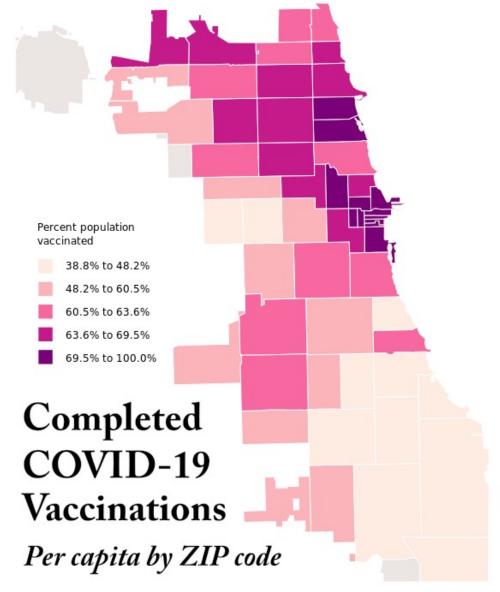


At least one dose (% vaccinated as of 11/14/2021)

Completed vaccine series (% vaccinated as of 11/14/2021)



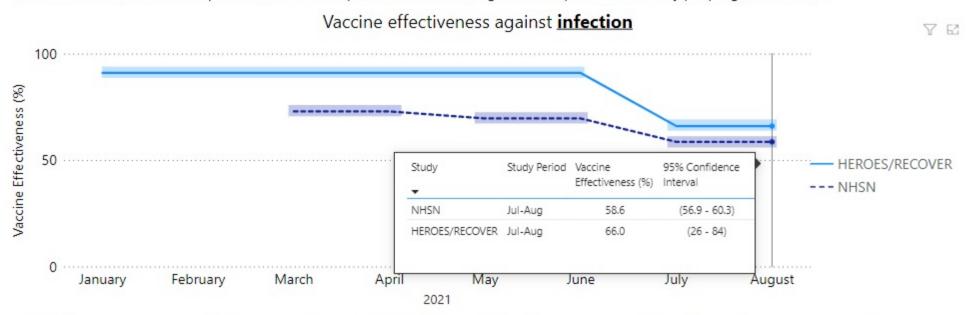




Vaccine effectiveness against **hospitalization** YE Vaccine Effectiveness (%) Study Study Period Vaccine 95% Confidence Effectiveness (%) Interval --- SUPERNOVA (85 - 90)IVY Aug-Sep ······ VISION SUPERNOVA Jul-Sep 83.1 (76.6 - 87.8) September February March April May August June

COVID-19 vaccines are effective at protecting people from being hospitalized with COVID-19. The vaccines help protect against Delta and other variants and continue to prevent COVID-19 hospitalizations even though time has passed since many people got vaccinated.

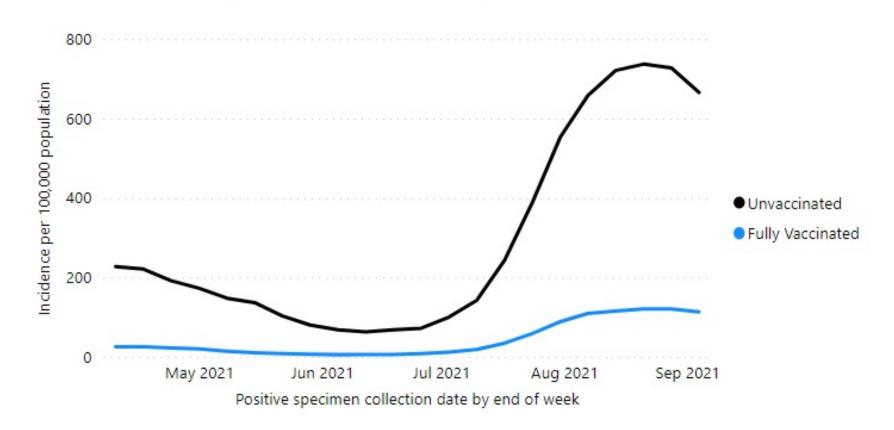
2021



COVID-19 vaccines were less effective at preventing COVID-19 infection in July and August compared to earlier months. Time has passed since people got vaccinated, and Delta became the predominant variant during this time period.

Rates of COVID-19 Cases by Vaccination Status

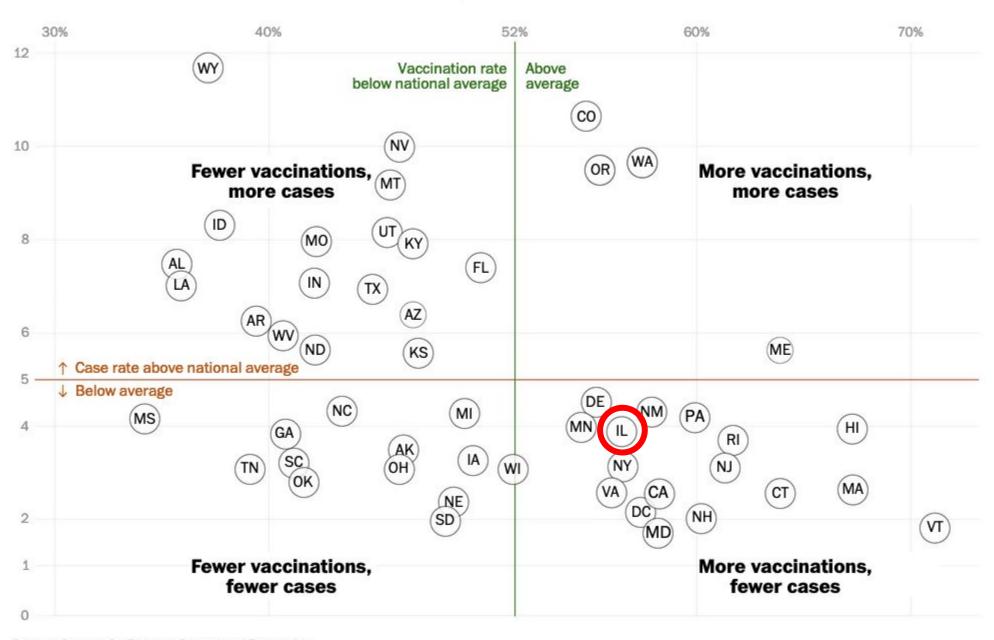
April 04 - September 04, 2021 (16 U.S. jurisdictions)



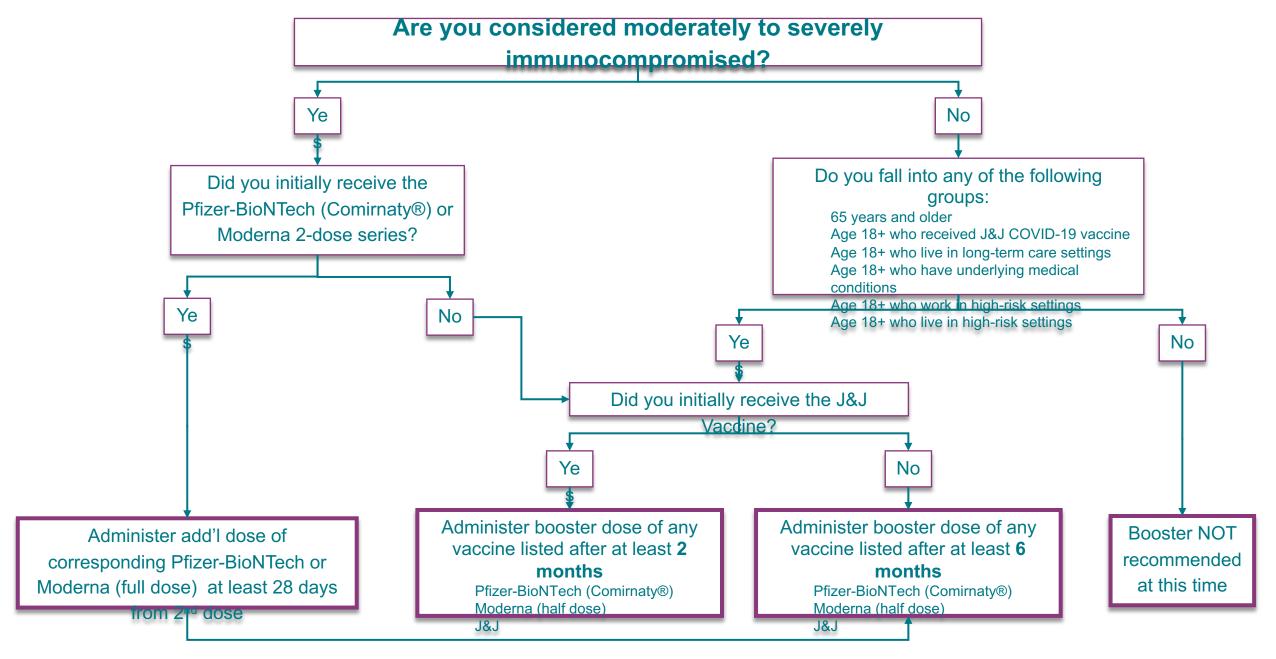
In August, unvaccinated persons had:



States where a larger share of the population have received at least one vaccine dose have significantly lower current case rates.



COVID-19 Vaccine Third Dose/Booster Dose Workflow



Am I eligible for a booster shot?



Who?

If you received a Pfizer or Moderna series:

- > 65 years and older
- > Age 18+ who live in long-term care settings
- > Age 18+ who have underlying medical conditions
- > Age 18+ who work or live in high-risk settings

If you received a J&J vaccine:

> Age 18+

When?

- > At least 6 months after Pfizer or Moderna
- At least 2 months after J&J

Which booster shot do I get?

You may have a preference, but you can get any booster shot.







How do Covid-19 vaccine boosters compare?1

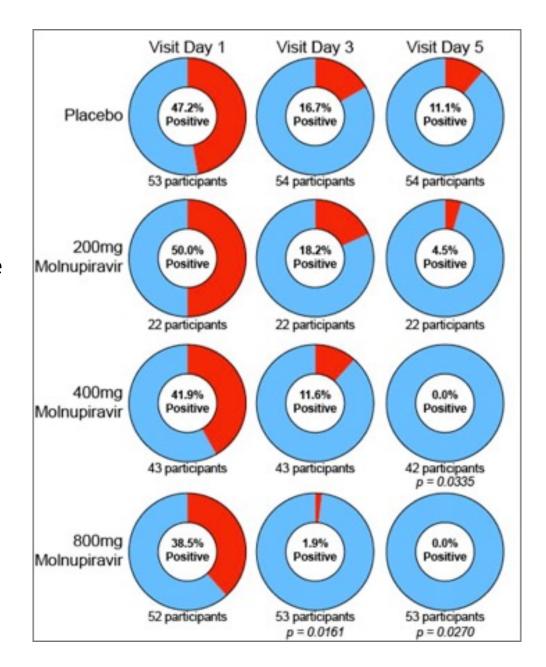
Initial Vaccine Administered	Pfizer BIONT≡CH			moderna			Janssen J Johnson-Johnson		
Initial Dose Regime	2			2			1		
Booster Shot Type	moderna-	Pfizer BIONT≣CH	Janssen J	∂ Pfizer BIONT≡CH	moderna ⁻	Janssen J	moderna ⁻	€ Pfizer BIONT≡CH	Janssen J
Binding & Neutralizing Antibody Assays (Geometric mean fold rise)	17.3 x	14.9 x	6.2 x	9.7 x	7.9 x	4.7 x	56.1 x	32.8 x	4.6 x
Rank	1st	2 nd	3 rd	1st	2 nd	3 rd	1st	2 nd	3 rd



Molnupiravir, an Oral Antiviral Treatment for COVID-19

William Fischer, Joseph J. Eron Jr, Wayne Holman, Myron S. Cohen, Lei Fang, Laura J. Szewczyk, Timothy P Sheahan, Ralph Baric, Katie R. Mollan, Cameron R. Wolfe, Elizabeth R. Duke, Masoud M. Azizad, Katyna Borroto-Esoda, David A. Wohl, Amy James Loftis, Paul Alabanza, Felicia Lipansky, Wendy P. Painter doi: https://doi.org/10.1101/2021.06.17.21258639

- Phase 2a clinical trial
- Prodrug of ribonucleoside analog -> serves as a competitive substrate for RNA polymerase
 - Once incorporated into viral RNA, induces accumulations of mutations that increase with each viral replication cycle.
- Enrolled outpatients with confirmed SARS-CoV-2 infection and symptom onset within 7 days
- Randomized 1:1 to 200mg molnupiravir or placebo, or 3:1 to molnupiravir (400 or 800mg) or placebo BID x 5 days
- Among 200 treated participants, virus isolation was significantly lower in 800mg molnupiravir (1.9%) versus placebo (16.7%) at Day 3 (p=0.02)
- At Day 5, virus was not isolated from any participants receiving 400 or 800mg molnupiravir versus 11.1% of those receiving placebo (p=0.03)
- Generally well tolerated, similar adverse events across all groups



Molnupiravir

- The UK's Medicines and Healthcare Products Regulatory Agency approved Merck & Co. and Ridgeback Biotherapeutics' molnupiravir for the treatment of COVID-19 on 11/4 -> first to authorize the use of the oral medication
- Reported to reduce risk of hospitalization and death in at-risk patients.
 - Phase 3 MOVe-OUT trial reduced the risk of hospitalization or death by approximately 50%
 - 7.3% of patients who received molnupiravir were either hospitalized or died through Day 29 following randomization compared with 14.1% of placebo (p=0.0012)
 - No deaths were reported in patients who received molnupiravir as compared to 8 deaths in patients who received placebo
 - Recruitment was stopped early after 775 patients (full expected 1550)
 - Symptom onset within 5 days of randomization
 - Consistent efficacy across all variants
- Licensed for adults 18 and older who have tested positive for COVID-19 and have at least one risk factor for developing severe disease, such as obesity or heart disease
- Course: Four pills of the drug twice a day for five days
- External advisory committee to FDA to discuss Nov 30, 2021

PF-07321332 (Paxlovid)+ ritonavir

- 3CL protease inhibitor
- 1219 non-hospitalized adults >18y with COVID-19 at risk of progressing to severe disease
- Interim analysis of phase 2/3 EPIC-HR study 89% reduction in risk of COVID-19 related hospitalization or death from any cause in patients treated with paxlovid compared to placebo within 3 days of symptom onset, with no deaths in the treatment group.
 - 1% of patients who received Paxlovid were hospitalized through Day 28 following randomization (6/607 hospitalized, with no deaths) compared to 6.7% of patients who received a placebo (41/612 hospitalized with 10 subsequent deaths (p,0.0001).
 - In the overall study population through Day 28, no deaths were reported in patients who received Paxlovid as compared to 10 (1.6%) deaths in patients who received placebo.
- Treatment-emergent adverse events comparable with placebo (19% v 21%, 1881 patients)
 - Most were mild
- Co-administration with a low dose of ritonavir helps to slow the metabolism of PF-07321332
- 2 tabs of PF-07321332 + 1 tab ritonavir BID x 5 days
- Applying for EUA

Effect of early treatment with fluvoxamine on risk of emergency care and hospitalisation among patients with COVID-19: the TOGETHER randomised, platform clinical trial

Gilmar Reis, Eduardo Augusto dos Santos Moreira-Silva, Daniela Carla Medeiros Silva, Lehana Thabane, Aline Cruz Milagres,
Thiago Santiago Ferreira, Castilho Vitor Quirino dos Santos, Vitoria Helena de Souza Campos, Ana Maria Ribeiro Nogueira,
Ana Paula Figueiredo Guimaraes de Almeida, Eduardo Diniz Callegari, Adhemar Dias de Figueiredo Neto, Leonardo Cançado Monteiro Savassi,
Maria Izabel Campos Simplicio, Luciene Barra Ribeiro, Rosemary Oliveira, Ofir Harari, Jamie I Forrest, Hinda Ruton, Sheila Sprague, Paula McKay,
Alla V Glushchenko, Craig R Rayner, Eric J Lenze, Angela M Reiersen, Gordon H Guyatt, Edward J Mills, for the TOGETHER investigators*

- Placebo-controlled, randomized, adaptive platform trial in high-risk symptomatic Brazilian adults with a known risk factor for progression to severe disease
- Fluvoxamine 100mg BID x 10 days vs placebo
- Primary outcome
 - Composite endpoint of hospitalization defined as either retention in a COVID-19 emergency setting or transfer to a tertiary hospital due to COVID-19 up to 28 days postrandomization on the basis of intent to treat (ITT)

SSRI and s1Receptor agonist

Potential MOA vs. SARS-CoV-2

- Anti-inflammatory
- Anti-viral
- Anti-platelet?

	Intent	ion-to-treat an	alysis	Modified intention-to-treat analysis			
	N	n (%)	Relative risk (95% BCI)	N	n (%)	Relative risk (95% BCI)	
Fluvoxamine	741	79 (11%)	0.68 (0.52-0.88)	740	78 (11%)	0.69 (0.53-0.90)	
Placebo	756	119 (16%)	1 (ref)	752	115 (15%)	1 (ref)	

BCI=Bayesian credible interval.

Table 2: Proportion of primary outcome events and relative risk of hospitalisation defined as either retention in a COVID-19 emergency setting or transfer to tertiary hospital due to COVID-19 for patients allocated fluvoxamine versus placebo

Per protocol - patients with high level of adherence (>80%)

mITT – received 24h of treatment before a primary outcome event

Fluvoxamine

- Trial arm stopped early
- One death in the fluvoxamine group and 12 in the placebo group for the per-protocol population [OR 0.09; 95% CI 0.01-0.47]
- No differences in number of treatment emergent adverse events in either group

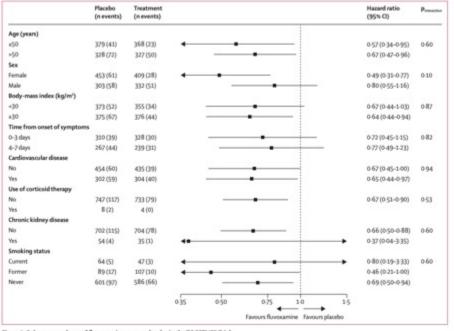


Figure 3: Subgroup analyses of fluvoxamine versus placebo in the TOGETHER Trial

	Fluvoxamine	Placebo	Estimated treatment effect (95% CI)	p value
Viral clearance (day 7)	40/207 (19%)	58/221 (26%)	0.67 (0.42–1.06)*	0.090
Hospitalised for COVID	75/741 (10%)	97/756 (13%)	0.77 (0.55–1.05)*	0.10
All-cause hospitalisation	76/741 (10%)	99/756 (13%)	0.76 (0.58–1.04)*	0.088
Time to hospitalisation, days	5 (3 -7)	5 (3-7·5)	0.79 (0.58-1.06)†	0.11
Period of hospitalisation, days	8 (5–13)	6 (3-10-75)	1.23 (0.99–1.53)‡	0.059
Emergency setting visit for at least 6 h	7/741 (1%)	36/756 (5%)	0.19 (0.08–0.41)*	0.0001
Time to the emergency visit for at least 6 h, days	4 (3-7)	5 (3-8-25)	0.20 (0.09–0.44)†	0.002
Death, intention to treat	17/741 (2%)	25/756 (3%)	0.69 (0.36-1.27)*	0.24
Time to death, days	17 (9–21)	14 (8-20)	0.80 (0.43-1.51)†	0.49
Mechanical ventilation	26	34	0.77 (0.45-1.30)	0.33
Time on mechanical ventilator, days	5.5 (3-12.75)	6.5 (2.25–12)	1.03 (0.64–1.67)‡	0.90
Adherence	548/741 (74%)	618/738 (82%)	0.62 (0.48-0.47)*	0.0003
Death, per protocol	1/548 (<1%)	12/618 (2%)	0.09 (0.01-0.47)	0.022
Treatment emergent adverse eve	ent			
Grade 1	20/741 (3%)	11/756 (1%)	1.88 (0.91-4.09)*	0.096
Grade 2	72/741 (10%)	81/756 (11%)	0.91 (0.64–1.25)*	0.52
Grade 3	38/741 (5%)	50/756 (7%)	0.76 (0.49-1.18)*	0.22
Grade 4	21/741 (3%)	20/756 (3%)	1.07 (0.58-2.01)*	0.82
Grade 4				

Data are n/N (%) or median (IQR) unless otherwise stated. *Unadjusted odds ratio. †Unadjusted hazard ratio. ‡Exponentiated unadjusted estimates from a log-transformed linear regression.

Table 3: Secondary outcomes of fluvoxamine versus placebo in the TOGETHER trial

Don't forget about mABs!

Bamlanivimab 700mg plus etesevimab 1400mg IV x 1
OR Casirivimab 600mg plus indevimab 600mg IV or as SC x 1
OR Sotrovimab 500mg IV x 1

- Treatment should be started ASAP and within 10 days of symptom onset
- High risk outpatients with conditions that were represented in patients in clinical trials and other medical conditions and factors that had limited representation in patients in clinical trials
- High risk inpatients with mild to moderate COVID-19 admitted for a reason other than COVID-19
- Available for patients admitted with severe COVID-19 who have not developed an antibody response (or are not expected to mount a response) through expanded access protocols
- As post-exposure prophylaxis (C/I) in high risk persons with significant exposures who are not fully vaccinated or not expected to mount a full immune response to vaccination

COVID-19 Vaccine Booster Shots

Updated Nov. 17, 2021

Languages *

Print

IF YOU RECEIVED

Pfizer-BioNTech or Moderna

You are eligible for a booster if you are:

- 65 years or older
- Age 18+ who live in <u>long-term care settings</u>
- Age 18+ who have <u>underlying medical</u> conditions
- Age 18+ who work or live in <u>high-risk settings</u>

When to get a booster:

At least 6 months after completing your primary COVID-19 vaccination series

Which booster should you get?

<u>Any of the COVID-19 vaccines</u> authorized in the United States

IF YOU RECEIVED

Johnson & Johnson's Janssen

You are eligible for a booster if you are:

18 years or older

When to get a booster:

At least 2 months after your shot

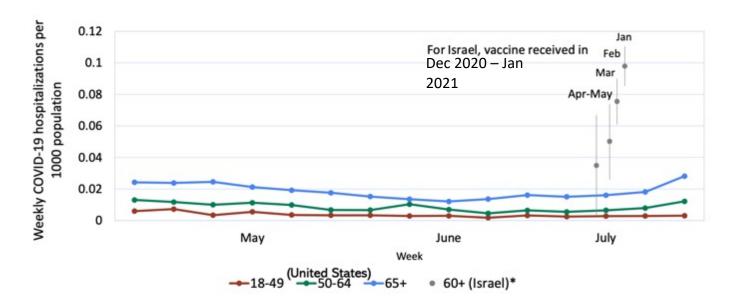
Which booster should you get?

Any of the COVID-19 vaccines authorized in the United States

Awaiting updates on continued expansion as early as 11/19/21!

Vaccine efficacy wanes overtime, especially for older adults

Incidence among vaccinated people, for hospitalization by month in United States and for severe disease by time since 2nd dose in Israel

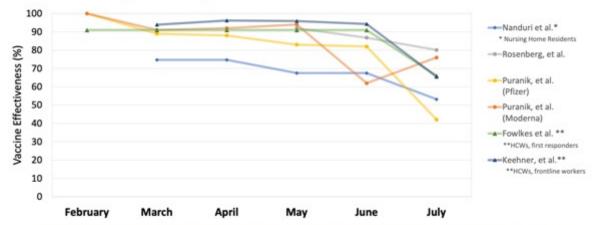


^{*}Israel estimates were derived from rate of severe COVID-19 (per 1,000 persons) from July 11, 2021 to July 31, 2021. Each data point represents all person stratified by when second dose of COVID-19 vaccine received.

Despite declines in VE, especially in older age groups, protection vs. hospitalization remains

15

Vaccine effectiveness against <u>infection</u> over time Adults ≥18 years of age

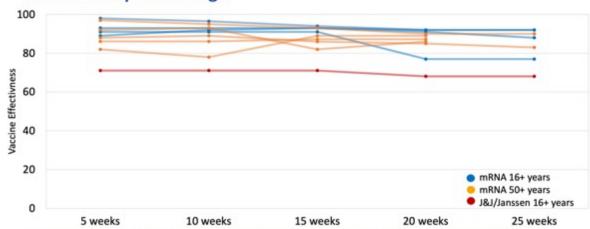


Rosenberg ES, Holgrave DB, Dorabawilla V, et al. New CDVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3-July 25, 2021. MMWR Morb Mortali Wily Rep. ePuls: 18 August 2021.
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Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medikuir 2021.08.06.21261707 Keehner J, Horton LE, Binkin NJ et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. NE/NA, September 1, 2021. 001: 10.1056/NEJMc2112981

Vaccine effectiveness against <u>hospitalization</u> over time Adults ≥16 years of age



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Thompson MK, Burgess II, Nailway AL, et al. Prevention and attenuation of Covid-19 with the BRTSEND and mRNA-1273 saccions. N Engl IMEd 2003,385:330—8.

Fell RM, Fedorica AL Comparative Efficiences of Minderina, Plear Modification, and consequences & Antonios Modern in Preventing CoVID-19 inseptializations Among Adults Without Inneurocompromising Conditions — United Minderina Among Adults W

March-August 2021. MWWR Morts Mortal kityk Rpp. ethbi: 17 September 2021.

America et al. mRMA vaccines effectivenes against COVID-19 hospitalizations and deaths in older adults: a cohort study based on data-linkage of national health negistries in Portugal. MedROV preprint.

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Andrews et al. Vaccine effectiveness and duration of protection of Commany, Vaxeuria and Spikevax against mild and severe COVID-29 in the UK. Preprint.

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18

Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study

Noam Barda*, Noa Dagan*, Cyrille Cohen, Miguel A Hernán, Marc Lipsitch, Isaac S Kohane, Ben Y Reist, Ran D Balicert

- Participants receiving a 3rd
 vaccine dose between 7/30
 and 9/23/21 were matched 1:1
 to demographically and
 clinically similar controls who
 did not receive a third dose.
- Participants received the 2nd
 vaccine dose at least 5 months
 before the recruitment date,
 no prior COVID-19 infection, no
 contact with healthcare system
 in 3 days prior to recruitment
- 728,321 individuals included following matching
- Mean age 52y, 51% female

	Vaccinated with two doses		Vaccinated with three doses		1-risk ratio (95% CI)	Risk difference per 100 000 individuals (95% CI)
	Events	Risk per 100 000 individuals	Events	Risk per 100 000 individuals	-	
Admission to hospital	231	220.8	29	14.4	93% (88–97)	206-4 (146-1–275-1)
Severe disease	157	158.9	17	12.9	92% (82-97)	145-9 (93-1-207-7)
Death	44	31.9	7	6.1	81% (59–97)	25.8 (13.0–38.5)

Estimates were obtained using the Kaplan-Meier estimator starting from day 7 after receipt of the third dose, in those who received it.

Table 2: Effectiveness of the third vaccine dose versus two vaccine doses of the BNT162b2 mRNA COVID-19 vaccine

Values and Acceptability

- In published surveys completed in August (n=5), 76%-87% of vaccinated adults reported they would get a booster dose, if available¹⁻⁵
 - In one survey, this increased to 93% of surveyed adults if it was recommended by their primary care provider

No Decrease in Effectiveness of COVID-19, Influenza vaccines when given together

^{1.} Axios Ipsos Poll. August 2, 2021.

^{2.} Axios Ipsos Poll. August 30, 2021.

^{3.} Marist Poll. September 3, 2021. https://maristpoll.marist.edu/polls/npr-pbs-newshour-marist-national-poll-covid-september-3-2021/

^{4.} Morning Consult Poll. August 25, 2021. https://morningconsult.com/2021/08/25/covid-booster-shot-poll/

^{5.} Reuters/Ipsos Poll. September 1, 2021. https://www.reuters.com/business/healthcare-pharmaceuticals/most-vaccinated-americans-want-covid-19-booster-shots-reutersipsos-poll-2021-09-01/

Anti-SARS-CoV-2 spike protein antibody responses after vaccination

Condition	Solid Organ Transplant (SOT) Recipient ^{1, 2, 3, 4}	Autoimmune/ Rheumatic Disease ⁵	Cancer 6,7	Hemodialysis ⁸
Incidence of anti-spike antibody response	14%–58%	74%-100%	51%-95%	96%
Risk factors for diminished antibody response Comment	Antimetabolites (e.g., mycophenolate mofetil) Shorter time after transplant Older age No clear surge in severe COVID-19 among vaccinated SOT recipients so far	Antimetabolites (e.g., methotrexate) B-cell depletion Corticosteroids Modest impact of tumor necrosis factor (TNF) inhibitors Lower titers in responders than in healthy controls	B-cell chronic lymphocytic leukemia (CLL) Older age On therapy Poor disease response Most with solid tumors had good response	Older age Lower lymphocyte counts Not immuno-compromised, but chronic disease has been associated with weaker response to vaccines NEJM Journal Watch

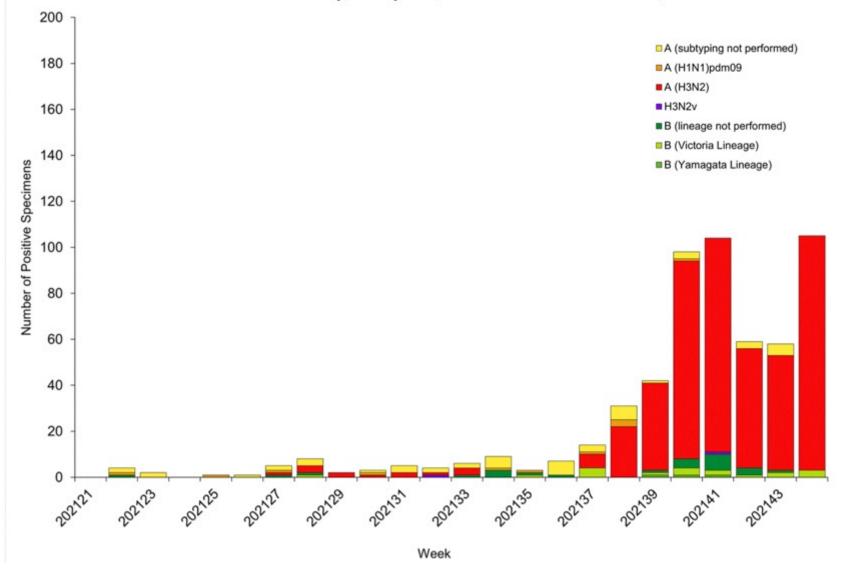
Remember! Serologic responses to not reflect potential T-cell responses to vaccines

Kaul D, NEJM Journal Watch, June 2021

Current approach to IC patients

- Recommendation for a 3rd dose of COVID-19 vaccine in immunocompromised hosts
- There are no current recommendations in routinely checking spike-protein antibody titers after vaccination
 - Spike protein Ab (+ after vaccination and natural infection) vs. nucleocapsid antigen Ab (+ only after natural infection)
 - Do not know clinical implications of titers at this time
- Because vaccination may be unreliable in IC patients, behavioral mitigation strategies of masking and social distancing should continue
- Vaccinate household/close contacts
- Vaccinate at times of reduced immunosuppression
 - Professional societies have specific guidelines that are evolving

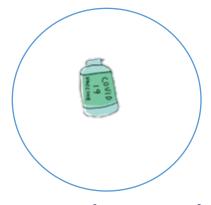
Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary, May 23, 2021 – November 6, 2021



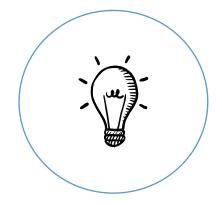
Influenza activity is low nationally, but the numbers of influenza viruses detected by labs has increased in recent weeks Majority are A (H3N2) >90% children and young adults ages 5-24

Last updated Nov 12, 2021

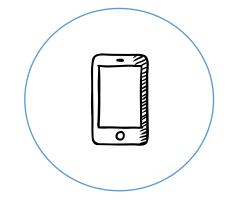




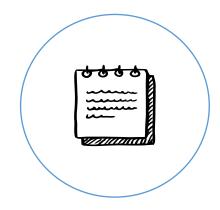
Foundational Training



Learning Collaboratives



Technical Assistance



Toolkit & Outreach
Materials

Website: https://www.illinoisvaccinates.com/

Jennie Pinkwater - jpinkwater@illinoisaap.com
Kathy Sanabria - ksanabria@illinoisaap.com

Stephanie Atella - satella@illinoisaap.com