Town Hall Technical Assistant Workshop

Arkansas Community Engagement Alliance Against COVID-19 Disparities

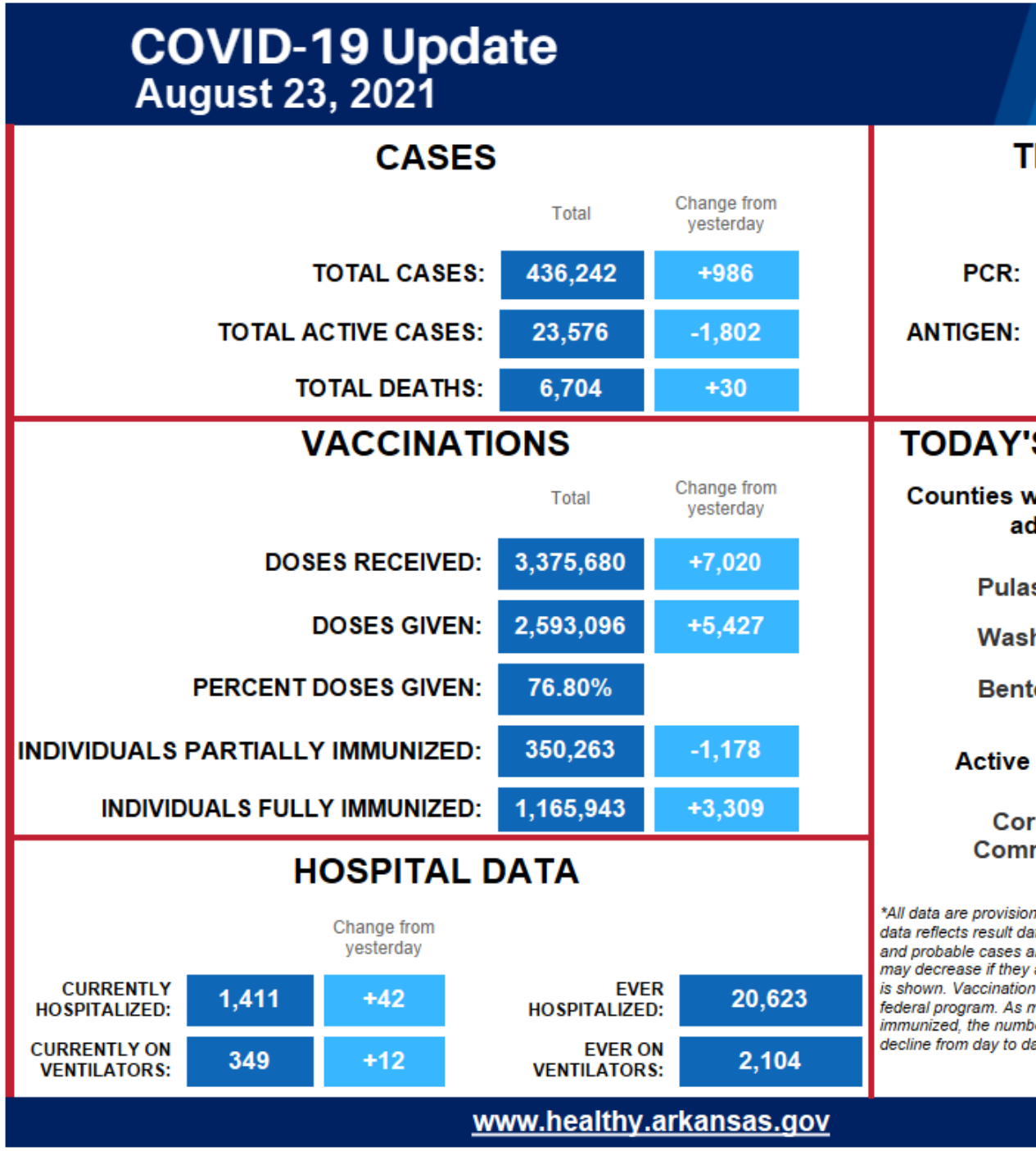
8/22/21

Goals for Today

- COVID-19 moments.
- Discuss boosters and other scientific updates.
- Updates on CEALFunds.
- Updates on the Door-to-Door campaign.
- Returning the Coalition Survey.

- Our **VISION** is to create a COVID-19 free state, where no one is left behind to suffer from the devasting effects of this infectious disease and its unintended consequences.

Updates on Cases



COVID-19 Update
August 23, 2021

CASES

	Total	Change from yesterday
TOTAL CASES:	436,242	+986
TOTAL ACTIVE CASES:	23,576	-1,802
TOTAL DEATHS:	6,704	+30

VACCINATIONS

	Total	Change from yesterday
DOSES RECEIVED:	3,375,680	+7,020
DOSES GIVEN:	2,593,096	+5,427
PERCENT DOSES GIVEN:	76.80%	
INDIVIDUALS PARTIALLY IMMUNIZED:	350,263	-1,178
INDIVIDUALS FULLY IMMUNIZED:	1,165,943	+3,309

HOSPITAL DATA

		Change from yesterday		
CURRENTLY HOSPITALIZED:	1,411	+42	EVER HOSPITALIZED:	20,623
CURRENTLY ON VENTILATORS:	349	+12	EVER ON VENTILATORS:	2,104

www.healthy.arkansas.gov

What do we know about additional doses and boosters?

Brief Update on COVID-19 Booster Shots; What is Emergency Use Authorization?

- The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.

- Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when the Secretary of HHS declares that an emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.

- The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretary of HHS, Homeland Security, or Defense.

Brief Update on COVID-19 Booster Shots

- All COVID-19 vaccines Pfizer, Moderna and J&J are **effective** at preventing COVID-19 disease in the majority of people.

- COVID-19 vaccination helps protect people from getting sick or severely ill with COVID-19 and might also help protect people around them.

- To receive the most protection, people should receive all recommended doses of a COVID-19 vaccine.

- **No vaccine is 100% protective.** Some people who are fully vaccinated against COVID-19 will still get sick.

Brief Update on COVID-19 Booster Shots

What is difference between a **booster** and **additional** dose?

- Some people who have compromised immune systems do not build enough (or any) protection when they first get a vaccination.
- When this happens, getting another dose of the vaccine can sometimes help them build more protection against the disease.
- CDC recommends that persons with moderate to severe compromised immune systems get a third dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial 2-dose mRNA COVID-19 vaccine series.
- August 12th, the FDA approved that immunocompromised people could get a **third dose** of the Pfizer-BioNTech or Moderna Vaccines.

Brief Update on COVID-19 Third Dose for Person with Low Immunity

- August 12th, the FDA approved the immunocompromised people could get a third dose of the Pfizer-BioNTech or Moderna vaccines, depending on the vaccine they started with.

Brief Update on COVID-19 Booster Shots

What is a booster shot?

- A “booster dose” refers to another dose of a vaccine that is given to someone who built enough protection after the vaccination, but then that protection decreased over time. This mean that your immunity, ability to ward of illness, may decrease over time.

Brief Update on COVID-19 Booster Shots

- On August 23, 2021, the FDA gave Pfizer full approval to manufacture the COVID-19 vaccine for persons aged 16 and over.
- Prior approvals were emergency approvals for Pfizer, Moderna, and J&J.
- The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as **Comirnaty,** 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.

Brief Update on COVID-19 Booster Shots

FDA has given Pfizer to a license to manufacture their COVID-19 vaccine for aged 16 and over.

Brief Update on COVID-19 Booster Shots

- **Why are boosters not yet approved for Moderna and J&J?**

- Pfizer approved for emergency use on Dec 11, aged 16 and over.
  - May 10th, approved for children aged 12-15.
  - Applied for a license in May.

- Moderna approved for emergency use on Dec 18 aged 18 and over.
  - Applied for a license in June.

- On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for J&J.
  - Not yet applied. Need at least 6 months of data to apply.

What do we know about treatments for COVID-19?

Brief Update: Treatment for COVID-19

- There were no treatments for COVID-19 when the pandemic first began.

- monoclonal antibody therapy helps prevent severe symptoms from developing in those who are high risk.

- https://youtu.be/a9ZdqAub0zA

Brief Update: Treatment for COVID-19

The monoclonal antibody treatments that have FDA emergency approval are:

- a combination of **casirivimab and imdevimab**, called REGN-COV, made by Regeneron;
- a combination of **bamlanivimab and etesevimab**, made by Eli Lilly and
- **sotrovimab**, made by GlaxoSmithKline.
- These treatments must be given intravenously in a clinic or hospital. These treatments are not currently authorized for hospitalized COVID-19 patients or those receiving oxygen therapy.

Brief Update: Treatment for COVID-19

- If you get the coronavirus, then FDA has authorized monoclonal antibody treatments for emergency use for adults and pediatric patients (ages 12 and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Brief Update: Treatment for COVID-19

What is monoclonal antibody treatment?

- Monoclonal antibodies are similar to antibodies you would develop against COVID-19.

- Monoclonal antibodies are mass-produced in a laboratory and are designed to recognize a specific component of this virus — the spike protein on its outer shell.

Brief Update: Treatment for COVID-19

- The clinical trial found the antibodies prevented symptoms in household contacts of people who recently tested positive.

- The one-hour treatment fusions are provided through an IV and prevent hospitalizations, reduce viral loads and lessen symptom severity.

Brief Update: Treatment for COVID-19

Monoclonal antibody therapy can be extremely effective, but it's not a replacement for vaccination.

Brief Update: Treatment for COVID-19

Monoclonal antibody **treatment** is available to individuals who:

- Are high risk for developing severe COVID-19 **and**
- Have a positive COVID-19 test and have not yet been admitted to the hospital **and**
- Are 12 years of age or older (and at least 88 pounds)

Brief Update: Treatment for COVID-19

High risk includes any of the following:

- 65 years of age or older
- Overweight (body mass index over 25)
- Pregnancy
- Chronic kidney disease
- Diabetes (Type 1 and Type 2)
- Weakened immune system
- Currently receiving immunosuppressive treatment
- Cardiovascular disease/hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders
- Medical-related technological dependence

Brief Update: Treatment for COVID-19

Preventive monoclonal antibodies are available to those who have been exposed **and** are at high risk for progression to severe COVID-19 **and** who are:

- Not fully vaccinated **or**
- Vaccinated but immunocompromised **and** have been directly exposed **or** are at are high risk for exposure due to the occurrence of an infection within the same setting, such as a nursing home or prison

- a combination of **casirivimab and imdevimab**, called REGN-COV, made by Regeneron was approved on August 10th as a preventive under emergency authorization.

Brief Update: Treatment for COVID-19

Challenges with treatment:

- There has been a rise in more contagious SARS-CoV-2 variants, some of which exhibit decreased susceptibility to the monoclonal antibodies.

- Difficulties have also arisen in administering these compounds to outpatients with mild and moderate disease in overwhelmed hospitals.

Brief Update: Treatment for COVID-19

People who have had symptoms for 10 days or less should be referred for treatment by their healthcare providers and directed to available infusion locations.

If you do not have a healthcare provider, call the Combat COVID Monoclonal Antibodies Call Center at 1-877-332-6585 to find out who to talk with about your symptoms and treatment.

There is **no cost** to anyone for the antibodies themselves, but there may be treatment fees. If you do not have insurance, ask the facility if there will be a charge.

Brief Update: Treatment for COVID-19

- After receiving monoclonal antibody therapy, it's recommended that you wait 90 days before receiving the COVID-19 vaccine.

- If you already received the first dose of vaccine before monoclonal antibody therapy, current CDC guidelines recommend you wait 90 days before receiving the second dose.

Brief Update: Treatment for COVID-19

Where can you get monoclonal antibody treatments in Arkansas?

- https://protect-public.hhs.gov/pages/therapeutics-distribution

Purposes of the Door-to-Door Campaign

- Build trust
- Reduce misinformation
- Increase protective behaviors
- (e.g. masks, social distancing, handwashing, screening/testing, isolation, vaccination)

Brief Update: CEAL Funds

- Completing vendor forms.
- Applications must focus on COVID-19.
- Budgets = $2K or less.
- These funds are directed to save community lives.

Brief Update: Coalition Survey

The survey help us understand how we can help you build capacity to address COVID-19.

The survey is to be completed by **one** organizational representative only.

This survey is only for those who have been participating in the coalition. Please do not forward it to others. We will not be able to use their responses or provide a gift card.

Other Discussions?