COVID-19 Series for Free & Charitable Clinics

August 12, 2021

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AT THE FOREFRONT UChicago Medicine

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

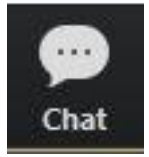
CDC's Strategy: **Empower Healthcare Personnel**: Promote confidence among healthcare personnel in their decisions to get vaccinated and recommend the vaccination to their patients.

Project Goal: Build and reinforce COVID-19 vaccine confidence among healthcare personnel in the safety net sector and, in turn, the patients they serve.

Partnerships: **The National Association of Free and Charitable Clinics** and **15 State Associations** and Federally Qualified Health Centers (FQHCs) in Puerto Rico and the U.S. Virgin Islands.

How: Provide tailored COVID-19 vaccine information to the free and charitable clinic sector through various channels and **give the FCC sector a direct line of communication to CDC**.

Reminders:

- Please use your first name and clinic name when you join the session
- Use the “chat” feature to ask questions 

- Please remember to mute your microphone 

- If you can’t connect audio via computer or you lose computer audio at anytime, you can call in to session at **(408) 638-0968, Meeting ID 961-0597-7825##**
- This activity has been approved for AMA PRA Category 1.25 Credit™ & Nursing CEUs

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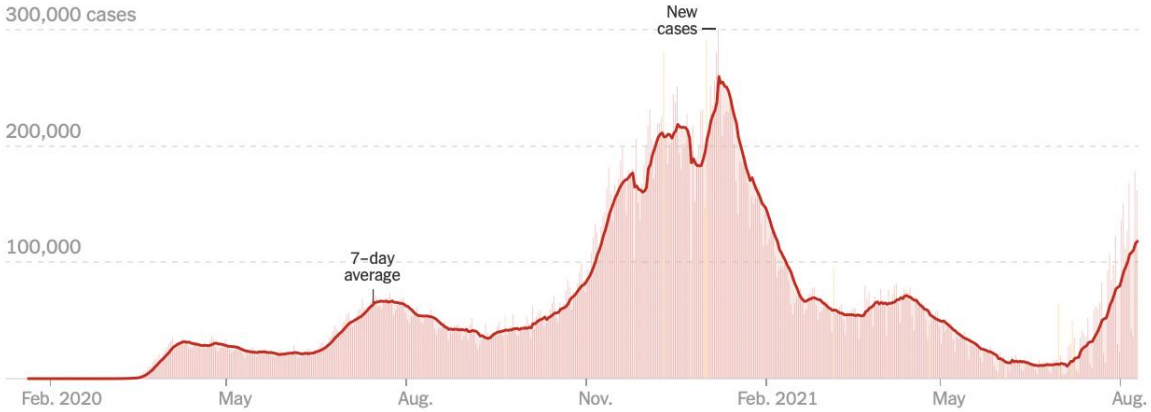
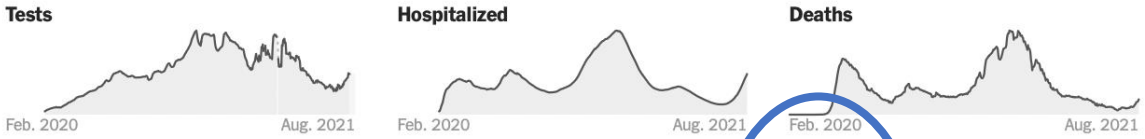
Disclosures

- We have no relevant financial interests to disclose.

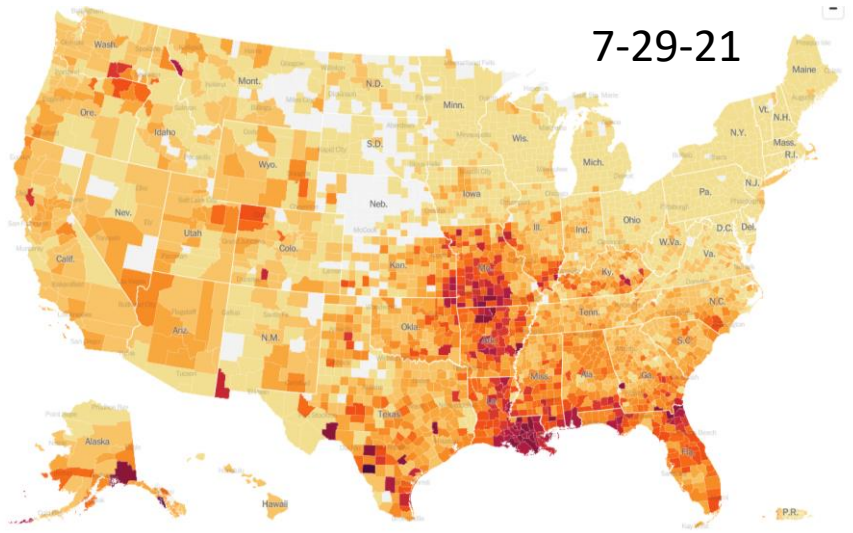
Coronavirus in the U.S.: Latest Map and Case Count

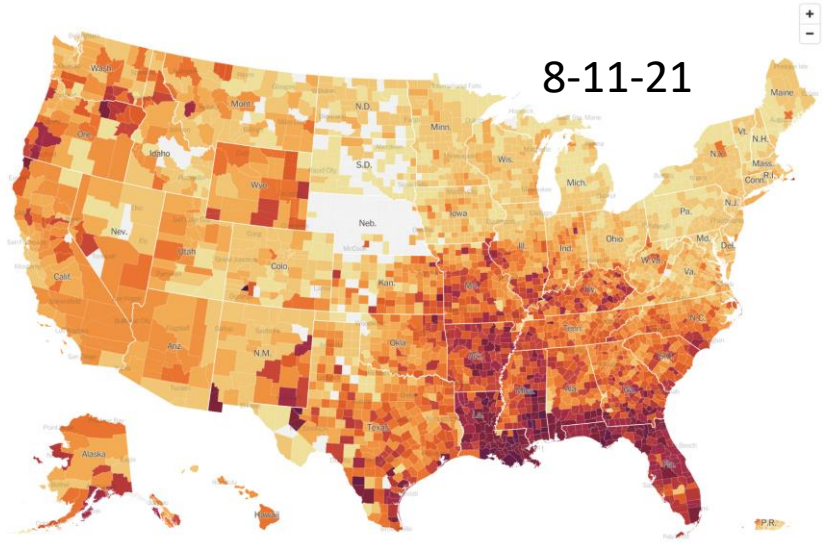
New reported cases





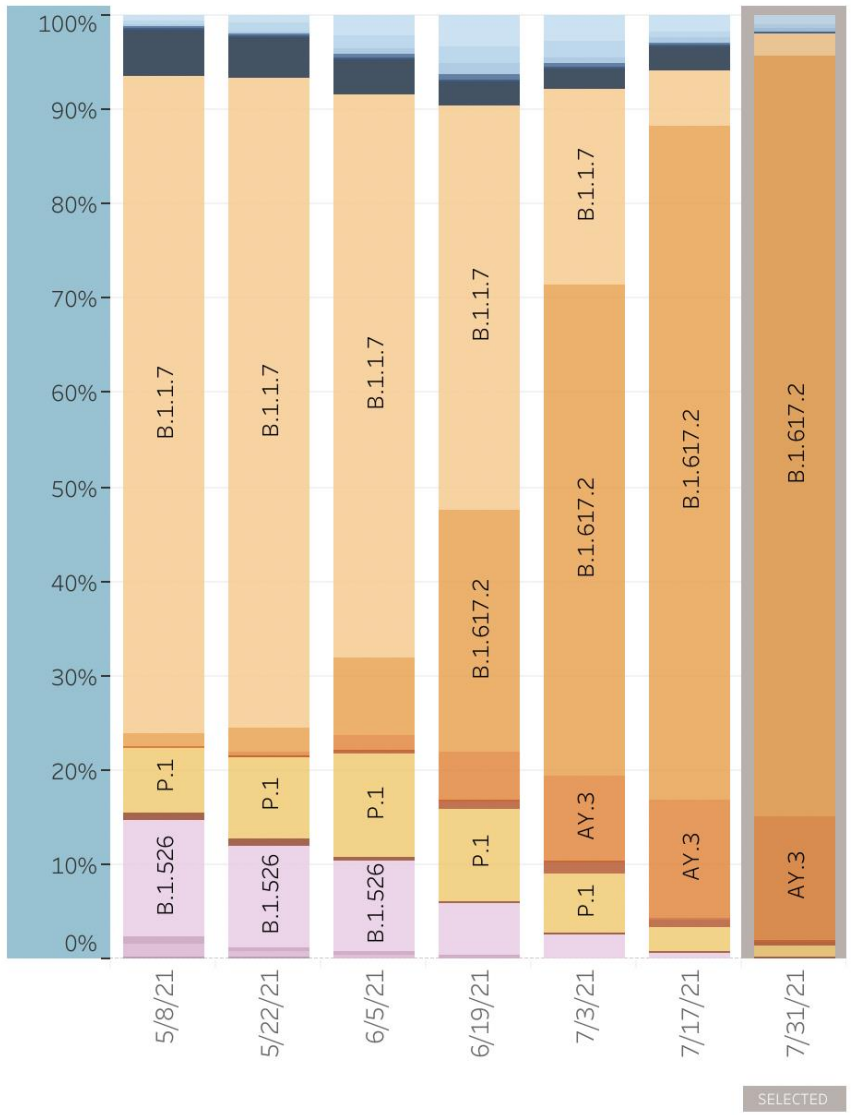
	DAILY AVG. ON AUG. 10	14-DAY CHANGE	TOTAL REPORTED
Cases	118,067	+86%	36,152,620
Tests	899,122	+47%	—
Hospitalized	66,429	+85%	—
Deaths	608	+102%	618,363





https://www.nytimes.com/interactive/2021/us/covid-cases.html?action=click&module=Top%20Stories&pgtype=Homepage

United States: 4/25/2021 – 7/31/2021



United States: 7/18/2021 – 7/31/2021 NOWCAST

USA

WHO label	Type	%Total	95%PI	
Alpha	B.1.1.7	VOC	2.4%	1.0-4.0%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	1.1%	0.2-2.2%
Delta	B.1.617.2	VOC	80.6%	76.7-84.4%
	AY.3	VOC	13.1%	9.9-16.4%
	AY.2	VOC	0.6%	0.0-1.5%
	AY.1	VOC	0.1%	0.0-0.5%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.2%	0.0-0.7%
	B.1.621		1.0%	0.2-2.0%
	B.1.621.1		0.3%	0.0-1.0%
	B.1.628		0.3%	0.0-1.0%
	Other*		0.2%	0.0-0.7%
	A.2.5		0.1%	0.0-0.5%
	B.1.626		0.0%	0.0-0.2%
	B.1.429	VOI	0.0%	0.0-0.2%
	B.1.427	VOI	0.0%	0.0-0.2%

"Delta Plus"

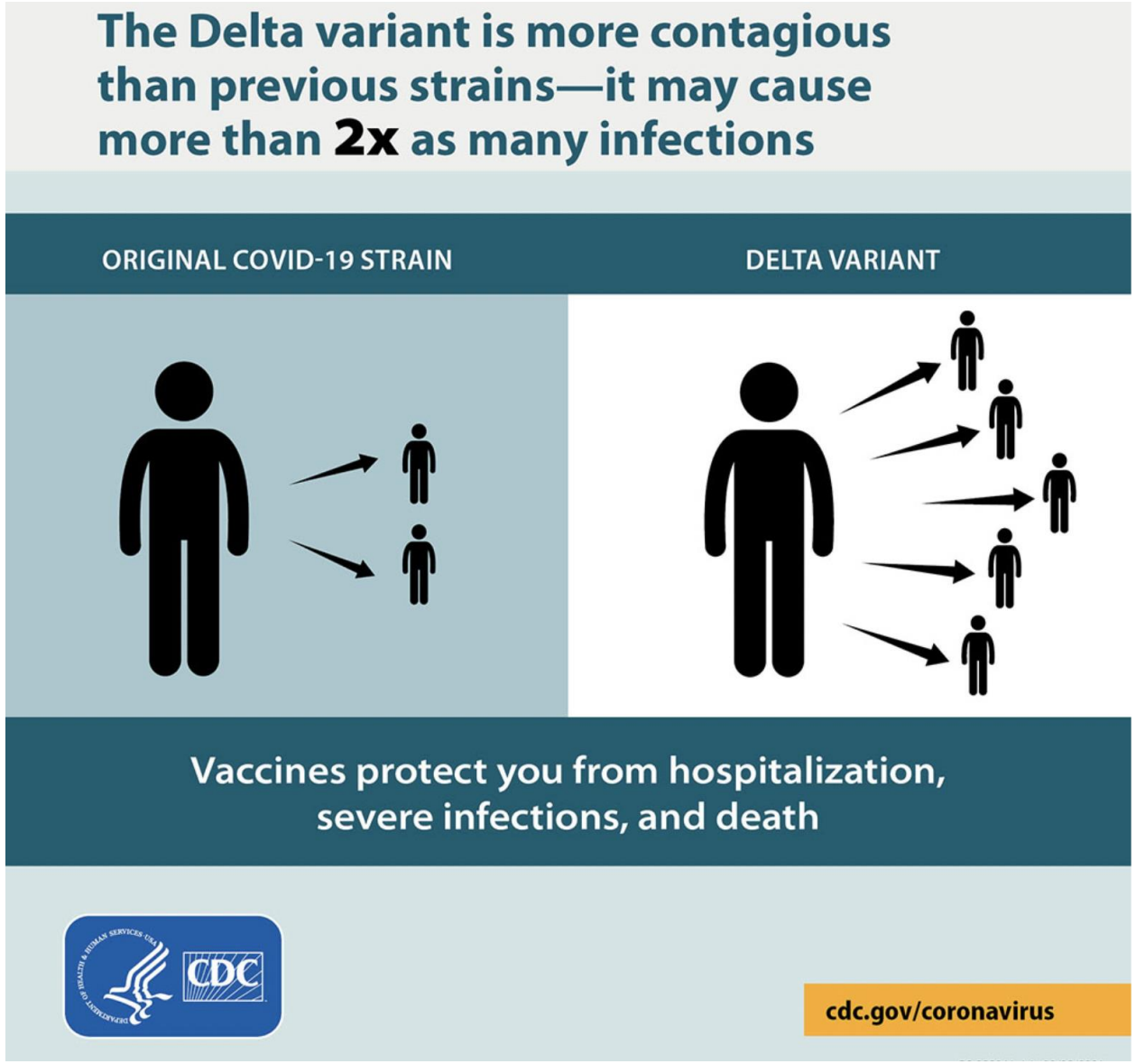
* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".

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

Sublineages of P.1 and B.1.351 (P.1.1, P.1.2, B.1.351.2, B.1.351.3) are aggregated with the parent lineage and included in parent lineage's proportion. AY.3.1 is agregated with its parent lineage AY.3.

Delta Variant

- **The Delta variant is more contagious:** The Delta variant is highly contagious, nearly twice as contagious as previous variants.
- **Some data suggest the Delta variant might cause more severe illness than previous strains in unvaccinated persons.** In two different studies from Canada and Scotland, patients infected with the Delta variant were more likely to be hospitalized than patients infected with Alpha or the original virus strains.
- **Unvaccinated people remain the greatest concern:** Although breakthrough infections happen much less often than infections in unvaccinated people, individuals infected with the Delta variant, including fully vaccinated people with symptomatic breakthrough infections, can transmit it to others. CDC is continuing to assess data on whether fully vaccinated people with asymptomatic breakthrough infections can transmit. However, the greatest risk of transmission is among unvaccinated people who are much more likely to contract, and therefore transmit the virus.
- **Fully vaccinated people with Delta variant breakthrough infections can spread the virus to others. However, vaccinated people appear to be infectious for a shorter period:** Previous variants typically produced less virus in the body of infected fully vaccinated people (breakthrough infections) than in unvaccinated people. In contrast, the Delta variant seems to produce the same high amount of virus in both unvaccinated and fully vaccinated people. However, like other variants, the amount of virus produced by Delta breakthrough infections in fully vaccinated people also goes down faster than infections in unvaccinated people. This means fully vaccinated people are likely infectious for less time than unvaccinated people.



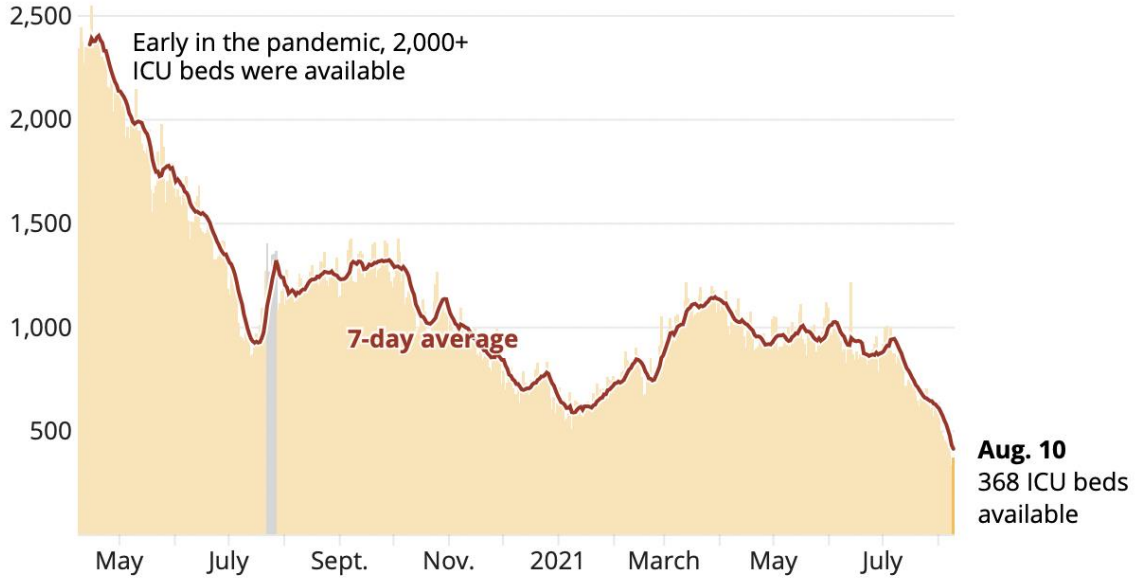
“Delta Plus” Variants

- Also known as AY.1, AY.2, AY.3
- Each has additional mutations on top of the Delta baseline mutation
- Of these configurations:
  - **None** more transmissible than original Delta
  - **None** more severe disease
  - **None** more able to evade vaccination
- Centers for Disease Control and Prevention categorizes coronavirus variants. They are, in ascending order of concern: variant of interest, variant of concern and variant of high consequence.
  - There have been NO variants of high consequence to date – this would require a new vaccine

Dozens of Texas hospitals are out of ICU beds as COVID-19 cases again overwhelm the state's capacity

> "This surge is by far the fastest and most aggressive that we've seen," said the health authority for Austin and Travis County, who urged eligible Texans to get vaccinated.

At least 53 Texas hospitals have no available ICU capacity, according to numbers reported to the federal government during the week ending Aug. 5. In Austin, five hospitals were at or above 90% of their ICU capacity during the same period, with two reporting no available ICU beds.



Waning effectiveness?

- Study at Mayo clinic, Puranik et al.
- January to July 2021, during which either the Alpha or Delta variant was highly prevalent. Defined cohorts of vaccinated and unvaccinated individuals from Minnesota (n = 25,589 each) matched on age, sex, race, history of prior SARS-CoV-2 PCR testing, and date of full vaccination
- Both vaccines were highly effective during this study period against SARS-CoV-2 infection (mRNA-1273: 86%, 95%CI: 81-90.6%; BNT162b2: 76%, 95%CI: 69-81%) and COVID-19 associated hospitalization (mRNA-1273: 91.6%, 95% CI: 81-97%; BNT162b2: 85%, 95% CI: 73-93%).
- However … July, 2021:
  - Effectiveness against infection was considerably lower for mRNA-1273 (76%, 95% CI: 58-87%)
  - Even more pronounced reduction in effectiveness for BNT162b2 (42%, 95% CI: 13-62%).
  - Delta variant prevalence in Minnesota increased from 0.7% in May to over 70% in July whereas the Alpha variant prevalence decreased from 85% to 13% over the same time period.
  - Comparing rates of infection between matched individuals fully vaccinated with mRNA-1273 versus BNT162b2 across Mayo Clinic Health System sites in multiple states (Minnesota, Wisconsin, Arizona, Florida, and Iowa), mRNA-1273 conferred a two-fold risk reduction against breakthrough infection compared to BNT162b2 (IRR = 0.50, 95% CI: 0.39-0.64).
  - In Florida, which is currently experiencing its largest COVID-19 surge to date, the risk of infection in July after full vaccination with mRNA-1273 was about 60% lower than after full vaccination with BNT162b2 (IRR: 0.39, 95% CI: 0.24-0.62).
- Observational study highlights that while both mRNA COVID-19 vaccines strongly protect against infection and severe disease, further evaluation of mechanisms underlying differences in their effectiveness such as dosing regimens and vaccine composition are warranted.

doi: https://doi.org/10.1101/2021.08.06.21261707

Johnson & Johnson ’s Covid-19 vaccine vs. Delta

- The South African study of nearly 480,000 healthcare workers, known as Sisonke, found that the J&J vaccine has an efficacy of up to 71% against hospitalization from the Delta variant, 67% against hospitalization from the Beta variant and up to 96% against death
- Conversely, BNT162b2 and mRNA-1273-elicited antibodies showed modest neutralization resistance against Beta, Delta, Delta plus and Lambda variants whereas Ad26.COV2.S-elicited antibodies from a significant fraction of vaccinated individuals were of low neutralizing titer (IC_{50} <50). The data underscore the importance of surveillance for breakthrough infections that result in severe COVID-19 and suggest the benefit of a second immunization following Ad26.COV2.S to increase protection against the variants.
- Recently San Francisco DPH said boosters would be allowed for those who received the J & J vaccine – they are “accommodating but not recommending this approach”

How Rates of New Covid-19 Hospital Admissions and Deaths Compare

Among fully vaccinated people and among people who were not fully vaccinated in each state since vaccination began.

	HOSPITALIZATION RATE PER 100,000			DEATH RATE PER 100,000		
STATE ▲	FOR VACCINATED PEOPLE	FOR UNVACCINATED PEOPLE		FOR VACCINATED PEOPLE	FOR UNVACCINATED PEOPLE	
Alabama	9	696	75x higher for unvaccinated people	3	124	48x higher for unvaccinated people
Alaska	9	154	17x	1	11	10x
Arizona	27	1,306	47x	2	182	73x
California	9	647	68x	1	58	58x
Colorado	24	567	22x	4	37	8x
Delaware	7	978	148x	2	26	14x
Georgia	5	735	161x	1	99	87x
Idaho	11	288	25x	2	30	16x
Illinois	20	1,001	48x	5	68	11x
Indiana	9	547	57x	4	29	7x

https://www.nytimes.com/interactive/2021/08/10/us/covid-breakthrough-infections-vaccines.html

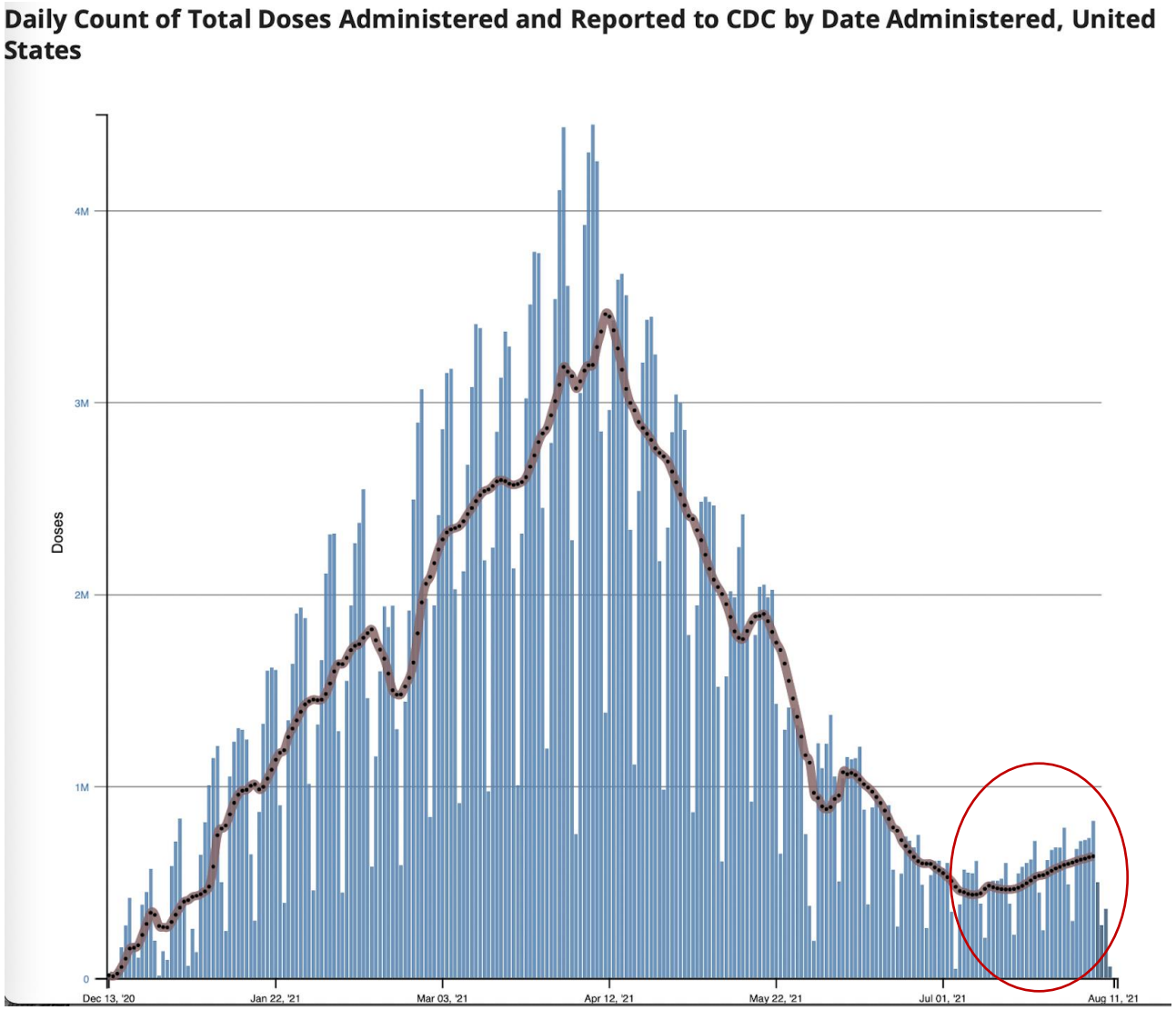
CDC Recommends Vaccine during Pregnancy

- COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
- Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy has been growing. These data suggest that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy.
- There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems in women or men.
- No adverse pregnancy-related outcomes occurred in previous clinical trials that used the same vaccine platform as the J&J/Janssen COVID-19 vaccine:
- Early data on the safety of receiving an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) during pregnancy are reassuring:
- CDC released the first U.S. data on the safety of receiving an mRNA COVID-19 vaccine during pregnancy. The report analyzed data from three safety monitoring systems in place to gather information about COVID-19 vaccination during pregnancy. These early data did not find any safety concerns for pregnant people who were vaccinated or their babies.
- Another report looked at pregnant people enrolled in the v-safe pregnancy registry who were vaccinated before 20 weeks of pregnancy. Scientists did not find an increased risk for miscarriage among people who received an mRNA COVID-19 vaccine during pregnancy.
- Early data suggest receiving an mRNA COVID-19 vaccine during pregnancy reduces the risk for infection: A recent study from Israel compared pregnant people who received an mRNA COVID-19 vaccine with those who did not. Scientists found that vaccination lowered the risk of infection from the virus that causes COVID-19.
- Vaccination of pregnant people builds antibodies that might protect their baby: When pregnant people receive an mRNA COVID-19 vaccine during pregnancy, their bodies build antibodies against COVID-19, similar to non-pregnant people. Antibodies made after a pregnant person received an mRNA COVID-19 vaccine were found in umbilical cord blood. This means COVID-19 vaccination during pregnancy might help protect babies against COVID-19. More data are needed to determine how these antibodies, similar to those produced with other vaccines, may provide protection to the baby.

Will Boosters Be Needed?

- Most likely, yes.
- When?
  - Soon
- For who?
  - Those most at risk and immunocompromised (transplants, immunosuppressant medications)
- Will we need a COVID-19 vaccine 2.0 aimed at newer variants?
  - IMHO, yes. We have started an arms race… ugh.

Maybe there is hope?



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Health is on the way.™

Protecting your clinics: New OSHA requirements and Vaccine mandates

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THIS WEEK'S TOPIC

Protecting Your Clinics: New OSHA Requirements and Vaccine Mandates

FREE EVENT

A COVID-19 Q&A Series for Free and Charitable Clinics

Thursday, August 12, 5:00 – 6:15 p.m. CST

REGISTER AND JOIN

THIS WEEK: Join infectious disease expert, Stephen Schrantz, MD (University of Chicago Medicine assistant professor of medicine), and Breanna Lathrop (Chief Operations Officer at Good Samaritan Health Center in Atlanta), for a 75-minute online discussion about meeting new OSHA requirements and the possibility of mandating vaccines in your clinics. This session will include an epidemiological update on COVID-19, tips for creating your written COVID-19 plan (the new OSHA requirement), and conversations about mandating vaccinations for staff and volunteers.

Come ready to build COVID-19 preparedness plans and learn from one another about:

- Writing your OSHA-required COVID-19 plan
- Things to consider when writing your COVID-19 plan
- Mandating vaccines in your clinic

This activity has been approved for AMA PRA Category 1.25 Credits™ and Nursing CEU Credits

This ongoing series is brought to you by a partnership between Americares and ECHO-Chicago at University of Chicago. This collaboration puts FQC providers and volunteers in direct contact with a panel of experts who will break down recent developments surrounding COVID-19 and provide strategies for clinical conversations and care that you can immediately implement in your free and charitable clinic.

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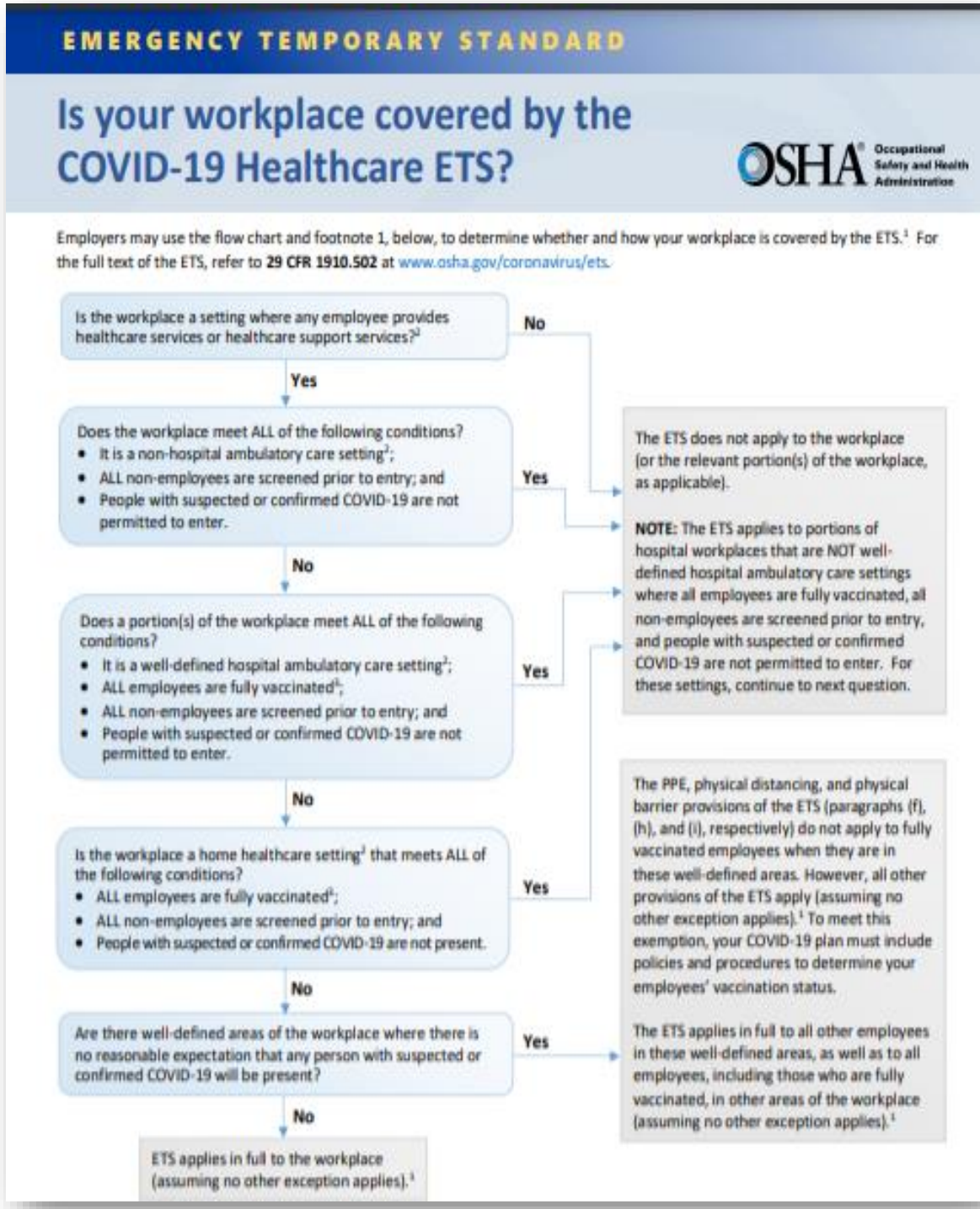
Americares is a health-focused relief and development organization that responds to people affected by poverty or disaster with life-changing health programs, medicine, medical supplies and emergency aid.

Disclaimer: This project was funded in part by a cooperative agreement with the Centers for Disease Control and Prevention grant number 1 NU50CK000588-01-00. The Centers for Disease Control and Prevention is an agency within the Department of Health and Human Services (HHS). The contents of this resource center do not necessarily represent the policy of CDC or HHS and should not be considered an endorsement by the Federal Government.

Creating your COVID-19 Plan

- June 2021 OSHA COVID-19 Emergency Temporary Standard
- *Are you covered under ETS?*
  - https://www.osha.gov/sites/default/files/publications/OSHA4125.pdf
- Applies at least in part if:
  - You provide any care to people with COVID-19, suspected COVID-19 or symptomatic individuals
  - Unvaccinated employees



EMERGENCY TEMPORARY STANDARD

Is your workplace covered by the COVID-19 Healthcare ETS?

OSHA Occupational Safety and Health Administration

Employers may use the flow chart and footnote 1, below, to determine whether and how your workplace is covered by the ETS.[1] For the full text of the ETS, refer to **29 CFR 1910.502** at www.osha.gov/coronavirus/ets.

Is the workplace a setting where any employee provides healthcare services or healthcare support services?[2]

No → The ETS does not apply to the workplace (or the relevant portion(s) of the workplace, as applicable).

Yes

Does the workplace meet ALL of the following conditions?
- It is a non-hospital ambulatory care setting[2];
- ALL non-employees are screened prior to entry; and
- People with suspected or confirmed COVID-19 are not permitted to enter.

Yes → The ETS does not apply to the workplace (or the relevant portion(s) of the workplace, as applicable).

NOTE: The ETS applies to portions of hospital workplaces that are NOT well-defined hospital ambulatory care settings where all employees are fully vaccinated, all non-employees are screened prior to entry, and people with suspected or confirmed COVID-19 are not permitted to enter. For these settings, continue to next question.

No

Does a portion(s) of the workplace meet ALL of the following conditions?
- It is a well-defined hospital ambulatory care setting[2];
- ALL employees are fully vaccinated[3];
- ALL non-employees are screened prior to entry; and
- People with suspected or confirmed COVID-19 are not permitted to enter.

Yes → The ETS does not apply to the workplace (or the relevant portion(s) of the workplace, as applicable).

The PPE, physical distancing, and physical barrier provisions of the ETS (paragraphs (f), (h), and (i), respectively) do not apply to fully vaccinated employees when they are in these well-defined areas. However, all other provisions of the ETS apply (assuming no other exception applies).[1] To meet this exemption, your COVID-19 plan must include policies and procedures to determine your employees' vaccination status.

No

Is the workplace a home healthcare setting[2] that meets ALL of the following conditions?
- ALL employees are fully vaccinated[3];
- ALL non-employees are screened prior to entry; and
- People with suspected or confirmed COVID-19 are not present.

Yes → The ETS does not apply to the workplace (or the relevant portion(s) of the workplace, as applicable).

No

Are there well-defined areas of the workplace where there is no reasonable expectation that any person with suspected or confirmed COVID-19 will be present?

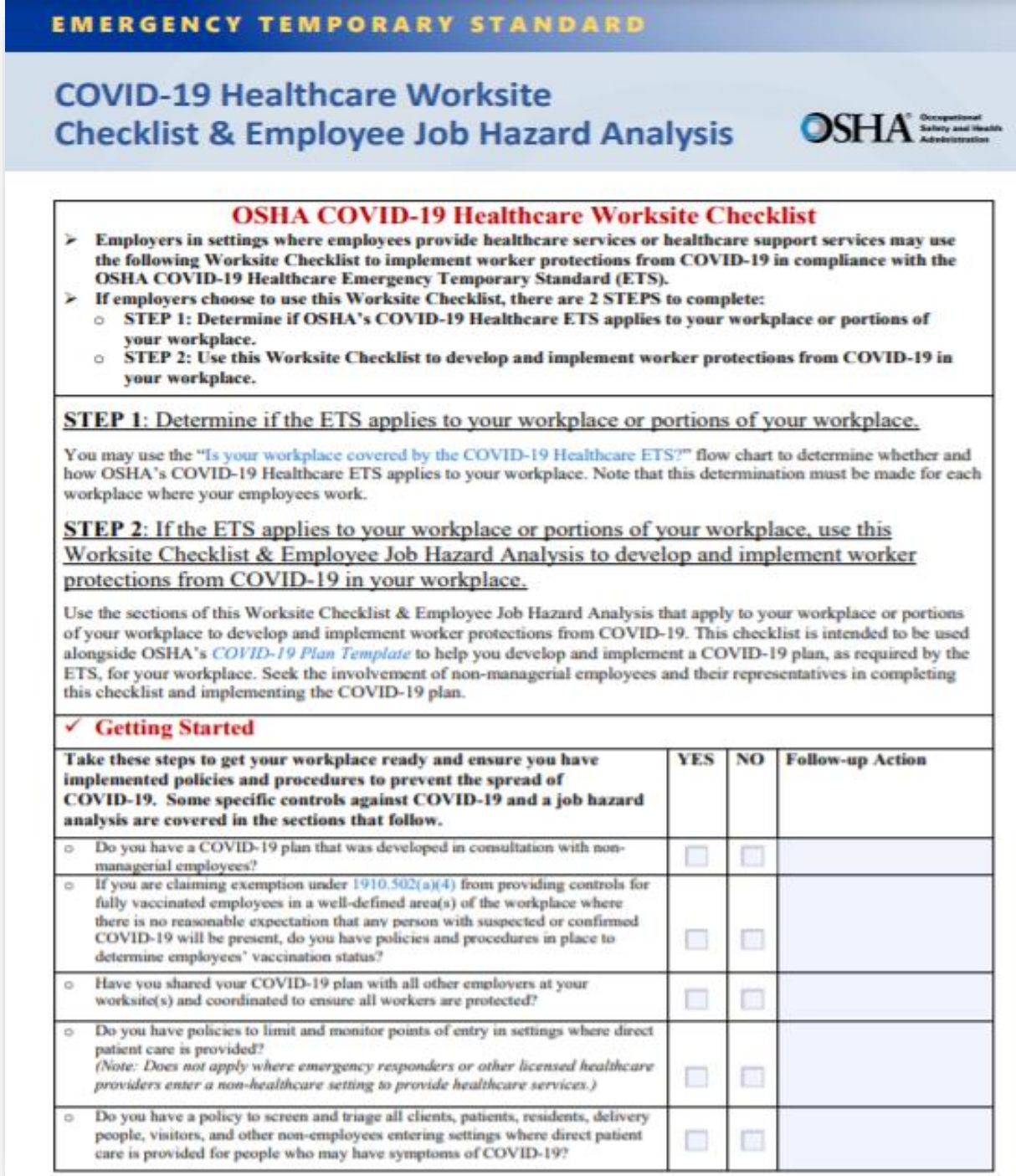
Yes → The ETS applies in full to all other employees in these well-defined areas, as well as to all employees, including those who are fully vaccinated, in other areas of the workplace (assuming no other exception applies).[1]

No → ETS applies in full to the workplace (assuming no other exception applies).[1]

Creating your COVID-19 Plan

- COVID-19 Plan Check-list
- https://www.osha.gov/sites/default/files/COVID-19_Healthcare_ETS_Worksite_Checklist_Employee_Job_Hazard_Analysis.pdf

- Template
  - Can download from OSHA.gov
  - Work with what you already have in place



EMERGENCY TEMPORARY STANDARD

COVID-19 Healthcare Worksite Checklist & Employee Job Hazard Analysis

OSHA Occupational Safety and Health Administration

OSHA COVID-19 Healthcare Worksite Checklist

- **Employers in settings where employees provide healthcare services or healthcare support services may use the following Worksite Checklist to implement worker protections from COVID-19 in compliance with the OSHA COVID-19 Healthcare Emergency Temporary Standard (ETS).**
- **If employers choose to use this Worksite Checklist, there are 2 STEPS to complete:**
  - **STEP 1: Determine if OSHA's COVID-19 Healthcare ETS applies to your workplace or portions of your workplace.**
  - **STEP 2: Use this Worksite Checklist to develop and implement worker protections from COVID-19 in your workplace.**

STEP 1: Determine if the ETS applies to your workplace or portions of your workplace.

You may use the "Is your workplace covered by the COVID-19 Healthcare ETS?" flow chart to determine whether and how OSHA's COVID-19 Healthcare ETS applies to your workplace. Note that this determination must be made for each workplace where your employees work.

STEP 2: If the ETS applies to your workplace or portions of your workplace, use this Worksite Checklist & Employee Job Hazard Analysis to develop and implement worker protections from COVID-19 in your workplace.

Use the sections of this Worksite Checklist & Employee Job Hazard Analysis that apply to your workplace or portions of your workplace to develop and implement worker protections from COVID-19. This checklist is intended to be used alongside OSHA's *COVID-19 Plan Template* to help you develop and implement a COVID-19 plan, as required by the ETS, for your workplace. Seek the involvement of non-managerial employees and their representatives in completing this checklist and implementing the COVID-19 plan.

✓ **Getting Started**

Take these steps to get your workplace ready and ensure you have implemented policies and procedures to prevent the spread of COVID-19. Some specific controls against COVID-19 and a job hazard analysis are covered in the sections that follow.	**YES**	**NO**	**Follow-up Action**
○ Do you have a COVID-19 plan that was developed in consultation with non-managerial employees?	☐	☐	
○ If you are claiming exemption under 1910.502(a)(4) from providing controls for fully vaccinated employees in a well-defined area(s) of the workplace where there is no reasonable expectation that any person with suspected or confirmed COVID-19 will be present, do you have policies and procedures in place to determine employees' vaccination status?	☐	☐	
○ Have you shared your COVID-19 plan with all other employers at your worksite(s) and coordinated to ensure all workers are protected?	☐	☐	
○ Do you have policies to limit and monitor points of entry in settings where direct patient care is provided? *(Note: Does not apply where emergency responders or other licensed healthcare providers enter a non-healthcare setting to provide healthcare services.)*	☐	☐	
○ Do you have a policy to screen and triage all clients, patients, residents, delivery people, visitors, and other non-employees entering settings where direct patient care is provided for people who may have symptoms of COVID-19?	☐	☐	

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Major Components of COVID-19 Plan

Plan developed with non-managerial staff

- Sharing plan

Monitoring points of entry and screening patients/visitors

Employee health

- Health screening and symptom notification
- Tracking employee cases and notification
- Support employee testing and vaccination
- Policies around Standard and Transmission-Based Precautions

Physical distancing (exempts vaccinated employees)

- Limiting visitors, signage, spacing demarcations
- Telehealth/teleworking

Major Components of COVID-19 Plan

Ventilation	HVAC upkeep and filters Maximizing ventilation options
Cleaning	Systems for cleaning patient care and high-touch areas Provision of cleaning products
PPE	Facemask provision N95 requirements
Fixed work location for employees outside of clinical care	

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Major Components of COVID-19 Plan

Job hazard analysis

Controls for distancing limitations
Controls for potential exposure

COVID-19 training program

Transmission and symptoms
Policies and procedures

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Mandating Vaccination

- Create a vaccine policy and distribute to all staff
- Purpose- Patient safety, employee protection
- Scope- Applies to who? Example, employees and volunteers, not patients
- Policy- Set the date by which vaccination must occur, method of proving vaccination, and consequence if remaining unvaccinated

"Depending upon individual circumstances, employees who do not fulfill one of these two requirements will be excluded from the workplace, placed on unpaid leave, and their employment will be subject to termination."

- Requests for exemptions- what exemptions exist and how to request them

Mandating Vaccination

Specific Dates

Provide specific dates

- Date by which you need to be fully vaccinated (2 weeks after second dose of Moderna/Pfizer, or single dose of Johnson&Johnson
- Date by which vaccination series must be started to be in compliance

Exemption

Provide information about exemption

- Religious exemption
- Medical exemption

Barriers

Plan to address barriers

- Vaccine information and space for questions/concerns
- Time off for vaccination and recovery
- Assistance with associated costs

Mandating Vaccination

- What if an employee refuses?
  - With exemption
    - Follow the process outlined in the American Disabilities Act
    - Depending on job, determine if the job or parts of it can be safely completed with modifications
  - Without exemption
    - Indefinitely “exclude” from work

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Email: infectionprevention@americares.org

Visit **americares.org/coronavirus** to learn more.

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Questions?

Thank you!

Next Session: Thursday, August 26th

Resources & recording of the session

https://www.echo-chicago.org/resources/covid19/

This project was funded in part by a cooperative agreement with the Centers for Disease Control and Prevention grant number 1 NU50CK000588-01-00. The Centers for Disease Control and Prevention is an agency within the Department of Health and Human Services (HHS). The contents of this resource center do not necessarily represent the policy of CDC or HHS and should not be considered an endorsement by the Federal Government.

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