Kentucky Hospital Research & Education Foundation
Emergency Preparedness Update
for December 2, 2020

CDC-convened committee votes to add nursing home residents to first phase of COVID-19 vaccine access

(USA Today) Public health officials voted Tuesday to add residents of long-term care facilities to front-line health care workers as the first Americans to get a COVID-19 vaccine. Nursing home residents previously had been further down the priority list to vaccinate as doses become available.

"My vote reflects maximum benefit, minimum harm, promoting justice and mitigating health care inequalities," said Advisory Committee on Immunization Practices chairman Dr. Jose Romero, chief medical officer of the Arkansas Department of Health

The ACIP is an independent group convened by the U.S. Centers for Disease Control and Prevention to offer advice on who should get specific vaccines and when.

Those in the so-called Phase 1a group would be followed by essential workers in Phase 1b, then adults with high-risk medical conditions and people 65 and older in Phase 1c. Other populations at lower risk of serious illness from COVID-19 would come later next year.

The ACIP vote is only for planning purposes, noted Dr. Sharon Frey of the Saint Louis University Medical School. The recommendations will not apply to a specific vaccine until one is authorized by the FDA and the ACIP votes on recommendations for that vaccine. The reason is that all vaccines are different, even all COVID-19 vaccines.

Full story: https://www.usatoday.com/story/news/health/2020/12/01/covid-19-vaccine-cdc-panel-votes-nursing-homes-first-access/3787703001/

UK approves Pfizer's COVID-19 vaccine, likely putting pressure on FDA

(STAT News) The United Kingdom on Wednesday became the first country to approve a Covid-19 vaccine developed by Pfizer and its partner BioNTech, a decision that will likely put pressure on the Food and Drug Administration to move swiftly to do the same.

The vaccine is also the first to run the gauntlet of clinical studies normally required for approval. Russia and China have authorized vaccines without Phase 3 clinical trial data.

Both the Pfizer/BioNTech and Moderna vaccines have been shown in large trials to reduce the risk of developing symptomatic Covid-19 infection by more than 90%. But full details on both trials have been made available only by press releases, not in medical journals.

The FDA normally conducts the most rigorous reviews of medical products in the world, re-analyzing the databases from clinical trials and conducting its own reviews of the safety and efficacy of products, as well as independent statistical reviews of their clinical trials.

Full story: https://www.statnews.com/2020/12/02/u-k-approves-pfizers-covid-19-vaccine-putting-pressure-on-fda/

Related - Pushed to rush, FDA head says feds will get vaccine 'right'

(AP) he head of the agency responsible for authorizing COVID-19 vaccines said Tuesday that it would take the time needed to "get this right," despite increasing pressure from President Donald Trump to speed up the process.

"No one at FDA is sitting on his or her hands. Everyone is working really hard to look at these applications and get this done," Stephen Hahn, the head of the Food and Drug Administration, told ABC in an interview on Instagram Live. "But we absolutely have to do this the right way."

Hahn's comments came not long after he was summoned to the White House by Trump's chief of staff Mark Meadows as the agency weighs whether to allow emergency use of the first vaccines that could begin the long road to defeating the coronavirus in the U.S.

Trump has been livid with the FDA for not moving faster to approve the shots, blaming the fact that a vaccine was not available ahead of the Nov. 3 election in part for his loss. He also has leveled unfounded claims that drug companies deliberately delayed vaccine development to hinder his reelection chances, though there is no evidence to suggest that took place.

As he has refused to accept his loss, Trump also has told close confidants that he believes the vaccine is still being slow-walked in a bid to undermine his efforts to challenge the results. If the vaccine were shipped out sooner, he has argued, it would rally public opinion to his side.

Hahn emerged from the White House meeting with his job intact, but it was a sign of the pressure he is under that the FDA offered guidance that "Dr. Hahn remains FDA Commissioner." Hahn said the FDA will thoroughly review each vaccine before making it available to the public.

Full AP story: https://apnews.com/article/election-2020-donald-trump-mark-meadows-coronavirus-pandemic-elections-d93bd92727e89e451a2be73ec3de8ede

Related story **- Moderna CEO expects emergency use nod for COVID-19 vaccine shortly after FDA's December 17 meet**

(Reuters Dec 2) Moderna Inc's COVID-19 vaccine could be approved for emergency use within 24 to 72 hours after the U.S. health regulator's advisory committee meeting, Chief Executive Officer Stéphane Bancel said on Wednesday.

The Food and Drug Administration is scheduled to hold the meeting on Dec. 17 to discuss the company's request for emergency use authorization for its vaccine.

Moderna currently has millions of doses of vaccines that can be shipped as soon as its request is granted, Bancel said, while speaking at the Piper Sandler healthcare conference.

Read more: https://www.reuters.com/article/us-health-coronavirus-moderna-vaccine/moderna-ceo-expects-emergency-use-nod-for-covid-19-vaccine-shortly-after-fdas-december-17-meet-idUSKBN28C28U

Related development **- US scientists developing nasal spray to prevent Covid-19**

Learn more: https://news360.com/article/543743857

Fauci: U.S. could hit herd immunity by end of summer 2021 if Americans embrace virus vaccines

(Axios) NIAID director Anthony Fauci said Tuesday the U.S. could achieve herd immunity to COVID-19 by the end of next summer or fall if there's a "good uptake" of Americans vaccinating against the virus.

Fauci said during an online video conversation with Colorado Gov. Jared Polis (D) he expects the general population to have access to the vaccines U.S regulators are now considering by April. He said if the "overwhelming majority" of Americans embraced coronavirus immunization by the end of the second quarter, the U.S. would achieve herd immunity — in which the pandemic would be curtailed as enough people in the community would be immune to the disease.

Full story: https://www.axios.com/fauci-us-herd-immunity-summer-covid-19-vaccines-756a55d5-7085-4ac3-ac62-42eb11e689d9.html

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The U.S. has spent billions stockpiling ventilators, but many won't save critically ill COVID-19 patients

(Reuters) With the COVID-19 pandemic sweeping across its shores earlier this year, the U.S. government in April announced orders for almost $3 billion of ventilators for a national stockpile, meant to save Americans suffering from severe respiratory problems brought on by the disease.

But of the 140,000 machines added since then by the government to the U.S. Strategic National Stockpile, almost half were basic breathing devices that don't meet what medical specialists say are the minimum requirements for ventilators needed to treat Acute Respiratory Distress Syndrome, the main cause of death among COVID-19 patients, according to a Reuters review of publicly-available device specifications and interviews with doctors and industry executives.

Only about 10% are full intensive care unit (ICU) ventilators of a type that doctors and ventilator specialists say they would normally use to intubate patients suffering from Acute Respiratory Distress Syndrome or ARDS, the Reuters review found. The remainder - or about 40% - are transport ventilators normally employed for shorter periods but are considered sophisticated enough to be used long enough for ARDS patients to recover.

A spokeswoman for the Department of Health and Human Services (HHS), which is responsible for making purchases for the national stockpile, said that an interagency task force on ventilators made recommendations on which models and quantities to procure in March, a time of "extreme projections for respiratory care needs."

There is currently no ventilator supply crisis in the United States as other treatments, including steroids, have reduced the need for intubation. HHS and manufacturers of the more basic devices said they can have a role in dealing with less acute cases of COVID.

Learn a lot more: https://www.reuters.com/article/us-health-coronavirus-ventilators-insigh/the-u-s-has-spent-billions-stockpiling-ventilators-but-many-wont-save-critically-ill-covid-19-patients-idUSKBN28C1N6

'Very dark couple of weeks': Morgues and hospitals overflow

(AP) Nearly 37,000 Americans died of COVID-19 in November, the most in any month since the dark early days of the pandemic, engulfing families in grief, filling newspaper obituary pages and testing the capacity of morgues, funeral homes and hospitals.

Amid the resurgence, states have begun reopening field hospitals to handle an influx of patients that is pushing health care systems — and their workers — to the breaking point. Hospitals are bringing in mobile morgues. And funerals are being livestreamed or performed as drive-by affairs.

Full story: https://apnews.com/article/pandemics-coronavirus-pandemic-2d8758a7bac85cd136248d5ce85533ed

Related - ***CBS:*** **U.S. reported more COVID-19 cases in November than most countries had all year**

Study: Coronavirus Was In U.S. Weeks Earlier Than Previously Known

(NPR) The coronavirus was present in the U.S. weeks earlier than scientists and public health officials previously thought, and before cases in China were publicly identified, according to a new government study published Monday.

The virus and the illness that it causes, COVID-19, were first identified in Wuhan, China, in December 2019, but it wasn't until about Jan. 20 that the first confirmed COVID-19 case, from a traveler returning from China, was found in the U.S.

However, new findings published in the journal *Clinical Infectious Diseases* suggest that the coronavirus, known officially as SARS-CoV-2, had infected people in the U.S. even earlier.

Researchers came to this conclusion after the U.S. Centers for Disease Control and Prevention analyzed blood donations collected by the American Red Cross from residents in nine states. They found evidence of coronavirus antibodies in 106 out of 7,389 blood donations. The CDC analyzed the blood collected between Dec. 13 and Jan. 17.

The presence of antibodies in a person's blood means they were exposed to a virus, in this case the coronavirus, and that their body's immune system triggered a defensive response.

Full story: https://www.npr.org/sections/coronavirus-live-updates/2020/12/01/940395651/coronavirus-was-in-u-s-weeks-earlier-than-previously-known-study-says

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CDC to shorten COVID-19 quarantine to 10 days, 7 with test

(AP) The Centers for Disease Control and Prevention is set to shorten the recommended length of quarantine after exposure to someone who is positive for COVID-19, as the virus rages across the nation.

According to a senior administration official, the new guidelines, which are set to be released as soon as Tuesday evening, will allow people who have come in contact to someone infected with the virus to resume normal activity after 10 days, or 7 days if they receive a negative test result. That's down from the 14-day period recommended since the onset of the pandemic.

The official, who spoke on the condition of anonymity to preview the announcement, said the policy change has been discussed for some time, as scientists have studied the incubation period for the virus. The policy would hasten the return to normal activities by those deemed to be "close contacts" of those infected with the virus, which has infected more than 13.5 million Americans and killed at least 270,000.

Full AP story: https://apnews.com/article/politics-pandemics-coronavirus-pandemic-fcbc8b93537033b749fb4900ee2027d5

CDC Coronavirus **What's New Extracts**

- ✓ EARLY RELEASE: Increase in Hospital-Acquired Carbapenem-Resistant Acinetobacter baumannii Infection and Colonization in an Acute Care Hospital During a Surge in COVID-19 Admissions --- New Jersey, February--July 2020 Tuesday, December 01, 2020
- ✓ COVID-19 Science Update released: December 1, 2020 Tuesday, December 01, 2020
- ✓ Know When to Delay your Travel to Avoid Spreading COVID-19 Tuesday, December 01, 2020
- ✓ Guidance for Health Departments about COVID-19 Testing in the Community Tuesday, December 01, 2020
- ✓ COVID-19 One-Stop Shop Toolkits Tuesday, December 01, 2020
- ✓ Commercial Laboratory Seroprevalence Survey Data Tuesday, December 01, 2020
- ✓ People with Certain Medical Conditions Tuesday, December 01, 2020
- ✓ Considerations for Inpatient Obstetric Healthcare Settings Tuesday, December 01, 2020
- ✓ What Long-Haul Truck Driver Employees Need to Know about COVID-19 Monday, November 30, 2020
- ✓ Healthcare Facilities That Have Implemented COVID-19 Electronic Case Reporting Monday, November 30, 2020

Ambulance companies at 'a breaking point' after receiving little Covid aid

(NBC) In a letter obtained exclusively by NBC News, the American Ambulance Association told the Department of Health and Human Services that "the 911 emergency medical system throughout the United States is at a breaking point."

Learn more: https://www.nbcnews.com/news/us-news/ambulance-companies-breaking-point-after-receiving-little-covid-aid-n1249586

FDA Sends Warnings on Unapproved COVID-19 Products; Adulterated and Mislabeled Test Kits

- As part of the FDA's effort to protect consumers, the agency issued a warning letter jointly with the Federal Trade Commission to Avazo-Healthcare, LLC for selling adulterated and misbranded COVID-19 test kits and unapproved drug products with fraudulent COVID-19 claims. In addition to COVID-19 test kits, the company sells CBD products with misleading claims that the products can mitigate, prevent, treat, diagnose, or cure COVID-19. The FDA requested that Avazo-Healthcare immediately stop selling these unapproved, uncleared and unauthorized test kits and unapproved products. Consumers concerned about COVID-19 should consult with their health care provider.
- The FDA has also posted the following warning letters for unapproved and misbranded products related to COVID-19: ChromaDex; Innovative Medicine LLC; Red Moon Herbs; Sage Woman Herbs, Ltd. dba Sage Consulting & Apothecary.

GAO calls for COVID-19 medical supplies, testing guidance

(CIDRAP) The US Government Accountability Office (GAO) Monday published a report calling for actions such as increasing transparency in COVID-19 vaccine and treatment development and meeting states' needs for scarce medical supplies.

In its fourth report on the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the GAO also recommended improved COVID-19 testing guidance, more accurate estimates of the number of people relying on unemployment benefits, better oversight of Veterans Affairs nursing homes, and more information on the status of economic impact payments to individuals.

The 11 new recommendations come on top of the 19 previous recommendations the GAO has already issued in regards to the CARES Act.

Read full CIDRAP story: https://www.cidrap.umn.edu/news-perspective/2020/12/gao-calls-covid-19-medical-supplies-testing-guidance

GAO Report Link: https://www.gao.gov/products/GAO-21-191

Lesson from history: (NPR/WNYC) - **Why the Press Downplayed the 1918 Flu**

Podcast: https://www.wnycstudios.org/podcasts/otm/segments/why-press-downplayed-1918-flu-on-the-media