Kentucky Hospital Research & Education Foundation
Emergency Preparedness Update
for August 26, 2021

Governor says "We are breaking our record for COVID-19 Hospitalizations"

(From full Press Release) On Thursday during his weekly Team Kentucky update, Gov. Andy Beshear said hospitalizations have increased every day without exception for the past 42 days, from 239 people July 14 to a record 2,074 people Aug. 25. Before the delta variant, Kentucky's record number of COVID-19 hospitalizations was 1,817 on Dec. 17, 2020.

The Governor highlighted other statistics from July 14: On that day, there were 60 Kentuckians in the ICU for COVID-19; as of yesterday, there were 549. On July 14, there were 25 Kentuckians with COVID-19 on a ventilator; as of yesterday, there were 338. On July 14, the state's COVID-19 test positivity rate was 3.81%, and it was down to a low of 1.79% June 24; yesterday, it was 13.16%, a record high in the time since the state has had adequate testing supplies.

"My point with all of these numbers is that we are in uncharted territory. We have been fighting this virus for almost 18 months, but we have never been here before," the Governor said.

FOR AUGUST 26 – there were 5,401 new cases recorded today, with 1,759 new cases 18 and under. The positivity rate is **13.24%.** 27 new deaths were recorded today, for a total of 7,667 to date. ALL 120 counties are still in the RED ZONE. 2,115 are hospitalized, with 590 in an ICU, and 345 on a vent. 69.9% of the ICU beds are occupied, along with 41.7% of the ventilators. Region 10 (South Central KY) has 100% of its ICU beds occupied. Region 4 (HEART/Barren River area) and 8 (Eastern KY) are over 80% full. (84.38% vs 81.6%). See the KY Daily Report for more detail: https://chfs.ky.gov/agencies/dph/covid19/COVID19DailyReport.pdf

Next KY COVID-19 Healthcare and Public Health Update Webinar #18
Tuesday, September 7, 11:30 AM – 1 PM ET
Please register at: https://attendee.gotowebinar.com/register/3541686799490195469

Team Kentucky COVID-19 Testing Location Survey

(KDPH) The Kentucky Department for Public Health is updating the KY COVID-19 website to include a listing of COVID-19 testing locations in Kentucky *searchable by zip code and county*. The search will result with testing locations that are within a zip code/county and will include options in the surrounding areas. Each listing will include test site information, types of testing, and cost of testing. A link to an identified testing website will be provided for individuals to schedule appointments.

They are currently collecting COVID-19 testing-related information from providers to advertise on the Kentucky Department for Public Health's KY COVID-19 Testing website. If your facility has a testing site, please complete the Team Kentucky COVID-19 Testing Location Survey. A survey should be submitted for *each* testing site location. If you need to make changes to testing site information, re-submit this testing location survey. Please allow 24-48 hours for testing information to be updated. If there are questions or concerns, please email KycovidTesting@ky.gov

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J & J Announces Data to Support Boosting its Single-Shot COVID-19 Vaccine

(From Press Release) Johnson & Johnson today announced data supporting the use of its COVID-19 vaccine as a booster shot for people previously vaccinated with the single-shot Johnson & Johnson vaccine.

In July, the Company reported interim Phase 1/2a data published in the *New England Journal of Medicine* that demonstrated neutralizing antibody responses generated by the Johnson & Johnson single-shot COVID-19 vaccine were strong and stable through eight months after immunization.

In anticipation of the potential need for boosters, the Company conducted two Phase 1/2a studies in individuals previously vaccinated with its single-shot vaccine. New interim data from these studies demonstrate that a booster dose of the Johnson & Johnson COVID-19 vaccine generated a rapid and robust increase in spike-binding antibodies, nine-fold higher than 28 days after the primary single-dose vaccination. Significant increases in binding antibody responses were observed in participants between ages 18 and 55, and in those 65 years and older who received a lower booster dose. The study summaries were submitted to *medRxiv* on August 24.

"We have established that a single shot of our COVID-19 vaccine generates strong and robust immune responses that are durable and persistent through eight months. With these new data, we also see that a booster dose of the Johnson & Johnson COVID-19 vaccine further increases antibody responses among study participants who had previously received our vaccine," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson.

Moderna Completes Submission to the FDA for its COVID-19 Vaccine

(From Press Release) Moderna, Inc. announced it has completed the rolling submission process for its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the full licensure of the Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 in individuals 18 years of age and older. As part of the completed BLA submission, Moderna has requested Priority Review designation.
The Moderna COVID-19 vaccine is currently available in the U.S. for individuals 18 years of age and older under an Emergency Use Authorization (EUA) granted by the FDA on December 18, 2020.

Pfizer and BioNTech Initiate Rolling Submission of Supplemental Biologics License Application to U.S. FDA for Booster Dose of COMIRNATY® in ***Individuals 16 and Older***

(From Press Release) Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) announced the initiation of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for the approval of a booster (third) dose of COMIRNATY® (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 16 years of age and older. The companies intend to complete submission of the sBLA by the end of this week.
A third dose of the Pfizer-BioNTech vaccine is not currently authorized for broad use in the U.S. However, under the current amended Emergency Use Authorization, a third dose was authorized on August 12 for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
View the full release here: https://www.businesswire.com/news/home/20210825005638/en/

Related - Biden Administration Likely to Approve Covid-19 Boosters at Six Months

Pfizer, BioNTech have requested clearance for Covid-19 vaccine boosters that an official said could be administered six months after previous dose

(Wall Street Journal) Data from vaccine manufacturers and other countries under review by the Food and Drug Administration is based on boosters being given at six months, the person said. The person said approval for boosters for all three Covid-19 shots being administered in the U.S.—those manufactured by Pfizer Inc. and partner BioNTech SE, Moderna Inc. and Johnson & Johnson —is expected in mid-September.

Johns Hopkins: Health Security Headlines
Extracts from August 26, 2021

Japan Suspends 1.63 Million Doses Of Moderna's COVID-19 Vaccine Over Contamination *(NPR)* Japan suspended use of about 1.63 million doses of Moderna vaccine Thursday after contamination was found in unused vials, raising concern of a supply shortage as the country tries to accelerate vaccinations amid a COVID-19 surge. The health ministry said contamination was reported from multiple vaccination sites. Some doses might have been administered, but no adverse health effects have been reported so far, officials said.

The Coronavirus Could Get Worse *(The Atlantic)* If evolution is a numbers game, the coronavirus is especially good at playing it. Over the past year and a half, it's copied itself quickly and sloppily in hundreds of millions of hosts, and hit upon a glut of genetic jackpots that further facilitate its spread. Delta, the hyper-contagious variant that has swept the globe in recent months, is undoubtedly one of the virus's most daring moves to date. This variant is the product of unfettered transmission, and will thrive further on it; if allowed to, Delta could morph into something even more formidable.

Holes in Reporting of Breakthrough Covid Cases Hamper CDC Response (*Politico*) Forty-nine states are now regularly sending CDC information on hospitalized breakthrough patients. But more than a dozen told POLITICO that they do not have the capacity to match patients' hospital admission data with their immunization records. Instead, those states rely on hospital administrators to report breakthrough infections. The resulting data is often aggregated, inaccurate and omits critical details for teasing out trends, such as which vaccine a person received and whether they have been fully vaccinated, a dozen state officials said.

Caribbean Disturbance Could Become a Tropical Storm or Hurricane Threat for U.S. Gulf Coast
Read more: https://weather.com/safety/hurricane/news/2021-08-26-caribbean-disturbance-tropical-storm-hurricane-gulf-coast
Western KY - SEE MAPS & KEY MESSAGES ON LAST PAGE BELOW

The FCC Contemplates "Persistent EAS Alerts"

(*Radio World,* August 26) The FCC wants to know what you think about possibly modifying the Emergency Alert System to provide "persistent alerts" in extreme emergencies, and how such alerts might work on radio stations and other audio platforms. Providing persistent alerts is one of several recommendations that were made to the commission by FEMA for improvements to EAS.

Providing persistent alerts is one of several recommendations that were made to the commission by FEMA for improvements to EAS. FEMA's recommendations are in addition to alerting changes recently adopted by the commission in June. At that time the FCC issued a further notice of proposed rulemaking to explore FEMA's ideas. <Read more >

FBI alerts organizations to new ransomware threat

(AHA Today) The FBI today released an alert on Hive ransomware, which uses mechanisms such as phishing emails with malicious attachments and Remote Desktop Protocol to access and move through victim networks, exfiltrate data and encrypt files. The alert highlights indicators of Hive ransomware compromise and recommended mitigation actions.

John Riggi, AHA senior advisor for cybersecurity and risk, said, "This new strain of ransomware may be of particular concern for health care and utilizes the 'double extortion' method — demand for ransom payment for decryption key to access on-site encrypted data along with ransom payment demand to prevent public release of stolen patient information. The FBI and AHA strongly discourage payment of ransom if at all possible. Regardless of whether you or your organization decide to pay the ransom, the FBI urges you to report ransomware incidents to your local field office. Doing so provides investigators with the critical information they need to track ransomware attackers, hold them accountable under U.S. law, and prevent future attacks."

Bio-Medical Equipment Service Co. Recalls Alaris Infusion Pump

FDA link: https://www.fda.gov/medical-devices/medical-device-recalls/bio-medical-equipment-service-co-recalls-alaris-infusion-pump-module-8100-bezel-due-possible-cracked

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Stop Using Certain N95 Respirators Manufactured by Shanghai Dasheng

(From FDA Notice) The U.S. Food and Drug Administration (FDA) is alerting health care facility risk managers, procurement staff, and health care personnel to stop using certain N95 respirators manufactured by Shanghai Dasheng Health Products Manufacturing Co., Ltd. (Shanghai Dasheng). The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) revoked all respirator approvals previously issued to Shanghai Dasheng because the company did not implement, maintain, and control a quality management system. All previously authorized Shanghai Dasheng respirators are no longer authorized for emergency use as a result of the loss of NIOSH-approval.

FDA letter has related TC numbers: https://www.fda.gov/medical-devices/medical-device-recalls/stop-using-certain-n95-respirators-manufactured-shanghai-dasheng-letter-health-care-providers

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Real-World Study Links Pfizer Vax to High Risk of Myocarditis

Though separate cohort found even higher risk with COVID infection

Learn more: https://www.medpagetoday.com/infectiousdisease/covid19vaccine/94213

Federal Agencies Plan To Expand Use of Facial Recognition Technology By 2023

(IACP "The Lead") The Washington Post (8/25, Harwell) reports the federal government "plans to expand its use of facial recognition to pursue criminals and scan for threats," despite growing concerns over "the technology's potential for contributing to improper surveillance and false arrests." Although most of the 10 agencies that intend to expand their use of such technology use it so that employees "can unlock their phones and laptops or access buildings," a growing number of federal agencies "said they are using the software to track people and investigate crime." Proponents of the new technology "say the software's accuracy is improving and that it has played a critical role in helping track and identify major criminals." Even so, "the technology's accuracy has been shown in research to vary wildly depending on the skin color of the person being surveilled," and civil liberties advocates in Congress have introduced legislation that would restrict facial recognition technology's use by federal authorities.

More info: https://kshe.org/page/2021hcc_homepage
Agenda: https://kshe.org/page/2021hcc_agenda

Register Today

The KHREF Emergency Preparedness Update is assembled several times a week. When events make it necessary, the Update may be sent out several times a day to keep our hospital and the healthcare community advised on preparedness news and information. Most of this information is compiled from open sources, and where possible reference links will be provided. There is an archive of Emergency Preparedness Updates available here. If you would like to added or deleted, or have something you would like to contribute to a future edition of the Emergency Preparedness Update, please contact Preparedness@kyha.com (include your current email address). The preparedness program for the Kentucky Hospital Association (KHA) and KHREF are supported by US DHHS ASPR HPP funds through a contract with Kentucky Public Health.

Key Messages for Tropical Depression Nine

Advisory 1: 11:00 AM EDT Thu Aug 26, 2021

1. Tropical storm conditions are likely in portions of the Cayman Islands tonight and western Cuba Friday and Friday night, with dangerous storm surge possible in portions of western Cuba, including the Isle of Youth, in areas of onshore flow.

2. The system is expected to produce life-threatening heavy rains, flash flooding and mudslides across Jamaica, the Cayman Islands, western Cuba, including the Isle of Youth and northeastern portions of the Yucatan Peninsula.

3. This system is forecast to approach the northern Gulf Coast at or near major hurricane intensity on Sunday, although the forecast uncertainty is larger than usual since the system is just forming. There is a risk of life-threatening storm surge, damaging hurricane-force winds, and heavy rainfall Sunday and Monday along the northern Gulf Coast from the Florida Panhandle to the upper Texas coast, with the greatest risk along the coast of Louisiana. Interests in these areas should closely monitor the progress of this system and ensure they have their hurricane plan in place.

For more information go to hurricanes.gov

Link to National Hurricane Center: https://www.nhc.noaa.gov/refresh/graphics_at4+shtml/144701.shtml?cone#contents