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Monkeypox Virus Outbreak, Update #3 JYNNEOS[™] Vaccine and Tecovirimat (TPOXX) Access

Key Points and Recommendations:

- Monkeypox virus infections are increasing in the <u>United States</u> and <u>globally</u> with spread of the virus occurring primarily through sexual networks affecting men who have sex with men (MSM); on July 23rd the World Health Organization (WHO) declared the escalating global outbreak a Public Health Emergency of International Concern (PHEIC).
- Recent studies have identified a median incubation period of ~7 days between exposure and onset of disease (<u>Thornhill et al. NEJM. Jul 2022</u>; <u>Tarín-Vicente et al. Lancet Pre-Print. Jul 2022</u>). Because of the short incubation period, post-exposure prophylaxis (PEP) vaccination is likely of lower benefit for disease control than identifying and vaccinating high-risk persons BEFORE exposure occurs. Therefore, NH Division of Public Health Services (DPHS) will continue to provide PEP but is also transitioning to a pre-exposure prevention vaccine strategy.
- NH DPHS recommends that the following highest-risk persons be vaccinated with JYNNEOS to protect against monkeypox virus infection:
 - Post-Exposure Prophylaxis (PEP) vaccination should be offered to:
 - Persons who report in the prior 14 days prolonged (i.e., hours of) face-to-face contact, or any direct physical/intimate contact to another person with suspect or confirmed monkeypox.
 - Persons who report in the prior 14 days coming into physical contact with items (e.g., clothing or linens) that are known to have previously touched the infectious rash or body fluids of a person with monkeypox.
 - Healthcare workers who in the prior 14 days have an exposure to monkeypox without wearing all recommended personal protective equipment (PPE), as outlined in CDC's <u>Exposure Risk Assessment</u> tables.
 - Pre-Exposure Prophylaxis (PrEP) vaccination should be offered to men who have sex with men (MSM) that report any of the following:
 - 3 or more new sex partners in the last month;
 - Engaging in group or anonymous sex;
 - Engaging in sex with people at sex-on-site venues or events;
 - Exchanging sex for money, drugs, or other services; or
 - Taking medications for HIV prevention (i.e., HIV PrEP)
 - Persons can be vaccinated using NH vaccine supply if they are residents of NH, work in NH, or have a NH primary care provider.
 - Persons with confirmed monkeypox infection during the 2022 outbreak should NOT be vaccinated even if they meet the criteria above, because disease is likely to be protective.

- NH DPHS will provide JYNNEOS vaccine through city health departments and provider clinics that have agreed to receive referrals for vaccination from clinicians both in and outside their health system.
 - Information about clinic locations, availability, and contact/referral information can be found on the NH DPHS <u>monkeypox website</u> starting Monday, August 15th.
 - This website will be routinely updated as new clinic locations are added.
- Review CDC's new Interim Guidance for use of the JYNNEOS vaccine.
 - The standard FDA-approved JYNNEOS dosing regimen for adults 18 years of age or older is 2 doses (0.5 mL per dose) administered by <u>subcutaneous</u> injection, separated by 28 days.
 - Provide the JYNNEOS <u>Vaccine Information Statement</u> (VIS) to all patients prior to vaccination occurring under the FDA-approved dosing regimen.
 - The FDA has also <u>issued an Emergency Use Authorization</u> (EUA) which allows the JYNNEOS vaccine to be given as follows:
 - Adults 18 years of age or older: 2 doses (0.1 mL per dose) administered by <u>intradermal</u> injection (doses separated by 28 days).
 - Children and adolescents younger than 18 years: 2 doses (0.5 mL per dose) administered by <u>subcutaneous</u> injection (doses separated by 28 days).
 - We recommend providers transition now to intradermal administration under the FDA's EUA (for adults 18 years of age or older) because this dose-sparing strategy increases vaccine availability by 5-fold.
 - Review the <u>FDA Fact Sheet for Healthcare Providers</u> administering the JYNNEOS vaccine under the FDA's EUA.
 - Provide the <u>FDA Fact Sheet for Recipients and Caregivers</u> being administered the JYNNEOS vaccine under the FDA's EUA.
 - The lower intradermal dose has been <u>studied</u> and shown to be immunologically non-inferior to the standard subcutaneous dose.
 - Counsel patients about the risk for local injection site reactions (e.g., redness, swelling, induration, itching) which can potentially last for a prolonged period of time with intradermal administration.
 - Resources for <u>administering an intradermal injection</u> will be available on CDC's website, and we will review intradermal injections on a Project ECHO webinar (see attached flyer).
- JYNNEOS is safe with few <u>contraindications and precautions</u> as summarized below.
 - <u>Contraindication</u>: Persons with a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine have a vaccine CONTRAINDICATION to receipt of a subsequent dose.
 - Precaution:
 - Persons with a previous severe allergic reaction to gentamicin or ciprofloxacin have a vaccine PRECAUTION because the JYNNEOS vaccine contains small amounts of gentamicin and ciprofloxacin.

- Persons with a previous severe allergic reaction to chicken or egg protein AND who are currently avoiding exposure to all chicken or egg products have a vaccine PRECAUTION because the vaccine is produced using chicken embryo cells.
- Persons with a vaccine PRECAUTION should be counseled about the potential increased risk of allergic reaction, and providers should discuss risks and benefits of vaccination. A 30-minute observation period after vaccination is recommended.
- The JYNNEOS vaccine is expected to be at least 85% effective at preventing monkeypox, based on historical data. Therefore, people who get vaccinated should continue to be counseled to take steps to protect themselves from monkeypox (see CDC's <u>prevention guidance</u>).
- Review the following short CDC videos for a refresher on vaccine administration:
 - o Intradermal vaccine administration
 - o <u>Subcutaneous vaccine administration</u>
- Providers should be familiar with CDC's <u>Interim Clinical Guidance for the Treatment of</u> <u>Monkeypox</u>.
 - Tecovirimat (TPOXX) is the primary therapeutic being used to treat monkeypox infection, including for outpatient therapy.
 - TPOXX can be accessed by a prescribing provider by contacting NH DPHS at: 603-271-4496.
 - Use of TPOXX to treat monkeypox virus infection occurs under a CDC Expanded Access Investigational New Drug (EA-IND) protocol, so providers must follow CDC's <u>requirements</u> for obtaining and using <u>TPOXX</u>, including obtaining informed consent before treatment and submitting the required forms to CDC Regulatory Affairs at <u>regaffairs@cdc.gov</u>.
 - Review also CDC's <u>Guidance for Tecovirimat Use</u>, <u>FDA Package Insert</u>, and <u>SIGA Fact</u> <u>Sheet</u>. UpToDate[®] online also has monkeypox and TPOXX information for clinicians.
- Testing for monkeypox is available at our NH public health laboratories (PHL) and <u>five</u> <u>commercial reference laboratories</u>. To request testing at our NH PHL, clinicians should first contact NH DPHS by calling 603-271-4496 (after hours 603-271-5300 and ask for the public health professional on call). Clinicians do NOT need to report testing that is occurring through commercial laboratories.
- Test for other sexually transmitted infections (STIs) in addition to monkeypox, because multiple studies (*Girometti et al. Lancet Infect Dis. Jul 2022*; *Thornhill et al. NEJM. Jul 2022*; *Tarín-Vicente et al. Lancet Pre-Print. Jul 2022*) have found that 17-29% of people diagnosed with monkeypox have concomitant STIs, including chlamydia, gonorrhea, and syphilis.
- Clinicians should immediately report any **confirmed** case of monkeypox to NH DPHS by calling 603-271-4496 (after hours 603-271-5300 and ask for the public health professional on call).
- Join our monthly NH DPHS healthcare provider webinar for additional monkeypox updates; the next webinar will be on **Thursday**, 8/11 from 12:00 1:00 pm:
 - o Zoom link: https://nh-dhhs.zoom.us/s/94059287404
 - o Call-in phone number: (646) 558-8656

- o Meeting ID: 940 5928 7404
- Password: 353809
- <u>Register here</u> for a three-part Project ECHO webinar series with just-in-time training about monkeypox testing, vaccination, and treatment, hosted by Dartmouth Health in collaboration with the NH DPHS (see attached flyer). **This training will review how to conduct intradermal injections**.

- For any questions regarding this notification, please call the NH DHHS, DPHS, Bureau of Infectious Disease Control at (603) 271-4496 during business hours (8:00 a.m. – 4:30 p.m.).
- If you are calling after hours or on the weekend, please call the New Hampshire Hospital switchboard at (603) 271-5300 and request the Public Health Professional on-call.
- To change your contact information in the NH Health Alert Network, please send an email to <u>DHHS.Health.Alert@dhhs.nh.gov</u>.

Message Type: Severity:	Actual Alert Moderate Not Sensitive NH-HAN 20220810 12 hours No Email, Fax Physicians, Physician Assistants, Practice Managers, Infection Control Practitioners, Infectious Disease Specialists, Community Health Centers, Hospitals, Hospital CEOs, Hospital Emergency Departments, EMS, Nurses, NHHA, Pharmacists, Laboratory Response Network, Manchester Health Department, Nashua Health Department, Public Health Networks, DHHS Outbreak Team, DPHS Investigation Team, DPHS Management Team, Northeast State Epidemiologists, Zoonotic Alert Team, Health Officers, Deputy Health Officers, MRC, NH Schools, EWIDS, Dialysis & Transplant Clinics, STD Clinics, Immunization Practices, Travel Centers, Influenza Sentinels, Urgent Care Centers, Ambulatory Surgical Centers, Walk-in Clinics, Poison Center, Alcohol and Other Drug Treatment Centers, Long-Term Care Facilities, Community Mental Health Centers, Health Departments, Internal Medicine, Occupational Health, Gastroenterology, Schools and Daycare Providers, Regional Public Health Networks, Environmental Services, Family Planning Programs, Department of Corrections, Home Care Providers, Local and State Partners, Area Agencies
From:	Benjamin P. Chan, MD, MPH; State Epidemiologist
Originating Agency:	NH Department of Health and Human Services, Division of Public Health

Services

Attachments: Project ECHO – Just In Time: Testing, Vaccination, and Treatment for Monkeypox



Just in time: Testing, Vaccination, and Treatment for Monkeypox

Course Description

The explosive global outbreak of Monkeypox has occurred while we are transitioning our COVID pandemic response from its emergency phase. The WHO has now declared Monkeypox a Public Health Emergency of international Concern that demonstrates we must now turn our attention to all available emerging evidence to become experts in control measures. This Project Echo session is a just in time, crash course about the epidemiology, strategies for prevention and medical countermeasures.

Who Should Attend

Clinicians, Nurses, PAs, LNAs, MAs, CHWs, and others in clinical settings in New Hampshire with interest (All states are welcome, but the ECHO will focus on NH recommendations)

Schedule

Sessions held weekly on Wednesdays from 12-1pm EST	
8/17/2022	Efficient effective testing
8/24/2022	Vaccine: PEP and PrEP : This session will be followed by a 30- minutes just-in-time training for how to give intradermal vaccination. Stay on if you are someone who may be giving the vaccine yourself, are supervising a team that does, or want to be able to address your patients' concerns about the administration.
8/31/2022	Treatment: TPOXX and beyond

Questions?

Email: ECHO @hitchcock.org

Website:

https://go.d-h.org/project-echo

What is Project ECHO?

Project ECHO (Extension for Community Healthcare Outcomes) is a telementoring model. Virtual technology is used to support casebased learning and provide education. This will assist participants to care for more people, right where they live.

Benefits

- Participants learn from experts.
- Participants learn from each other.
- Experts learn from participants as best practices emerge.

Registration Information

To register, visit:

https://echo.zoom.us/meeting/register/tZYsdOuorzkoEtCtQzp3oWQclFc_Cup7pJaa Sessions are free or charge



