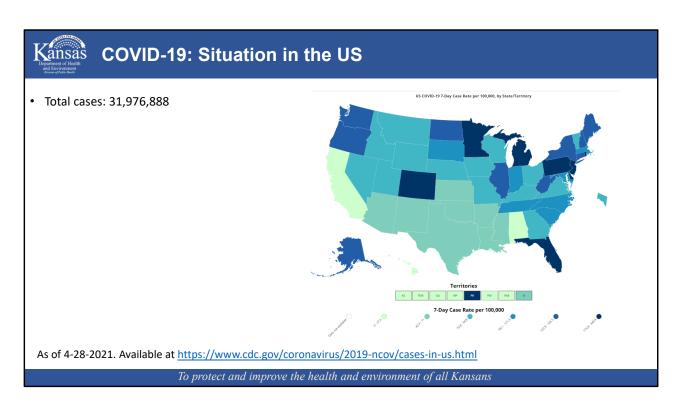


Global Map: https://www.cdc.gov/coronavirus/2019-ncov/locations-confirmed-cases.html.

Last week, we had 143.3 million cases around the world and 3 million deaths.

This week, there are almost 149.2 million cases and we have 3,145,239 deaths around the world.



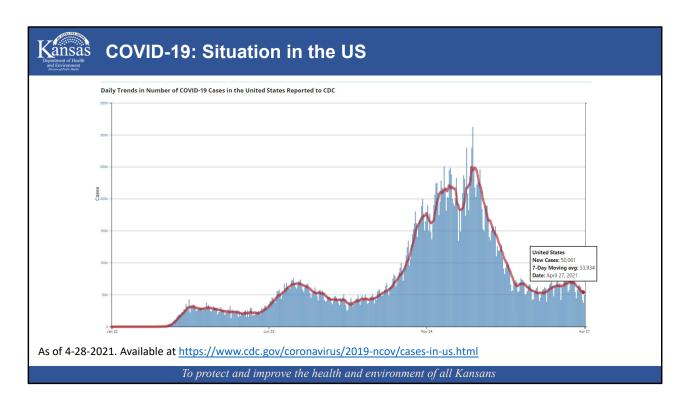
Last week in the US:

Total cases: 31,602,676 (31.6 million)

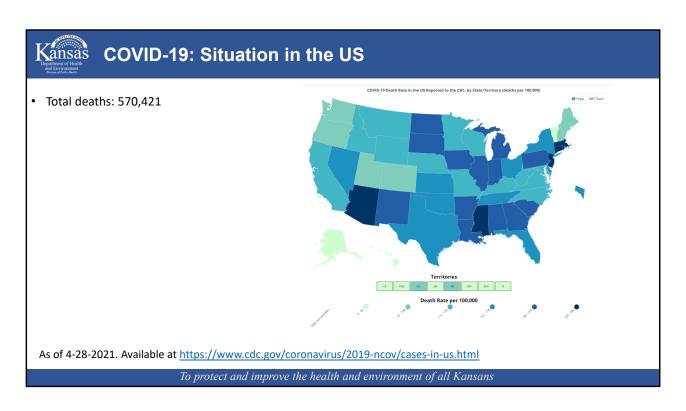
As of yesterday

This week:

Total cases: 31,976,888



In the US, you can see that we are averaging almost 54,000 new cases each day according to the 7-day average. That is down from 66,000 from the previous week.



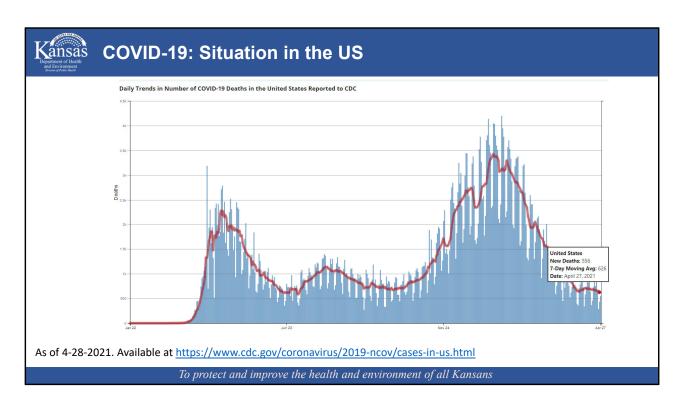
Last week in the US:

Total deaths: 565,613 (over 565,000)

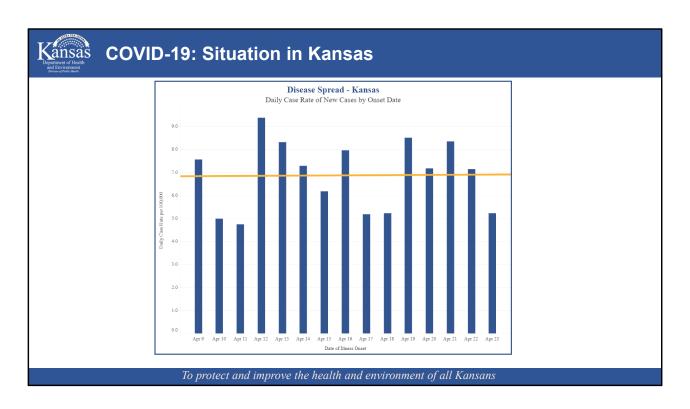
As of yesterday

This week:

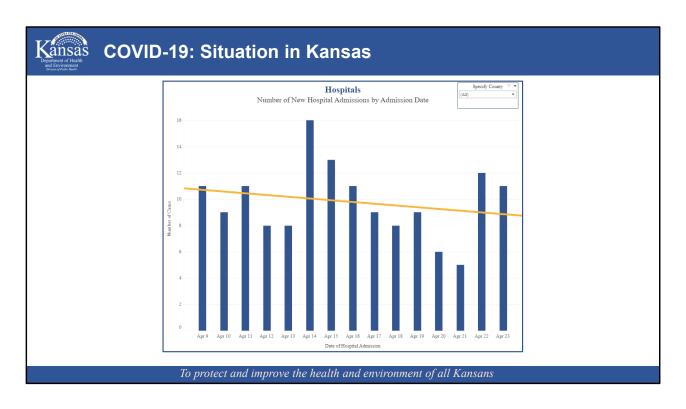
Total deaths: 570,421



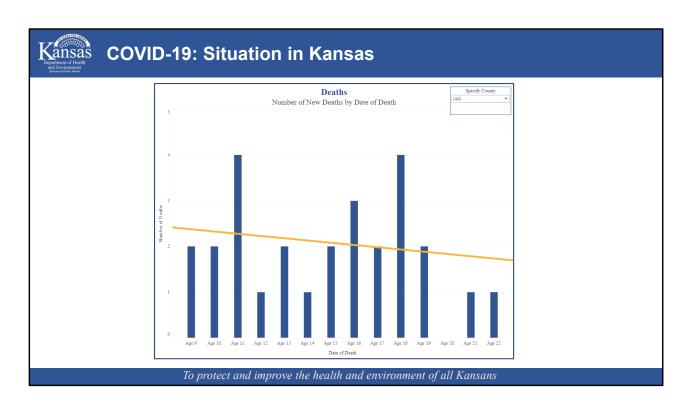
The 7-day moving average daily death trend in the United States is about 625 deaths per day.



Moving on to KS specific data. For our first Disease Spread metric, which is the daily rate of new cases, the trend line last week was pretty flat and looks similar this week.



For hospitalizations, the trend last week was flat and is decreasing slightly this week.

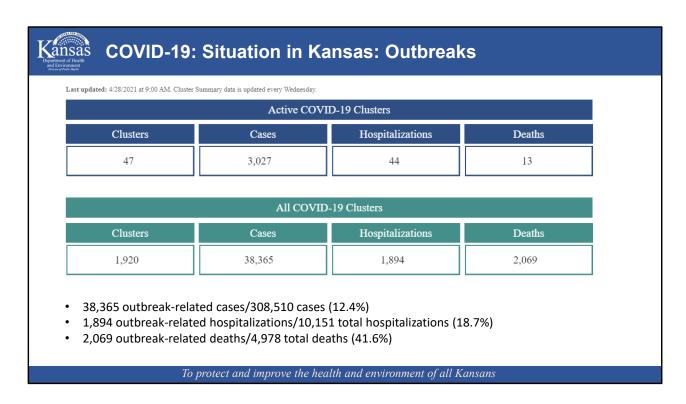


And for deaths, last week the trend was flat and this week it is decreasing.

COVID-19 Cases  308,510  Data are preliminary and subject to quality improveme Last updated: 4/28/2021 at 9:00 AM. There were 645		Statewide Deaths  4,978  ospitalizations reported since Monday, 4/26/2021.	People Tested 1,370,861
Data are preliminary and subject to quality improveme	ent and quality assurance validation.		
		ospitalizations reported since Monday, 4/26/2021.	
		nd environment of all Kansans	

As of yesterday, we had 308,510 cases (which is an increase of 1,627 cases since last week) and 4,978 deaths statewide (that's an increase of 17 deaths since last week).

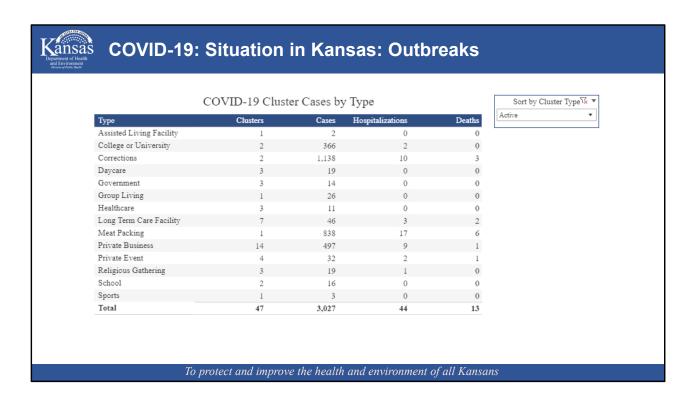
There were 645 new cases and 8 new deaths reported from Monday 4/26 to Wednesday 4/28.



### Moving on to outbreaks:

As of late Tuesday night, we had 1,920 outbreaks across the state; This week we have 47 active clusters which is down from 48 last week.

Our percentage of outbreak related cases is 12.4%, outbreak-related hospitalizations is about 18.7% and outbreak-related deaths is about 41.6%.



We currently have 2 active clusters in colleges and universities, 2 in corrections, 7 in LTCFs (that's down from 9 last week), 14 in private businesses and 2 in schools.

Don't forget, if you are interested in seeing the list of named locations with 5 or more cases within the last 14 days, you can go to the dashboard.



# Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January—March 2021

Early Release / April 28, 2021 / 70

Mark W. Tenforde, MD, PhD¹; Samantha M. Olson, MPH¹; Wesley H. Self, MD²; H. Keipp Talbot, MD²; Christopher J. Lindsell, PhD²; Jay S. Steingrub, MD³; Nathan I. Shapiro, MD⁴; Adit A. Ginde, MD⁵; David J. Douin, MD⁵; Matthew E. Prekker, MD⁶; Samuel M. Brown, MDˀ; Ithan D. Peltan, MDˀ; Michelle N. Gong, MD⁶; Amira Mohamed, MD⁶; Akram Khan, MD⁰; Matthew C. Exline, MD¹⁰; D. Clark Files, MD¹¹; Kevin W. Gibbs, MD¹¹; William B. Stubblefield, MD²; Jonathan D. Casey, MD²; Todd W. Rice, MD²; Carlos G. Grijalva, MD²; David N. Hager, MD, PhD¹²; Arber Shehu, MD¹²; Nida Qadir, MD¹³; Steven Y. Chang, MD, PhD¹³; Jennifer G. Wilson, MD¹⁴; Manjusha Gaglani, MBBS¹5.¹6; Kempapura Murthy, MPH¹⁵; Nicole Calhoun, LMSW, MPA¹⁵; Arnold S. Monto, MD¹¬; Emily T. Martin, PhD¹¬; Anurag Malani, MD¹®; Richard K. Zimmerman, MD¹⁰; Fernanda P. Silveira, MD¹⁰; Donald B. Middleton, MD¹⁰; Yuwei Zhu, MD²; Dayna Wyatt²; Meagan Stephenson, MPH¹; Adrienne Baughman²; Kelsey N. Womack, PhD²; Kimberly W. Hart²; Miwako Kobayashi, MD¹; Jennifer R. Verani, MD¹; Manish M. Patel, MD¹; IVY Network; HAIVEN Investigators (View author affiliations)

#### Available at:

https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm?s\_cid=mm7018e1\_e&ACSTrackingID=usCDC\_921-DM55819&ACSTrackingLabel=MMWR%20Early%20Release%20-

%20Vol.%2070%2C%20April%2028%2C%202021&deliveryName=usCDC 921-DM55819

To protect and improve the health and environment of all Kansans

#### MMWR article:

Adjusted vaccine effectiveness (VE) against COVID-19—associated hospitalization among adults aged ≥65 years was estimated to be 94% (95% confidence interval [CI] = 49%—99%) for full vaccination and 64% (95% CI = 28%—82%) for partial vaccination.



# Kansas COVID-19: New Literature

Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021

Early Release / April 27, 2021 / 70

Jessica R. MacNeil, MPH<sup>1</sup>; John R. Su, MD, PhD<sup>1</sup>; Karen R. Broder, MD<sup>1</sup>; Alice Y. Guh, MD<sup>1</sup>; Julia W. Gargano, PhD<sup>1</sup>; Megan Wallace, DrPH<sup>1</sup>; Stephen C. Hadler, MD1; Heather M. Scobie, PhD1; Amy E. Blain, MPH1; Danielle Moulia, MPH1; Matthew F. Daley, MD2; Veronica V. McNally, JD<sup>3</sup>; José R. Romero, MD<sup>4</sup>; H. Keipp Talbot, MD<sup>5</sup>; Grace M. Lee, MD<sup>6</sup>; Beth P. Bell, MD<sup>7</sup>; Sara E. Oliver, MD<sup>1</sup> (View author affiliations)

View suggested citation

Summary

Article Metrics

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s cid=mm7017e4 e&ACSTrackingID=USCDC 921-DM55766&ACSTrackingLabel=MMWR%20Early%20Release%20-

%20Vol.%2070%2C%20April%2027%2C%202021&deliveryName=USCDC 921-DM55766

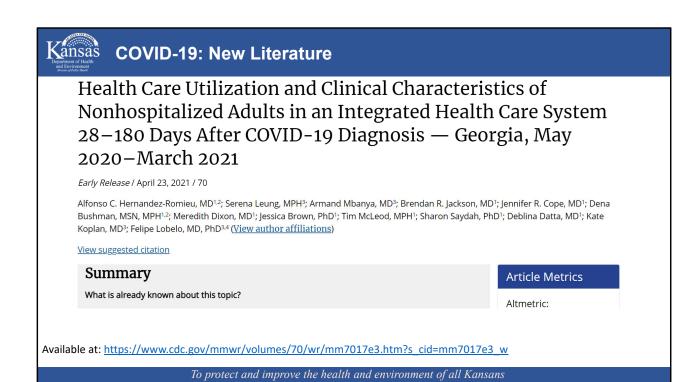
To protect and improve the health and environment of all Kansans

#### MMWR article:

On April 13, 2021, CDC and FDA recommended a pause in the use of the Janssen COVID-19 vaccine after reports of six U.S. cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, a rare thromboembolic syndrome, among Janssen COVID-19 vaccine recipients (3).

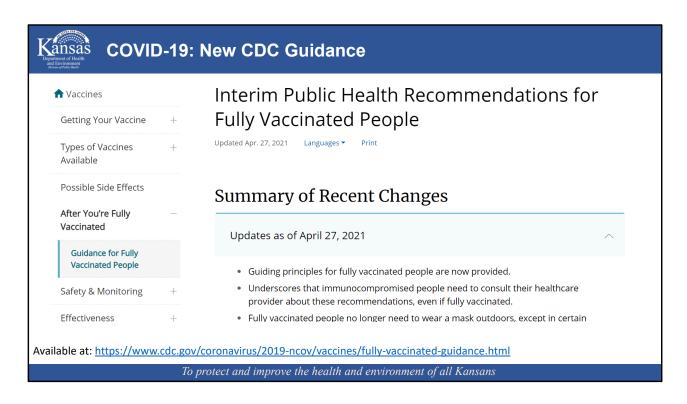
On April 23, 2021, after a discussion of the benefits and risks of resuming vaccination, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under the FDA's EUA, which now includes a warning that rare clotting events might occur after vaccination, primarily among women aged 18–49 years. Patient and provider education about the risk for TTS with the Janssen COVID-19 vaccine, especially among women aged <50 years, as well as the availability of alternative COVID-19 vaccines, is required to guide vaccine decision-making and ensure early recognition and clinical management of TTS.

As of April 21, 2021, approximately 7.98 million doses of the Janssen COVID-19 vaccine had been administered in the United States. During March 2-April 21, 2021, the Vaccine Adverse Event Reporting System (VAERS) (7), the national vaccine safety monitoring system, had received 15 reports of TTS after Janssen COVID-19 vaccination, with clot's located in the cerebral venous sinuses and other unusual locations, including in the portal vein and splenic vein, and a combination of venous and arterial thromboses. These 15 reports were confirmed by physician reviewers at CDC and FDA and reviewed with Clinical Immunication Safety Assessment Project investigators, including hematologists. Thirteen TTS cases occurred among women aged 18-49 years, and two occurred among women aged ≥50 years; no cases postauthorization were reported among men. ¶ TTS reporting rates to VAERS were 7.0 cases per million Janssen COVID-19 vaccine doses administered to women aged 18–49 years and 0.9 per million to women aged 250 years. Among subgroups by age (18–29, 30–39, 40–49, 50–64, and ≥65 years), the reported rate was highest among women aged 30–39 years, with 11.8 TTS cases per 1 million Janssen COVID-19 doses administered. The median age was 37 years (range = 18–59 years), and the median interval from vaccination to symptom onset was 8 days (range = 6–15 days). Certain patients had underlying medical conditions or risk factors for hypercoagulability (e.g., obesity [seven patients], combined oral contraceptive use Itwo patients], hypothyroidism [two patients], and hypertension [two patients]); no cases occurred among women who were pregnant or had given birth in the previous 12 weeks, and none had a documented history of previous thrombotic events, a known diagnosis of an underlying clotting disorder, or a family or personal history of clotting disorders. None of the patients had any known previous exposure to heparin. All 15 patients were hospitalized, and 12 were admitted to an intensive care unit (ICU). As of the most recent follow-up,\*\* three patients had died, four remained in an ICU, three remained hospitalized (not in an ICU), and five had been discharged home.

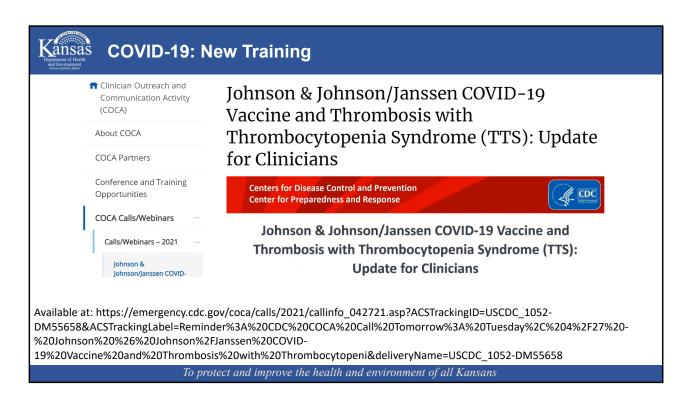


#### MMWR article:

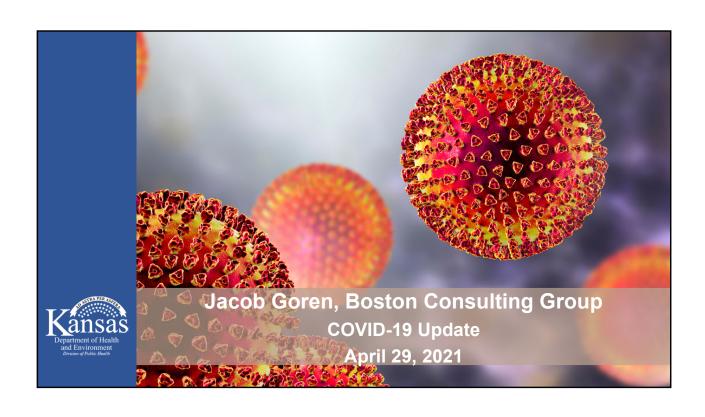
Health care needs in the months after COVID-19 diagnosis among nonhospitalized adults have not been well studied. CDC and Kaiser Permanente Georgia (KPGA) analyzed electronic health record (EHR) data from health care visits in the 28–180 days after a diagnosis of COVID-19 at an integrated health care system. Among 3,171 nonhospitalized adults who had COVID-19, 69% had one or more outpatient visits during the follow-up period of 28–180-days. Among adults with outpatient visits, 68% had a visit for a new primary diagnosis, and 38% had a new specialist visit. The presence of diagnoses of COVID-19 and related symptoms in the 28–180 days following acute illness suggests that some nonhospitalized adults, including those with asymptomatic or mild acute illness, likely have continued health care needs months after diagnosis.

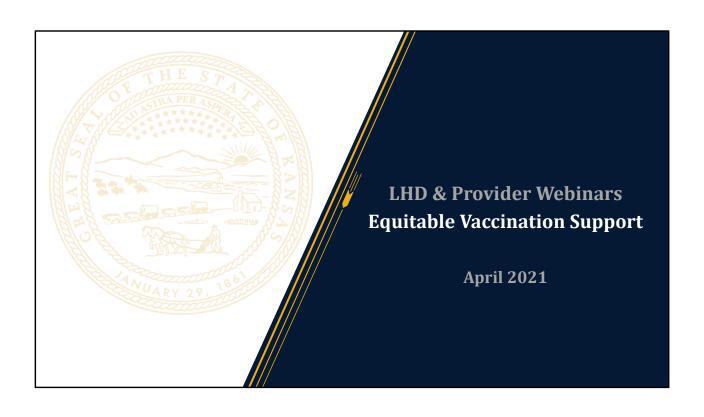


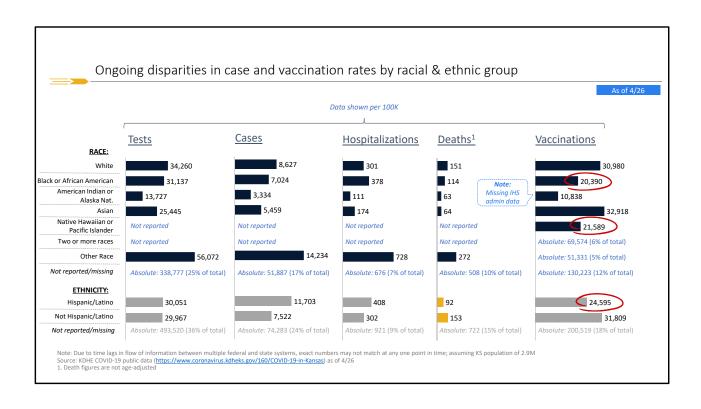
CDC updated their Interim Public Health Recommendations for Fully Vaccinated People on April 27<sup>th</sup>. The biggest change is the guidance that fully vaccinated people no longer need to wear a mask outdoors, except in certain crowded settings and venues. KDHE is working on updating our recommendations for fully vaccinated people to reflect this change.

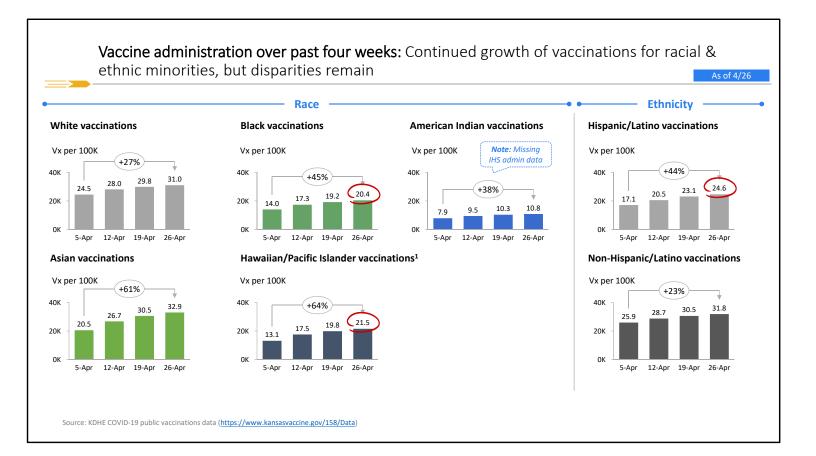


There was a COCA call earlier this week about the J and J vaccine and TTS. I have included the link here where you can find the recording of the webinar.









Two major drivers of inequitable vaccine uptake for Kansan communities of color



# Vaccine uncertainty

- Weak relationship with healthcare system
- Historically rooted mistrust
- Misinformation & disinformation

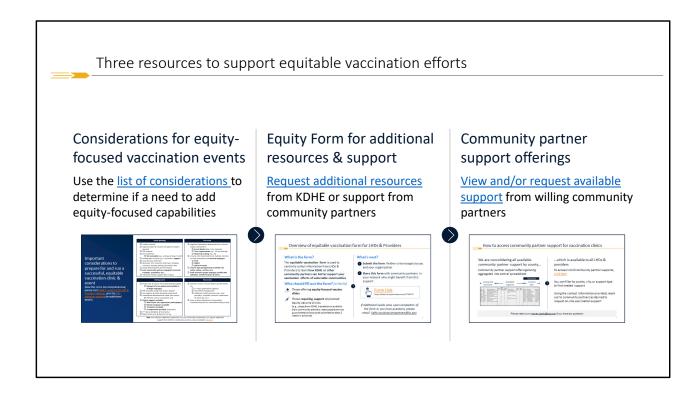


#### Barriers to access

- Physical barriers:
  - Location of providers
  - Hours of operation
- Information access:
  - Internet access & technological comfort
  - Language
  - Literacy levels

Ongoing need to address barriers to ensure and support equitable vaccination in Kansas, with community partners well positioned & eager to support

23



Important considerations to prepare for and run a successful, equitable vaccination clinic & event

Note this list is not comprehensive; please visit <u>KDHE's website for LHD</u> <u>& Provider Manuals</u> and the <u>CDC</u> <u>planning website</u> for additional details

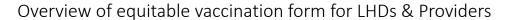
Event planning	Pre-event	
<ul> <li>□ Vaccine secured</li> <li>□ Approved plan for vaccine storage &amp; transport planned</li> <li>□ PPE ordered</li> <li>□ Site confirmed</li> <li>□ Site accessible (e.g., walkup, driving, transit)</li> <li>□ Staffing plan secured (e.g., vaccinators, support)</li> <li>□ Security plan confirmed</li> <li>□ Necessary site resources confirmed, including restroom, seating, parking, &amp; weather plan</li> <li>□ Social distancing site plan developed</li> <li>□ Local community partners engaged (to provide transport, translation, etc.)</li> <li>□ Advanced medical support plan in place</li> </ul>	□ Logistical information disseminated to relevant target communities: □ Event details (date, time, location) □ Time requirements (e.g., 15 min waiting) □ Materials to bring (e.g., ID) □ Vaccine info. disseminated via multiple channels to local communities in relevant languages: □ Print □ Digital □ Word of mouth □ Vaccine sign up/registration available (via online, phone, written, etc.) □ Staff trained in proper language on R&E data collection, misinformation, & safety	
During event	Post event	
<ul> <li>□ Proper fact &amp; consent forms distributed &amp; signed</li> <li>□ Signage &amp; forms posted and available in multiple languages</li> <li>□ PPE available along with proper disposal</li> <li>□ Site hygiene &amp; social distancing maintained</li> <li>□ Vaccinations documented &amp; input into system</li> <li>□ Patients receive vaccination card</li> <li>□ Patient support available:</li> <li>□ Walk ins/on site registration (online/paper)</li> <li>□ Patient navigators available</li> </ul>	□ Patients receive relevant follow up information on: □ 2 <sup>nd</sup> dose appointment logistics □ Side effects management □ Additional health practices (e.g., local providers, available resources, importance of check ups, etc.) □ Data on doses administered successfully transmitted (if not live transmitted during event)	

**Bold** text indicates additional importance to reach vulnerable communities; to request additional support from KDHE or community partners, please complete this form

☐ Transportation provided (if possible)

2<sup>nd</sup> doses scheduled (if necessary)
 Observation area & observer set up

Notes view: 25





#### What is the form?

The equitable vaccination form is used to centrally collect information from LHDs & Providers to learn how KDHE or other community partners can better support your vaccination efforts of vulnerable communities

## Who should fill out the form? (criteria)



Those offering equity-focused vaccine clinics



Those **requiring support** at planned equity vaccine clinics

(e.g., doses from KDHE, translation or publicity from community partners; note supports are not guaranteed and should be submitted at least 2 weeks in advance)

#### What's next?

- Submit the form if either criteria apply to you and your organization
- 2 Share this form with community partners in your network who might benefit from this support



If additional needs arise upon completion of the form or you have questions, please email: kdhe.covidvaccinepartners@ks.gov





#### What is the form?

The **equitable vaccination form** is used to centrally collect information from community partners to learn **how KDHE or other community partners can better support your vaccination efforts** 

# Who should fill out the form? (criteria)



Those who can **offer support** at equity vaccine clinics



Those who **require support** at established equity vaccine clinics



Those who **need a provider partner** to arrange a vaccine equity clinic



Those with **additional needs** beyond equity vaccine clinics

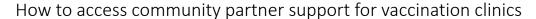
### What's next?

- **Submit the form** if any of the 4 criteria apply to you and your organization
- 2 Share this form with others in your network who might benefit from this support





If additional needs arise upon completion of the form or you have questions, please email: kdhe.covidvaccinepartners@ks.gov





We are consolidating all available community partner support by county...

Community partner support offerings being aggregated into central spreadsheet



...which is available to all LHDs & providers

To access list of community partner supports, click here

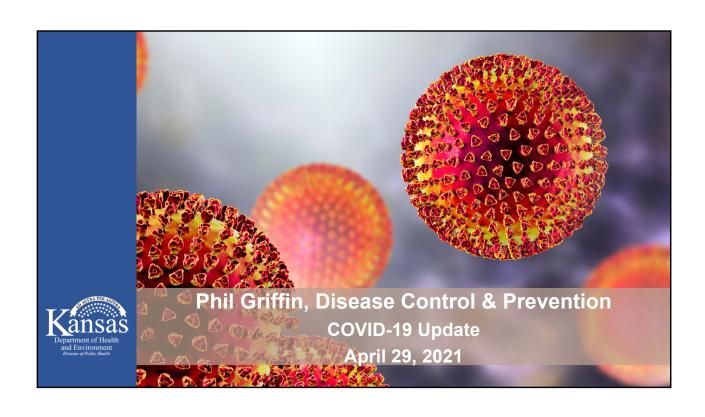


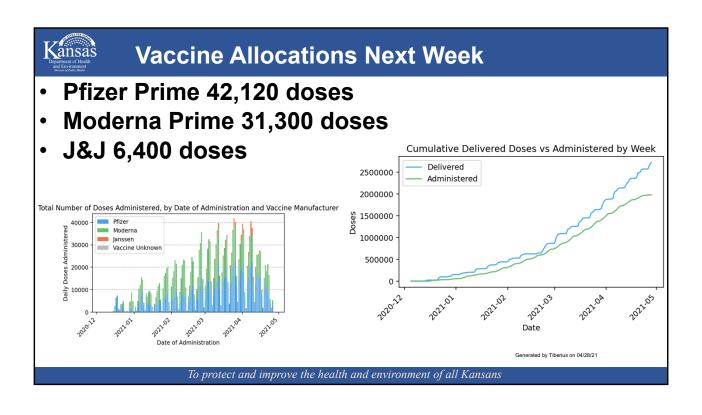
You can filter by county, city, or support type to find needed support

Using the contact information provided, reach out to community partners as desired to request on-site vaccination support

Please reach out to <a href="mailto:goren.jacob@bcg.com">goren.jacob@bcg.com</a> if you have any questions









# Change in Vaccine Distribution Process

- Effective immediately
- COVID Vaccine Order Request Action Required
- Email went out at 1:00 PM on Wednesday
- Reponses to order form due by 5:00 PM on Thursday
- · Order delivery will depend on demand
- Pragya will demonstrate form and explain process

To protect and improve the health and environment of all Kansans



On April 13<sup>th</sup> – FDA and CDC recommended a pause on Janssen vaccine out of an "abundance of caution" due to 6 reported cases of severe and rare blood clots within 2 weeks of vaccinations.

- Examine available data to assess risk of condition
- Conduct extensive outreach to providers

To protect and improve the health and environment of all Kansans

On April 13<sup>th</sup> the FDA and CDC recommended a pause on the use of Janssen vaccine out of an abundance of caution due to 6 reported cases of severe and rare blood clots within 2 weeks of vaccination. During the pause, the FDA and CDC examined available data to assess the risk of the condition as well as conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

For clinicians – – – – Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the Jansen COVID-19 vaccine, including severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae (tiny red spots on the skin), or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia. In patients with a thrombotic event and thrombocytopenia after the Jansen COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended. Do not treat patients with thrombotic events and thrombocytopenia following receipt of Janssen COVID-19 vaccine with heparin, unless HIT testing is negative. If HIT testing is positive or unable to be performed in patient with thrombotic events and thrombocytopenia following receipt of Jansen COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered. Report adverse events to VAERS, including serious and life-threatening adverse events and deaths in patients following receipt of COVID-19 vaccines as required under the Emergency Use Authorizations for COVID-19 vaccines.



On April 14<sup>th</sup> – The Advisory Committee on Immunization Practices (ACIP) met to review data on the 6 reported cases.

- All cases among white women between 18 and 48
- Symptoms occurred 6 to 13 days after vaccination
- Use of estrogen/progesterone with only 1 case
- No pregnant or postpartum cases
- Pre-existing conditions include obesity (3), hypothyroidism (1), hypertension (1), and asthma (1)

To protect and improve the health and environment of all Kansans

The Advisory Committee on Immunization Practices (ACIP) meet on two occasions – Wednesday, April 14<sup>th</sup> and Friday, April 23<sup>rd</sup>.

CDC and FDA reviewed data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia).

Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.

All six cases occurred among white women between the ages of 18 and 48
Symptoms occurred 6 to 13 days after vaccination
Use of estrogen/progesterone with only 1 case
No pregnant or postpartum cases
Pre-existing conditions include obesity (3), hypothyroidism (1), hypertension (1), and asthma (1)

ACIP Safety Team wanted time to review and gather more data so the pause remained in effect until they met again.



On April 23<sup>rd</sup> – The ACIP met to review additional data using the Evidence to Recommendations (EtR) Framework

Policy Question: Should vaccination with the Janssen COVID-19 vaccine (1 dose) be recommended for persons 18 years of age and older under an Emergency Use Authorization?

To protect and improve the health and environment of all Kansans

#### EtR Framework –

- Structure to describe information considered in moving from evidence to ACIP vaccine recommendations
- Provide transparency around the impact of additional factors on deliberations when considering a recommendation

Note: The Centers for Disease Control and Prevent (CDC) and FDA recommended a pause 10 days ago out of an "abundance of caution." The joint recommendation came after six reported cases (a rate of less than 1 in 1 million) of vaccine recipients who developed "severe and rare" blood clots within two weeks of vaccination. Since then there have been nine, new cases of the clotting disorder, bringing the total to 15 cases.

Thrombosis-thrombocytopenia syndrome (TTS).



# 4/23 ACIP Vote -

- Janssen COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.
- The EUA for providers and vaccine recipients will now be labeled to note a rare risk of blood clots with low platelets within two weeks of vaccination.

To protect and improve the health and environment of all Kansans

On Friday, April 23<sup>rd</sup>, the ACIP voted 10-4 with 1 abstention to recommend the Johnson and Johnson vaccine for persons 18 and over, ending the pause.

"The Janssen COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."

The vaccine will now be labeled to note a rare risk of blood clots with low platelets within two weeks of vaccination.



## Janssen (Johnson & Johnson) Vaccine

# Providers in Kansas can resume vaccinating with Janssen vaccine immediately.

- Review updated Emergency Use Authorization for Providers
- Provide updated Emergency Use Authorization for Vaccine Recipients

To protect and improve the health and environment of all Kansans

#### From FDA & CDC Press Release:

### What should you expect next?

There are tremendous potential benefits for the population to re-starting administration of the Johnson & Johnson vaccine, as more people will have access to vaccines. According to a model presented by Dr. Sara Oliver, a C.D.C. scientist, if Johnson & Johnson vaccinations resume for all adults, 26 to 45 cases of the clotting disorder would be expected over the next six months. In contrast, 600 to 1,400 fewer COVID-19 related deaths would be expected over the same time period.

While the cases are extremely rare, it is important to note that the pause helped inform clinicians how to identify and appropriately treat these uncommon clots, which can be appropriately treated if identified.

While we know concerns may linger, we are determined to increase vaccine confidence and access --- especially among the populations that have been hardest hit by the pandemic. We are standing strong in our role as an advocate for these communities to ensure they have access to the vaccines, and as an information hub that quickly shares concerns, ideas and promising practices, and guidance we hear from our trusted community partners.



# Janssen (Johnson & Johnson) Vaccine

### 4/23/2021 EUA for Providers:

• <u>Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)</u>

# 4/23/2021 EUA for Vaccine Recipient:

 Janssen COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers 04232021 (fda.gov)



All Updated on Website

https://www.kansasvaccine.gov/194/Janssen-J-J-Vaccine

<u>Home</u> • <u>Providers</u> • <u>About the Vaccine</u> • Janssen (J & J) Vaccine

#### Janssen Vaccine

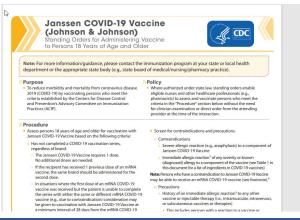
The Janssen vaccine may also be referred to as the Johnson & Johnson or J&J vaccine.

- Janssen Preparation & Administration Summary (PDF)
- Janssen Storage & Handling Summary (PDF)
- Janssen Administration Resources & FAQs
- Janssen Standing Orders (PDF)
- Janssen Emergency Use Authorization Letter (PDF)
- Janssen Emergency Use Amendment Letter (PDF) 4-23-21
- Advisory Committee on Immunization Practices' Interim Recommendation for Janssen January
- Janssen Fact Sheet (PDF) 4-13-21
- Additional Provider Information (PDF) 4-13-21
- J&J Fact Sheet for Recipients and Caregivers 4-23-21
- Fact Sheet for Healthcare Providers Administering Vaccine 4-23-21

# Kansas Johnson and Johnson Vaccine Standing Order

Updated Standing Orders

Janssen COVID-19 Vaccine (Johnson & Johnson): Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older (cdc.gov)





All Updated on Website

https://www.kansasvaccine.gov/194/Janssen-J-J-Vaccine

<u>Home</u> • <u>Providers</u> • <u>About the Vaccine</u> • Janssen (J & J) Vaccine

#### Janssen Vaccine

The Janssen vaccine may also be referred to as the Johnson & Johnson or J&J vaccine.

- Janssen Preparation & Administration Summary (PDF)
- Janssen Storage & Handling Summary (PDF)
- Janssen Administration Resources & FAQs
- Janssen Standing Orders (PDF)
- Janssen Emergency Use Authorization Letter (PDF)
- Janssen Emergency Use Amendment Letter (PDF) 4-23-21
- Advisory Committee on Immunization Practices' Interim Recommendation for Janssen (PDF)
- o Janssen Fact Sheet (PDF) 4-13-21
- Additional Provider Information (PDF) 4-13-21
- J&J Fact Sheet for Recipients and Caregivers 4-23-21
- Fact Sheet for Healthcare Providers Administering Vaccine 4-23-21



- With the FDA's EUA revisions announced April 1, the Moderna vaccine will be available in two different vials by early May: the current Maximum 11 dose vial and a new Maximum 15 dose vial. The vial will remain the same size but will be filled to the higher volume.
  - Moderna is planning to transition all manufacturing to the new vial during the month of May. During the month, awardees and partners will receive allocations that include quantities of both Moderna vaccine vials. The proportion of existing Moderna NDC/new Moderna NDC in each awardee's and partner's allocation will evolve over the course of the transition period.

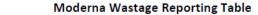


- The Moderna larger volume vial may contain 15 0.5mL doses of vaccine. However, it will not always be possible to extract the 15th dose. This is based on the overfill in the vial and the type of syringes used to administer the vaccine. Therefore, vaccination providers should expect to withdraw 13-15 doses from each vial.
  - Each dose must contain 0.5mL of vaccine.
  - When the amount of vaccine remaining in the vial is not a complete 0.5mL dose, discard the vial and the residual vaccine regardless of the number of doses withdrawn. Do NOT save vials to combine residual vaccine from more than one vial to get a complete dose. An unextracted 15th dose does NOT count as waste.
  - Vaccination sites should continue to reliably extract 10 doses from the current volume vial and plan to extract 14 doses from the new larger volume vial using the ancillary kit supplies provided.



- Ancillary kits will be reconfigured to extract a maximum of 14 doses per vial, plus a 5% surplus to account for damage or wastage.
  - Moderna worked closely with CDC and United States Pharmacopeia (USP) to test combinations of available needle and syringe supplies to optimize the number of available doses.
  - Results demonstrate that a combination of low dead-volume and non-low dead-volume syringes and needles may be required to consistently extract 11 and 15 doses from both vials addressed in the EUA.
  - Ancillary kits for the Moderna large volume vials will be configured to support 14 doses per vial (minimum order: 140 doses).
  - USG cannot provide supplies to withdraw a 15th dose. If a provider chooses to withdraw a 15th dose from the vial, USG cannot replace the supplies used or provide additional syringes.







Manufacturer	Dose	Was the dose extracted in full?	Is it counted as waste?
Moderna 6.3mL vial	10 <sup>th</sup> dose	Yes	No
		No	Yes
	11 <sup>th</sup> dose	Yes	No
		No	No
Moderna 8mL vial	13 <sup>th</sup> dose	Yes	No
		No	Yes
	14 <sup>th</sup> dose	Yes	No
		No	Yes
	15 <sup>th</sup> dose	Yes	No
		No	No



### Frozen Vaccine

Moderna vials can now be stored frozen between -50° to -15° C (-58° to 5°F). This is an
increased range from the original temperatures. This new, wider temperature range is
consistent with temperature requirements for other recommended vaccines stored in the
freezer.

### Refrigerated Vaccine/Unpunctured Vials

- Unchanged: Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours. This is an increase from 12 hours.

#### Punctured Vials

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F) for up to 12 hours. Vials should be discarded 12 hours after the first puncture. This is an increase from 6 hours.



# · All Updated on Website

# Moderna Vaccine | KDHE Vaccine KS (kansasvaccine.gov)

### **Moderna Vaccine**

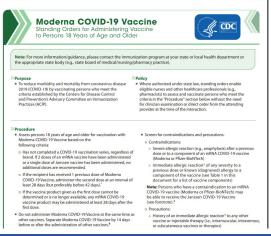
- Moderna Standing Orders (PDF)
- o Moderna Fact Sheet for Healthcare Providers (PDF) & Moderna Fact Sheet for Recipients (PDF)
- o MMWR Moderna (PDF)
- FDA Letter regarding Moderna EUA (PDF)
- o Moderna COVID-19 Vaccine Preparation and Administration Summary (PDF)
- Moderna Storage and Handling Summary (PDF)
- o Moderna Beyond Use Date/Time (BUD) Tracking Label for Vaccine During Refrigerator Storage (PDF)
- o Moderna COVID-19 Vaccine Storage and Handling Label (PDF
- o Moderna Effect of Ionizing Radiation on COP Color
- <u>Moderna EUA Amendments FAQs, Talking Points, Packaging Images and Wastage Reporting Table</u>





# Updated Standing Orders

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf





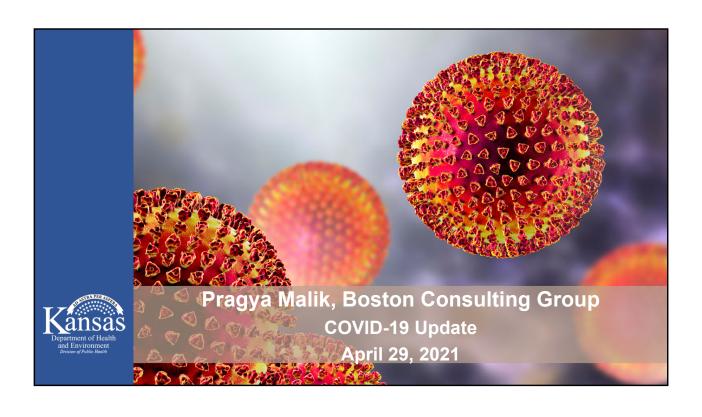
All Updated on Website

Moderna Vaccine | KDHE Vaccine KS (kansasvaccine.gov)

### **Moderna Vaccine**



- o Moderna Standing Orders (PDF)
- o Moderna Fact Sheet for Healthcare Providers (PDF) & Moderna Fact Sheet for Recipients (PDF)
- o MMWR Moderna (PDF)
- o FDA Letter regarding Moderna EUA (PDF)
- o Moderna COVID-19 Vaccine Preparation and Administration Summary (PDF)
- Moderna Storage and Handling Summary (PDF)
- o Moderna Beyond Use Date/Time (BUD) Tracking Label for Vaccine During Refrigerator Storage (PDF)
- o Moderna COVID-19 Vaccine Storage and Handling Label (PDF
- o Moderna Effect of Ionizing Radiation on COP Color
- Moderna EUA Amendments FAQs, Talking Points, Packaging Images and Wastage Reporting Table



As vaccine supply exceeds demand, an ordering-based allocation system can help streamline the vaccine distribution process

## Where we were a month ago

- Provider **demand exceeded supply:** required prioritization and allocation
- Demand was high, with mass vax clinics as main way to rapidly vaccinate willing Kansans: possible to order federal minimum quantities without waste



### "Centrally-pushed" allocations

KDHE uses bottoms-up approach to determine optimal provider-level allocations based on several public health parameters (e.g., county pop. & SVI, provider throughput or type)

### Where we are now

- Available supply exceeds demand: requires less dose management
- Demand is stalling and administration moving to in-house settings: requires decreases / fine-tuning in vaccine orders



### "Order-and-authorize" allocations

Providers submit order requests, which KDHE reviews and fulfills for distribution

Starting today, KDHE will move away from an allocations-based system to an order-based system for COVID-19 vaccine distribution

At this time, there is sufficient supply of Moderna and Pfizer vaccine across the state of Kansas to meet provider demand



### What WILL change

No allocations (including boost doses) will be automatically sent or proposed. Any shipments require an order submission.

• If you do not submit the form, you will receive 0 doses.

#### There are no minimum order requirements for vaccine.

- · Please indicate the exact number of doses you are interested in receiving. KDHE will aim to meet this either via manufacturer order or redistribution via courier.
- All shipments will come with ancillary supplies.

#### **Provider deadlines**

- All orders must be submitted by Thursday 5pm CT
- Orders after that deadline cannot be changed or adjusted



## What WILL NOT change

All emails will be sent to each location's primary contact.

KDHE will provide order confirmation in advance of delivery

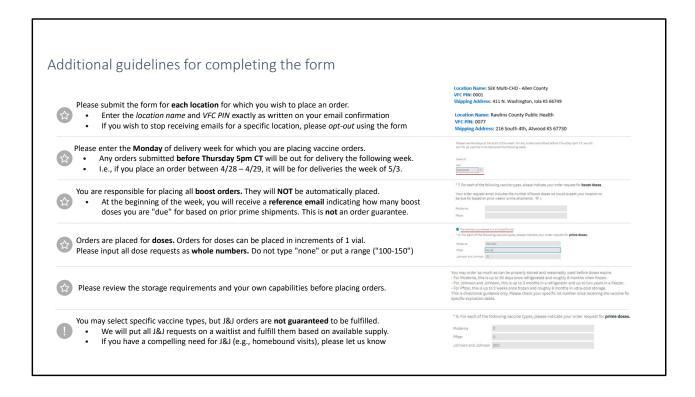
Please continue to work closely with your LHD. You are not required to receive doses from KDHE.

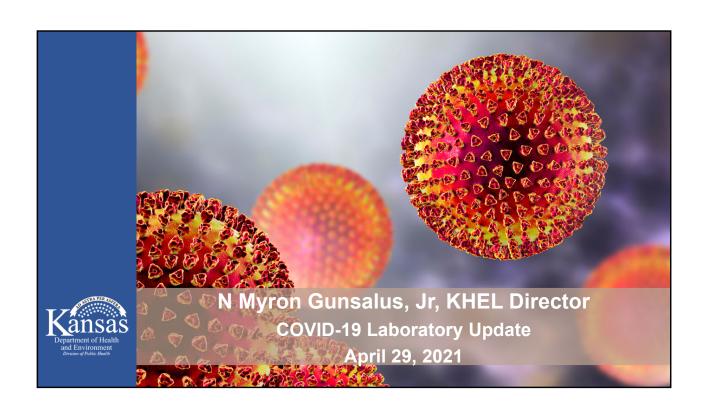
#### Only enrolled providers can receive vaccines

This is true for transferred doses as well: please register each location and report all transfers on WebIZ

#### **Provider reporting obligations**

- KSWebIZ: administration, inventory recommended
- VaccineFinder: inventory
- Weekly Snapshot: doses received, administered, on-hand, and transferred, daily and cumulatively







# Kansas COVID-19: Laboratory Update

# FDA Approved Tests as of 4/29/21

FDA has currently authorized 372 tests under EUAs:

- 241 molecular tests (excluding Lab Developed Tests)
- 76 antibody tests
- 23 antigen tests, 18 CLIA Waived + 6 At Home Tests

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitrodiagnostics-euas

To protect and improve the health and environment of all Kansans

No major changes or updates in the authorized testing arena.



# Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2

On April 20, 2021, the FDA issued an amendment allowing certain authorized molecular diagnostic SARS-CoV-2 tests to be distributed and used to pool anterior nasal respiratory specimens from asymptomatic individuals as part of a serial testing program after developers submit a complete notification, including meeting required validation data, as set forth in the letter.

This means that tests with EUAs that are amended by this authorization may be used with pooled anterior nasal specimens from individuals without known or suspected COVID-19 when such individuals are tested as part of a testing program that includes testing at regular intervals, at least once per week.

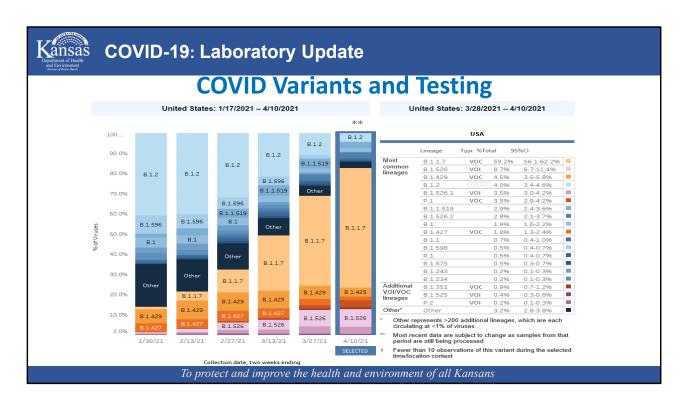
 $\frac{\text{https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2\#amendment}$ 

To protect and improve the health and environment of all Kansans

Update from FDA to formally approve certain molecular diagnostic tests to be used for pooled specimens from asymptomatic individuals.

This is for High complexity labs and requires the vendor to submit application and data to support the change.

On this page will be an Exhibit that will list these, but nothing has been posted there yet.



https://covid.cdc.gov/covid-data-tracker/?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fvariant-surveillance%2Fgenomic-surveillance-dashboard.html#variant-proportions

3 different areas that have P.1 variants

2 areas in the state have had India strain identified. This is not even identified by CDC as a variant of interest or concern yet.

As of April 25<sup>th</sup> 335,887 sequences have been uploaded into the GISAID public database.



# Kansas COVID-19: Laboratory Update

### SARS-CoV-2 Viral Mutations Detection with COVID-19 Tests

- Variant Detection is not diagnostic
- Variants are usually a combination of various mutations.
- PCR techniques can detect some aspects of some variants
  - e.g. S-gene dropout
- PCR alone cannot positively identify a variant, only if a particular mutation is present.

To protect and improve the health and environment of all Kansans

For example, what has been termed the India variant (B.1.617) is related to an additional mutation that we normally see in the California variants. So if you only had primers and probes for the S:L452R mutation (typical in the California strains) but were not looking for the additional mutation S:T478K, you would not know that you had a B.1.617 lineage/variant.

Both of these mutations are on the spike protein where the 452 mutation is associated with increased transmissibility (approximated around 20%). The 478 mutation may have a potential impact on immune response.



# Kansas COVID-19: Laboratory Update

### SARS-CoV-2 Viral Mutations Detection with COVID-19 Tests

- PCR alone cannot positively identify a variant, only if a particular mutation is present.
- Be aware of misleading claims by vendors to "identify variants".
- These PCR mutation identifications can provide "indications" of a potential variant
- Good for screening which samples could be related to variants
- Should not report as having found a variant until whole genome sequencing is performed.

To protect and improve the health and environment of all Kansans

For example, what has been termed the India variant (B.1.617) is related to an additional mutation that we normally see in the California variants. So if you only had primers and probes for the S:L452R mutation (typical in the California strains) but were not looking for the additional mutation S:T478K, you would not know that you had a B.1.617 lineage/variant.

Both of these mutations are on the spike protein where the 452 mutation is associated with increased transmissibility (approximated around 20%). The 478 mutation may have a potential impact on immune response.

If you are a lab that is running PCR for COVID detection, we are looking for ways to increase our statewide sequencing efforts



KHEL is looking to partner with labs to increase sequencing



#### **Criteria**

KHEL is asking labs to send any positive samples

However, KHEL is particularly interested in the following cases if all samples are not available

• Examples: Areas with high transmission (different age groups, geographic locations, severity), cases in areas with a significant increase of cases over a few weeks (not explained by relaxing public health measures), children in areas with increased incidence of pediatric disease, clusters of cases in people aged <60 without underlying conditions, cases in fully-vaccinated people or when reinfection is suspected

Samples with a CT value <30 are preferred, but higher CT values are OK if samples are of interest



#### **Next steps**

- To sign up for the program, Contact KDH.KHELINFO@KS.gov and include Subject Line: ATTENTION SEQUENCING
  - Samples can be submitted through a form or lab online
  - For regular surveillance tell us how many PCR positives you typically have per week and could send.
- If there is a known case of reinfection or potential vaccine break through or "S-Deletion", then contact KHEL for sequencing.
- You should not report PCR mutation screening to anyone as an identified variant. Variants are only identified after confirmation whole genome sequencing
  - Send us extract if possible or a second sample in VTM

**Please note:** CMS has stated so far that sequencing results cannot be reported back to providers but only to Public Health. We will be working with Public Health staff regarding results of sequences but can only provide aggregate data back to any given laboratory



# Kansas COVID-19: Laboratory Update

# **General Thoughts**

- Rapid Antigen Kits Available from KDHE at no charge.
- Community Testing Partners for Antigen Tests
- CLIA Certification Questions: KDHE.CLIA2@ks.gov
- Mobile Labs and Collection Vans available.

To protect and improve the health and environment of all Kansans

If you have a need or an idea on using rapid antigen tests for a particular purpose, please let us know and we may be able to supply the kits at no charge. Go through your County EM.

We are looking for partners to ensure that testing is available across the state and there are still some gaps. If you are doing testing or can do antigen testing for public use (no charge to patient) we may have an opportunity to engage you as a community testing partner in order to fill a gap in current service. You would need to be accessible to the public and we can provide supplies but you would either collect specimens for PCR testing or perform an onsite rapid antigen test.

If you need help with certification to use these Waived Tests, then contact our CLIA office.

If you have an idea on how a mobile laboratory or collection event would support your community or situation, please reach out and let us know.





The next webinar from the National Emerging Special Pathogens Training and Education Center (NETEC) will take place Friday, April 30<sup>th</sup> at noon CST. This webinar's topic is "Overcoming Challenges to Supporting Your Workforce: Let's Talk." This webinar will: identify three sources of stress for healthcare workers; discuss three obstacles to providing psychological support to healthcare workers; distinguish between healthcare worker and leader responsibility for providing psychological support; and summarize key messages leadership can send to the workforce to encourage help-seeking. To register for the webinar, click the link on the screen or visit: https://netec.org/education-and-training/.



The National Resource Center for Refugees, Immigrants and Migrants (NRC-RIM) worked with IDEO.org, a nonprofit design studio, to <u>build vaccination campaigns</u> in genuine partnership with specific RIM communities. They will be presenting three different sessions of this webinar to discuss their resources obtained by working alongside community leaders to lead the creation and dissemination of their messaging campaigns.

Join this webinar to hear from experts from NRC-RIM and IDEO.org on how they approached this community-led, hyperlocal communications strategy. You'll also learn how you can use <u>templates and tools</u> to make a customized vaccine campaign that resonates with your community, and about other resources NRC-RIM offers that support your work.

As you can see, webinar sessions are available today at 12:00pm CST, and again on May 13 and May 27. To register for the webinar, click on the link on the slide or visit https://nrcrim.org/webinar-community-led-covid-19-messaging-supports-vaccine-confidence.



On April 12, FEMA began implementing Funeral Assistance nationwide to provide financial support for funeral costs specifically related to Coronavirus Disease (COVID-19). The DHS Center for Faith Based and Neighborhood Partnerships invites you to join their Funeral Assistance Program webinar. This webinar will provide information regarding the implementation of this new policy and guidance on applicability, conditions of eligibility, required documentation, how can you support, and other important topics.

To register for the webinar, click the link on the slide or visit https://femacqpub1.connectsolutions.com/content/connect/c1/7/en/events/event/private/110765447/182752975/event\_landing.html?connect-session=breezbreez3gg3zwcwkx2v9mc9&sco-id=187513599&\_charset\_=utf-8.



The May ECHO COVID-19 Program webinar will take place Thursday, May 6 and cover "The COVID-19 Vaccine for Adult Genetics Patients." This webinar will aim: to improve understanding of COVID-19 vaccine physiology and reactogenicity among genetics practitioners; to address providers' concerns around recommending the COVID-19 vaccine to adult genetics patients; to utilize case studies to exemplify how practitioners approach and manage the COVID-19 vaccines with their patients; and to empower genetics practitioners to answer patients' questions about the COVID-19 vaccine. TO register, use the link on the screen or visit:

https://med.emory.edu/departments/medicine/divisions/infectious-diseases/serious-communicable-diseases-program/covid-19-resources/echo-upcoming-session.html.





- Open to Kansas students in middle school and high school
- Free t-shirt for all participants who enter
- Entries must include:
  - #JustBecauseKS
  - Must say "just because" in the video
  - Tag @JustBecauseKS on TikTok or submit through website
- Winners will be announced after it closes May 12
- We can send an email to you with all of the details just let us know.

Click **HERE** for more information

To protect and improve the health and environment of all Kansans

KDHE has been working to get the message out that getting a COVID test to keep family and friends safe is still of the utmost importance. This week we launched a TikTok "Just Because" campaign encouraging Kansas middle and high schoolers (and their teachers or classrooms) to submit a video outlining why getting a COVID test is important.

While the campaign is primarily being conducted on TikTok, there are other ways to enter. Visit JustBecauseKS.com for a full list of contest rules, or to enter. We've also included a TikTok video (<a href="https://youtu.be/EG3ITdMMCWg">https://youtu.be/EG3ITdMMCWg</a>) from Christian Trotter (@thetrotterlife) to help us get started. All entries will receive a t-shirt, and possibly be entered for other prizes. Below are a few more details.

#### **Just Because Contest Guidelines:**

- Entries must be school-appropriate no profanity, inappropriate actions, or provocative clothing keep it clean!
- Must say "Just Because" in your video, and explain why you think it's important to get a test. ex- I'm getting tested, just because I want to go to prom, or "I'm getting tested, just because I want to see my grandparents."

For the entry to be official, **you must use**:

#JustBecauseKS AND tag the TikTok account with @JustBecauseKS (Note: If students enter through the website, the entry is official, but may be utilized on other campaign social media)

All entries will receive a t-shirt, but they must be in by Wednesday, May 12. Questions can be sent through JustBecauseKS.com

