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Update on COVID-19 Vaccine Administration & Current Status Regarding Mpox

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December 13, 2023

DISCLAIMER

The information presented today is based current preliminary data and on CDC's recent guidance. Information is subject to change.

December 13, 2023

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Updated 2023-2024 COVID-19 Vaccines

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- September 11, 2023, the Food and Drug Administration (FDA) submitted the following press release highlighting:
  - Bivalent mRNA COVID-19 vaccines are no longer authorized
  - Approval and authorization of updated 2023-2024 COVID-19 vaccines targeting XBB.1.5 sub-lineage
- September 12, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) issued updated clinical guidance for COVID-19 vaccination.
- September 19, 2023, the new COVID-19 2023-2024 formulations went live in the Vaccine Allocation and Ordering System (VAOS) for all TVFC/ASN providers.
- This is the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the United States Government for those providers not involved in programs within DSHS.
- October 3, 2023, the FDA authorized the updated 2023-2024 Novavax COVID-19 for individuals ≥12 yrs and ACIP updated the clinical guidance in accordance with this.

COVID-19 Vaccine Program Transition to Texas Vaccines for Children (TVFC) Program

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- The COVID-19 vaccines are now available to under the TVFC program.
- TVFC program patient eligibility for all ACIP-recommended vaccines, including COVID-19, is birth through 18 years of age who are:
  - Uninsured
  - Underinsured
  - Children's Health Insurance Program (CHIP) - enrolled
  - Medicaid-enrolled/Medicaid-eligible
  - American Indian or Alaskan Native
- TVFC providers can charge an administrative fee up to $13.75 for the COVID-19 vaccine however must not:
  - Deny administration of a TVFC vaccine to an eligible child because of the inability of the child's parent/guardian to pay the administration fee.
  - Charge an administration fee to Medicaid or CHIP patients.
  - Send a patient to collection or charge additional fees for non-payment of a TVFC administration fee.

COVID-19 Vaccine Program Transition to Adult Safety Net (ASN) Program

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- The COVID-19 vaccines are now available under the ASN program.
- ASN program patient eligibility for the COVID-19 vaccine is 19 years of age and older who are uninsured or underinsured.
  - Uninsured - a person who does not have Medicare, Medicaid, or private insurance.
  - Underinsured - a person who has health insurance, but the insurance does not cover COVID-19 vaccines; a person whose medical insurance does not provide first-dollar coverage (i.e., copay-free coverage) of COVID-19 vaccinations.
    - First-dollar coverage: Refers to health care services, such as COVID-19 vaccinations, covered pre-deductible and without any cost-sharing.
- ASN providers cannot charge an administration fee for the COVID-19 vaccine.

Recent FDA MedWatch

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- FDA has become aware that some providers may not recognize that the single dose vial of Moderna COVID-19 Vaccine (2023-2023 Formula) contains more than 0.25 mL of the vaccine.
- The correct volume of a single dose of Moderna COVID-19 Vaccine (2023-2024 Formula) is only 0.25 mL.
- Any excess should be discarded.
- The Moderna COVID-19 Vaccine (2023-2024 Formula) is authorized for use in individuals 6 months through 11 years of age.

*U.S. Food and Drug Administration sent the bulletin on 11/01/2023

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Updated 2023-2024 COVID-19 Vaccination Data Texas, 9/12/2023 – 12/06/2023

Age Group	Number of Updated 2023-2024 COVID-19 Vaccine Doses Administered* (September 12, 2023 – December 6, 2023)
6 months – 4 years	12,111
5-11 years	25,518
12-17 years	41,909
18-49 years	189,104
50-64 years	230,225
65+ years	467,521
Total	**966,388**

*Data as of December 07, 2023 from Texas Immunization Registry

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2023 Mpox Update

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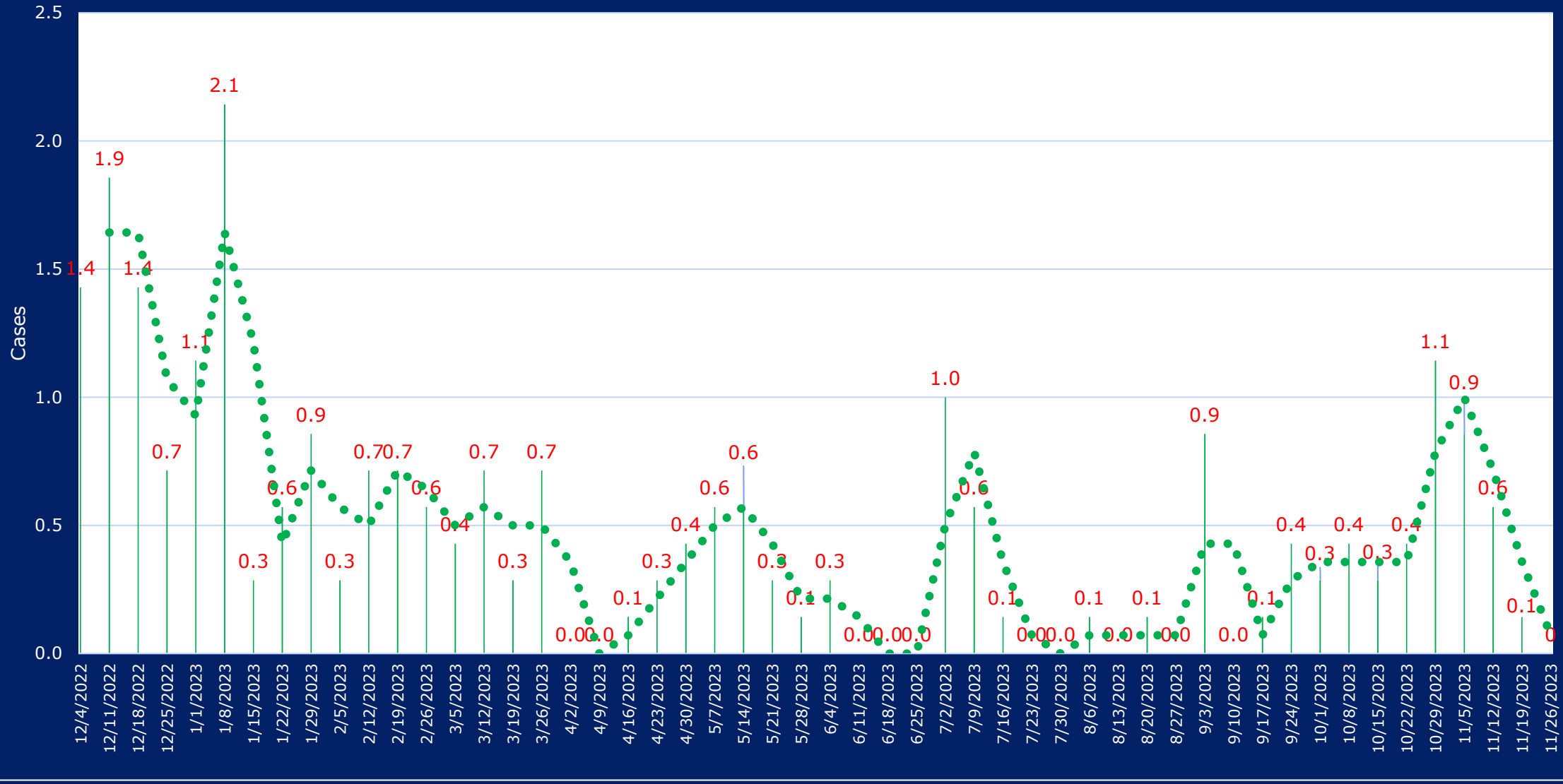
Chief State Epidemiologist

Office of the Chief State Epidemiologist

Average Mpox Cases Reported per Day by Week
12/4/2022 to 12/3/2023*

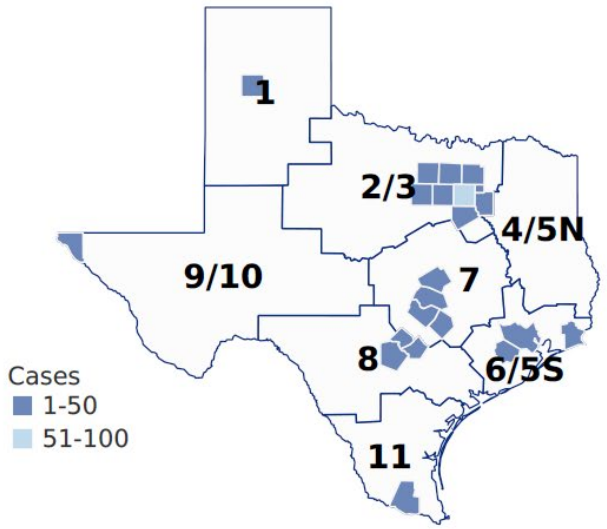


Data as of 12/4/2023
*2023 data is provisional and subject to change.

Mpox Situation Report Surveillance
(01/01/2023 through 12/3/2023)**

Cases by Public Health Region

	Confirmed	Probable	Total Cases	% of Total Cases
1	0	1	1	0.6%
2/3	49	41	90	54.5%
4/5N				
6/5S	14	9	23	13.9%
7	10	27	37	22.4%
8	3	9	12	7.3%
9/10	1	0	1	0.6%
11	0	1	1	0.6%
UNK				
Total	**77**	**88**	**165**	**100.0%**



	# of Cases	% of Cases
<18 Years	*suppressed*	
18-29 Years	22	13.3%
30-39 Years	51	30.9%
40-49 Years	17	10.3%
50-59 Years	12	7.3%
60+ Years	*suppressed*	
Total	165	100.0%

	# of Cases	% of Cases
Asian	*suppressed*	
Black	46	27.9%
Hispanic	58	35.2%
Other	*suppressed*	
Unknown	7	4.2%
White	49	29.7%
Total	165	100.0%

Data as of 12/4/2023
*Case counts of 1-4 are suppressed to prevent potential identification of individuals.
**2023 data is provisional and subject to change.

Current Situation (10/1/2023 - 12/3/2023)

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- Preliminary data indicate an upward trend in cases
- Over the past 2 months:
  - 33 cases and positive labs have been reported
  - 21 (64%) are from PHR 2/3 but seeing additional geographic spread
  - 32 (97%) are male
  - 46% are Black or African American, 27% are Hispanic, 15% are White, and 12% are another race or unknown
  - More than half of the cases were between 30-39 years of age

Health Advisory: Mpox Caused by Human-to-Human Transmission of Monkeypox Virus Clade I with Geographic Spread in the Democratic Republic of the Congo

HEALTH ADVISORY

December 12, 2023

Summary

With the increased number and geographical spread of mpox cases caused by Clade I monkeypox virus (MPXV) in the Democratic Republic of the Congo (DRC), the Texas Department of State Health Services (DSHS) recommends clinicians and public health departments take action to quickly identify cases. Cases of Clade I MPXV, which may be more transmissible and cause more severe infection than Clade II, have not been reported in the United States at this time. However, clinicians should be aware of the possibility of Clade I MPXV in travelers who have been in DRC. Clinicians should notify their health department and pursue MPXV clade-specific testing if they have a patient with mpox-like symptoms and recent travel to DRC within 21 days of illness onset.

Vaccines and other medical countermeasures are available and expected to be effective for both Clade I and Clade II MPXV infections. However, vaccination coverage in the United States remains low. The Centers for Disease Control and Prevention (CDC) recommends that clinicians encourage vaccination for eligible patients.

Background

Available at: Health Advisory: Mpox Caused by Human-to-Human Transmission of Monkeypox Virus Clade I with Geographic Spread in the Democratic Republic of the Congo | Texas DSHS, accessed on 12/12/23.

Interim Clinical Guidance for the Treatment of Mpox

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- For patients with severe disease or at high risk for progression to severe disease, tecovirimat should be administered early in the course of illness along with supportive care and pain control.
- The following treatment options are available for the treatment of mpox.

MCMs	ACCESS/APPROVAL	SOURCE/SHIPPED FROM
Tecovirimat(TPOXX), Oral tablet	STOMP trial / HPOP	Trial site / SNS
Tecovirimat(TPOXX), IV	CDC approval	SNS
Brincidofovir, tablets or oral suspension	FDA	SNS
Cidofovir, IV	Commercially available	
Trifluridine ophthalmic solution (drops)	Commercially available	
Vaccinia immune globulin intravenous (VIGIV)	CDC approval	SNS

- Email DSHS MPX Consult at dshsmpxconsult@dshs.texas.gov to request CDC clinical consult.

Available at cdc.gov/poxvirus/mpox/clinicians/treatment.html, accessed on 11/28/23.
Available at stomptpoxx.org, accessed on 11/28/23.

Interim Clinical Guidance for the Treatment of Mpox - Oral TPOXX Access

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- Oral tecovirimat for treatment of mpox is available through enrollment in the Study of Tecovirimat for Human Mpox Virus (STOMP) clinical trial.
  - Visit stomptpoxx.org or call 1-855-876-9997, for more information on patient enrollment.
- Providers with patients with mpox who decline enrollment in or are ineligible for STOMP, or who require intravenous tecovirimat treatment, and meet treatment eligibility under the EA-IND protocol (e.g., have severe disease or involvement of anatomic areas that might result in serious sequelae, are at high risk for severe disease), can gain access to tecovirimat on CDC approval.
  - Send requests to dshsmpxconsult@dshs.texas.gov.

Available at cdc.gov/poxvirus/mpox/clinicians/obtaining-tecovirimat.html accessed on 11/28/2023.

Mpox Vaccine (JYNNEOS)

- Route of vaccine administration based on the best option and individual preferences.
  - Providers can administer JYNNEOS either subcutaneously (0.5 mL/dose) or intradermally (0.1 mL/dose) to individuals ≥18 yrs.
  - Individual less than 18 years of age, administer subcutaneously only (0.5 mL/dose).
- JYNNEOS is a 2-dose vaccine series given 28 days apart regardless of route of administration.
  - Either route, the vaccine must be administered as a 2-dose series given 28 days apart.
  - If its longer than 28 days, administer the second dose as soon as possible. There is no need to repeat dose 1.

Available at: JYNNEOS Vaccine | Mpox | Poxvirus | CDC, accessed 12/11/2023

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Mpox Vaccine Ordering Process

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- Local Health Departments (LHDs) are eligible to order from the DSHS central pharmacy.
- LHDs must be enrolled in the "outbreak response" module to request JYNNEOS from the DSHS central pharmacy.
- A provider enrolled in other programs (eg. TVFC) may request a transfer from their LHD or responsible entity (RE).
- All reporting of orders, administrations, waste, transfers is done in VAOS.
- Providers may transfer JYNNEOS in VAOS to any other DSHS-enrolled site.
- JYNNEOS is available under the "outbreak response" section of the VAOS ordering page for eligible providers.
- While there are no limitations to ordering, providers must be able to store all requested vaccines and reasonably minimize waste.

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Thank you