



Kentucky Hospital Research & Education Foundation Emergency Preparedness Update for August 23, 2021

FDA Fully Approves First COVID-19 Vaccine

(FDA) Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.

Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty is only present in the body for a short time and is not incorporated into - nor does it alter - an individual's genetic material. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

Full press release: <https://content.govdelivery.com/accounts/USFDA/bulletins/2edf3f5>

Related story - Pentagon to mandate COVID-19 vaccine for military

(The Hill) The U.S. military will move to mandate the COVID-19 vaccine for all service members now that the Pfizer vaccine has full approval from the Food and Drug Administration, the Pentagon's top spokesperson announced Monday. The Defense Department is preparing "guidance to the force" to make the vaccine mandatory, with a timeline to be provided in the coming days, Pentagon press secretary John Kirby told reporters. <[Read more](#)>

Governor Beshear announces more than 2,500 new COVID-19 cases across the Commonwealth

(WYMT) Governor Andy Beshear announced more than 2,500 new cases of COVID-19 across the Commonwealth during a news conference on Monday. Specifically, the Governor announced 2,596 new COVID-19 cases on Monday, bringing the statewide total to 543,031. The governor said this is the highest total for a Monday since the pandemic began.

695 of Monday's new cases were children 18 and younger. 1,893 Kentuckians remain hospitalized (an increase of 113 since Friday) with 529 in the ICU (an increase of 42 since Friday). 301 patients remain on a ventilator (an increase of 46 since Friday).

Gov. Beshear also announced 17 new deaths on Monday, bringing the state's death toll to 7,558.

Full story with video link: <https://www.wyvt.com/2021/08/23/watch-governor-beshear-holds-covid-19-news-conference/>

DHS Officers 'On the Lookout' for Fake COVID-19 Vaccine Cards After Seizing Thousands in Recent Weeks

Read story: <https://www.govexec.com/management/2021/08/dhs-officers-lookout-fake-covid-19-vaccine-cards-after-seizing-thousands-recent-weeks/184729/>

Israel finds COVID-19 vaccine booster significantly lowers infection risk

(Reuters) New data from Israel showed a [significant reduction in COVID infections and serious cases](#) following a third dose of Pfizer's vaccine in older adults, a group [at higher risk for breakthrough cases](#).

Story link: <https://www.reuters.com/world/middle-east/israel-finds-covid-19-vaccine-booster-significantly-lowers-infection-risk-2021-08-22/>

Kentucky governor suffers legal defeat in combating Covid surge

(Politico) The Kentucky governor's efforts to aggressively combat COVID-19 suffered a legal defeat Saturday as the state's high court cleared the way for new laws to rein in his emergency powers. In a landmark

separation-of-powers case, the Kentucky Supreme Court said the legislature wields policy-making authority to limit the emergency powers granted to the governor by state law.

One of the contested laws limits the governor's executive orders in times of emergency to 30 days unless extended by lawmakers. Under another measure, businesses and schools have to comply either with COVID-19 guidelines from the governor or the federal Centers for Disease Control and Prevention. They could follow whichever standard is least restrictive.

In a concurring opinion, Deputy Chief Justice Lisabeth T. Hughes said the 30-day limit on a governor's emergency authority deserves legal review from the lower court when the case is returned. "The 30-day limit operates as a 'kill switch' that essentially transfers the day-to-day management of emergencies to the legislature by rendering the executive branch powerless to act after 30 days, forcing the call of a special legislative session," she wrote. "This type of special legislative session trigger has no antecedent in Kentucky law to my knowledge and requires careful constitutional analysis." Chief Justice John D. Minton Jr. joined in the concurring opinion. Full story: <https://www.politico.com/news/2021/08/21/kentucky-supreme-court-gov-beshear-506499>

Johns Hopkins: Health Security Headlines

Extracts from [August 20, 2021](#) and [August 23, 2021](#)

[Early US Vaccine Efforts may have Prevented 140K COVID Deaths, 3 Million Cases](#) (*CIDRAP*) The first push of the US COVID-19 vaccination campaign averted an estimated 140,000 deaths and more than 3 million infections by early May, saving \$625 billion to \$1.4 trillion, suggests an observational study yesterday in Health Affairs. In the first known study to evaluate the effects of state-level vaccination campaigns, a team led by Indiana University-Purdue University Indianapolis (IUPUI) researchers modeled the number of COVID-19 deaths that would have occurred from Dec 21, 2020, to May 9, 2021, had it not been for vaccines.

[Delta's Rise is Fuelled by Rampant Spread from People who Feel Fine](#) (*Nature*) People infected with the Delta variant of SARS-CoV-2 are more likely to spread the virus before developing symptoms than are people infected with earlier versions, suggests a detailed analysis of an outbreak in Guangdong, China. Cowling and his colleagues analysed exhaustive test data from 101 people in Guangdong who were infected with Delta between May and June this year, and data from those individuals' close contacts. They found that, on average, people began having symptoms 5.8 days after infection with Delta — 1.8 days after they first tested positive for viral RNA. That left almost two days for individuals to shed viral RNA before they showed any sign of COVID-19.

[Kindergarten or 'Russian Roulette'? To Some Parents, the Delta Variant and Lax Mask Rules Make Those One and the Same](#) (*STAT News*) Just two weeks into the school year, 30 classrooms already had reports of exposure to Covid-positive students, district spokesperson Emily Shockley said. And three more classrooms were quarantined because they'd had at least three students in them test positive. Masks are still not required for all. Even though the Centers for Disease Control and Prevention recommends "universal indoor masking" in schools regardless of vaccination status, schools across the country are grappling with mask requirements, including for students under 12 who aren't yet eligible to receive protective vaccines.

['Nursing Is in Crisis': Staff Shortages Put Patients at Risk](#) (*New York Times*) Nursing shortages have long vexed hospitals. But in the year and a half since its ferocious debut in the United States, the coronavirus pandemic has stretched the nation's nurses as never before, testing their skills and stamina as desperately ill patients with a poorly understood malady flooded emergency rooms. They remained steadfast amid a calamitous shortage of personal protective equipment; spurred by a sense of duty, they flocked from across the country to the newest hot zones, sometimes working as volunteers. More than 1,200 of them have died from the virus. Now, as the highly contagious Delta variant pummels the United States, bedside nurses, the workhorse of a well-oiled hospital, are depleted and traumatized, their ranks thinned by early retirements or career shifts that traded the emergency room for less stressful nursing jobs at schools, summer camps and private doctor's offices.

[New Evidence Points To Antibodies As A Reliable Indicator Of Vaccine Protection](#) (*NPR*) When Dr. Anthony Fauci spoke recently at a White House briefing about the need for COVID-19 booster shots, buried in his slideshow of charts and data points was a little-noticed scientific paper that offers evidence for a reliable way to predict how much protection a COVID-19 vaccine offers. As Fauci explained, the paper showed that higher levels of these antibodies are associated with higher levels of vaccine efficacy. The findings suggest that giving people a booster vaccine, which has been shown to raise antibody levels, would go a long way toward protecting them against the coronavirus, including some of the newer and more dangerous variants. While more studies are needed to confirm the findings, discovering that these markers correlate with immune protection has implications for future COVID-19 vaccine research. It means that researchers now can measure whether a new COVID-19 vaccine might work — without necessarily having to repeat large-scale efficacy studies.

[Congressional Watchdog: HHS, DHS, DOD, USDA Must Mutually Prepare for Biological Threats](#) (*Homeland Preparedness News*) While key federal agencies prepared interagency response plans and conducted 74 interagency exercises from 2009 through 2019 to prepare for and respond to a wide variety of biological incidents, the Government Accountability Office (GAO) recently determined that the agencies weren't

on the same page when it came to monitoring exercise results to identify potential patterns of problems and how to solve them. And to better achieve National Biodefense Strategy objectives, that needs to change, specifically among the U.S. Departments of Homeland Security (DHS), Defense (DOD), Health and Human Services (HHS), and Agriculture (USDA), according to the GAO's August 2021 report to Congress, "After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness."

Now Available from ASPR TRACIE

**HCC Radiation Emergency Surge Annex Template
Updated Radiological/Nuclear Topic Collection**

The [Healthcare Coalition Radiation Emergency Surge Annex Template](#) and updated [Radiological/Nuclear Topic Collection](#) are now available on the ASPR TRACIE site.

The 2019-2023 ASPR HPP Funding Opportunity Announcement (FOA) requires HCCs to develop a complementary coalition-level radiation emergency surge annex to their base medical surge/trauma mass casualty response plan. This annex aims to improve capacity and capabilities to manage exposed or potentially exposed patients during a radiation emergency. HCCs are not required to use the ASPR TRACIE template but are encouraged to do so to promote consistent operational planning and formatting of the specialty annexes.

The ASPR TRACIE team will also be developing an accompanying HCC Radiation Emergency Surge Annex Tabletop Toolkit to assist with the exercise requirement of the FOA. Please keep a look out for the draft toolkit for your review in the mid-September timeframe. You can see an example of these complimentary tools in our [ASPR TRACIE HCC Burn Surge Annex Template](#) and [HCC Burn Surge Annex TTX Template Toolkit](#).

22 dead, many missing after 17 inches of rain in Tennessee

(AP News, August 23, 2021) Saturday's flooding in rural areas took out roads, cellphone towers and telephone lines, leaving families uncertain about whether their loved ones survived the unprecedented deluge. Emergency workers were searching door to door, said Kristi Brown, a coordinator for health and safety supervisor with Humphreys County Schools. <[Read more](#) >

Louisville Could Force Doctors To Report Gunshot Wounds To Police

(WFPL) A Louisville Metro Council member is proposing an ordinance that would mandate doctors report gunshot wounds and other firearm-related injuries to public health officials and the police. The proposal from Council Member Anthony Piagentini (R-19) would require doctors to collect data on patients who seek treatment for those injuries, including name, sex, race and the date and location of the injury. They would then have to share that data with the Louisville Metro Department of Health and Wellness. As written, the proposed ordinance requires the Health Department to share all of the data it collects, including identifiable information, with the police, regardless of the victim's consent.

Read more: <https://wfpl.org/louisville-could-force-doctors-to-report-gunshot-wounds-to-police/>

**State Attorneys General Push Back Against
Administration's Proposed Firearms Parts Regulation**

(IACP "[The Lead](#)") [Fox News](#) (8/21, Schultz) reports on its website the "attorneys general of 20 states" (including Kentucky) led by Arizona AG Mark Brnovich and West Virginia AG Patrick Morrisey "are fighting back against an 'unconstitutional' new rule proposed by the Bureau of Alcohol, Tobacco, Firearms and Explosives "on firearms parts that followed President Biden's effort to regulate so-called ghost guns." Fox News adds that "the GOP-led states contend that federal law authorizes the ATF to regulate complete firearms and receivers, not the individual parts of an incomplete receiver, and new regulations could put certain gun parts manufacturers out of business."

Link to letter: <https://ago.wv.gov/Documents/2021.08.19%20ATF%20Comments.pdf>

Gang Shootings Behind Rise In Homicides In Several Cities

(IACP "[The Lead](#)") The [Wall Street Journal](#) (8/20, Elinson, Subscription Publication) reports gang shootings are propelling an uptick in homicides in several cities throughout the nation, including Los Angeles.

MOREmpowerment Conference

August 25; 9 AM to 4:15 pm ET

The Richmond, KY-based Madison Opioid Response and Empowerment program, or MORE, will host a virtual opioid conference, "Addressing the Growing Opioid Crisis," August 25 from 9 a.m. to 4:15 p.m. via Zoom webinar. This regional conference is free and open to the public and will focus on efforts related to prevention, education, harm reduction, treatment, recovery, family supports, community engagement, and more.

Operated by Kentucky River Foothills, MORE works to sustain the fight against Opioid Use Disorder/Substance Use Disorder in Madison County through a Rural Community Opioid Response Program grant funded by the U.S. Health Resources and Services Administration.

Gov. Andy Beshear will provide opening remarks, followed by Kentucky's Public Health Commissioner, Dr. Stephen Stack. Dr. Stack will provide insight into the Kentucky Department for Public Health's work to address Kentucky's opioid crisis. His presentation will focus on prevention, collaborative responses to the opioid crisis, and progress being made in Kentucky.

[Click here](#) to register for the conference. For more information, visit foothillscap.org.

***Related story* - Affordable Naloxone Is Running Out,
Creating a Perfect Storm for More Overdose Deaths**

After a manufacturing issue halted Pfizer's production of the single-dose injectable naloxone in April, groups that distribute a significant amount of the lifesaving medicine say they are facing an unprecedented obstacle to reverse drug overdoses as they reach an all-time high, according to a recent article in the *Washington Post*. Organizers say the insufficient supply has been felt unequally across the country. (Note: The shortage mentioned in the linked article does not affect the availability of the nasal form of naloxone [Narcan] most commonly utilized in Kentucky.) Pfizer, which offers naloxone at a discount to a national buyer's club made up of harm prevention programs, said it may take until February before it can meet demand again. To read the article, [click here](#)

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 add or delete, 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.