August 25, 2022

LTC COVID-19 Update

Presented by:

Lori Davenport, Director of Regulatory & Clinical Affairs

Indiana Department of Health Team

Indiana Department of Health

IHCA INCAL

INDIANA HEALTH CARE ASSOCIATION

INDIANA CENTER FOR ASSISTED LIVING

Today's Topics

- Probari Strike Team project – Russ Evans
- Monkeypox update and how to manage exposures – Dr. Vuppalanchi
- Survey reset – Brenda Buroker
- Q&A

Equipping Staff: Infection Control Focused Training & Competency Assessments, *a webinar on Sept. 20, details HERE*

Assisted Living Symposium*, an in-person event on Nov. 18, details coming soon!*

PROBARI

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Probari Strike Team Project

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What is the Strike Team program?

1. Funded completely by Federal COVID Strike Team dollars

1. Designed to provide short and long term support

1. 12 month total project - each facility gets 3 months

1. Probari RNs reviewing records with support of software

2. Launched in June 2022

Strike Team Project Overview

1

Probari Virtual Model

2

Infection Preventionist Software

Indiana Department of Health

Probari Virtual Model

Admission and Infection Reviews

Focused and Easy Interventions

Data Reporting and Quality Improvement

Facility

Save PDF

Testing Facility

Email

PROBARI

Testing Facility
DAILY CHECKLIST 05-23-2022

Note from Probari:

Edit Note

Save Note

Great work on documentation, Nicole in particular. Very detailed on wounds!

Time Sensitive Recommendations

Luke, Skywalker

- [ ] [New Admission Review] Reduce medication by 25 mg per Hospital records.

Standard Recommendations

Yoda, Baby

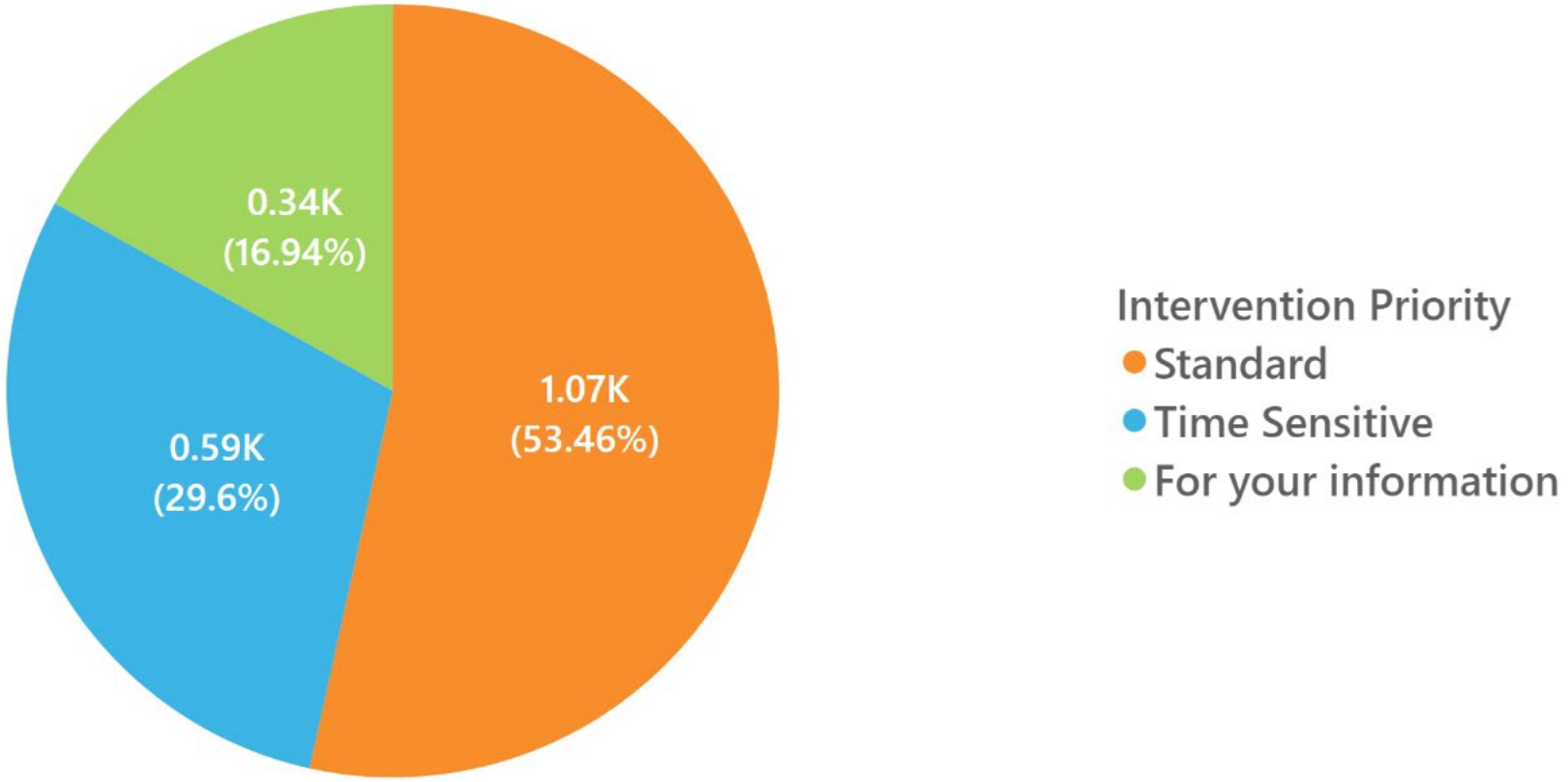
- [ ] [New Admission Review] Call orders from medications not entered into the medical record.

For Your Information

Vader, Darth

- [ ] [New Admission Review] Follow up appointment for heart failure needs to be scheduled.

Intervention Priority



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Current Project Stats

- 17 Total facilities
- 790 Unique Residents touched
- 1367 Total Reviews
- Over 2000 Total Interventions
- *Currently* averaging 2.4 interventions/review
- Less than 2 day implementation average

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Facility Feedback

- No recommended changes to the current focus
- Reported to enhance quality and save time
- 15 minutes per day time commitment
- IHIE access has increased intervention quality

Probari Infection Preventionist Software

Resident Name:
Vader, Darth

Date Of Birth:
05/06/1931

Type of Resident:
Short Stay

Resident Status:
Active

Room/Unit:

Advanced Directives:
CPR

Next Follow Up:
NONE

Notes:
tester patient

Diagnosis List:
CHF

Annual Vaccination Status & Testing

COVID:
Last Tested 12/31/1969

Flu:

Pneumonia:

+ Additonal Actions

+ Antibiotic Tracking

+ COVID Vaccinations

+ COVID Testing

+ Annual Vaccinations

Edit Resident

Resident Interactions

Last Name	First Name	Facility	Status	Type	Tags	Created Date	
Vader	Darth	Testing Facility	New	Review		2022-05-23T11:33:55.4643963Z	•••
Vader	Darth	Testing Facility	Open	Intervention		2022-05-23T15:01:48.4328031Z	•••

Showing 1 to 2 of 2 Resident Interactions « ‹ 1 › » 10

In total there are 2 Resident Interactions

Benefits of the program

- Free to all participating facilities
- Quality review support to free up staff
- Extra eyes from an RN
- Access to Probari Software for data analysis

Data - how is it handled?

- All specific recommendations remain with the facility
- Only aggregate data reported to IDOH (all facilities)
- Data from IP Software kept with the facility

Commitment from facility

- 15 minutes a day to dedicate to checklist
- 2 Meetings and 2 surveys
- Access and communication

Updates

- 20 facilities going forward
- Rolling enrollment (5 spots per month)
- Booking for October
- Reach out to Probari for more information

Thank you!

outreach@probarisystems.com

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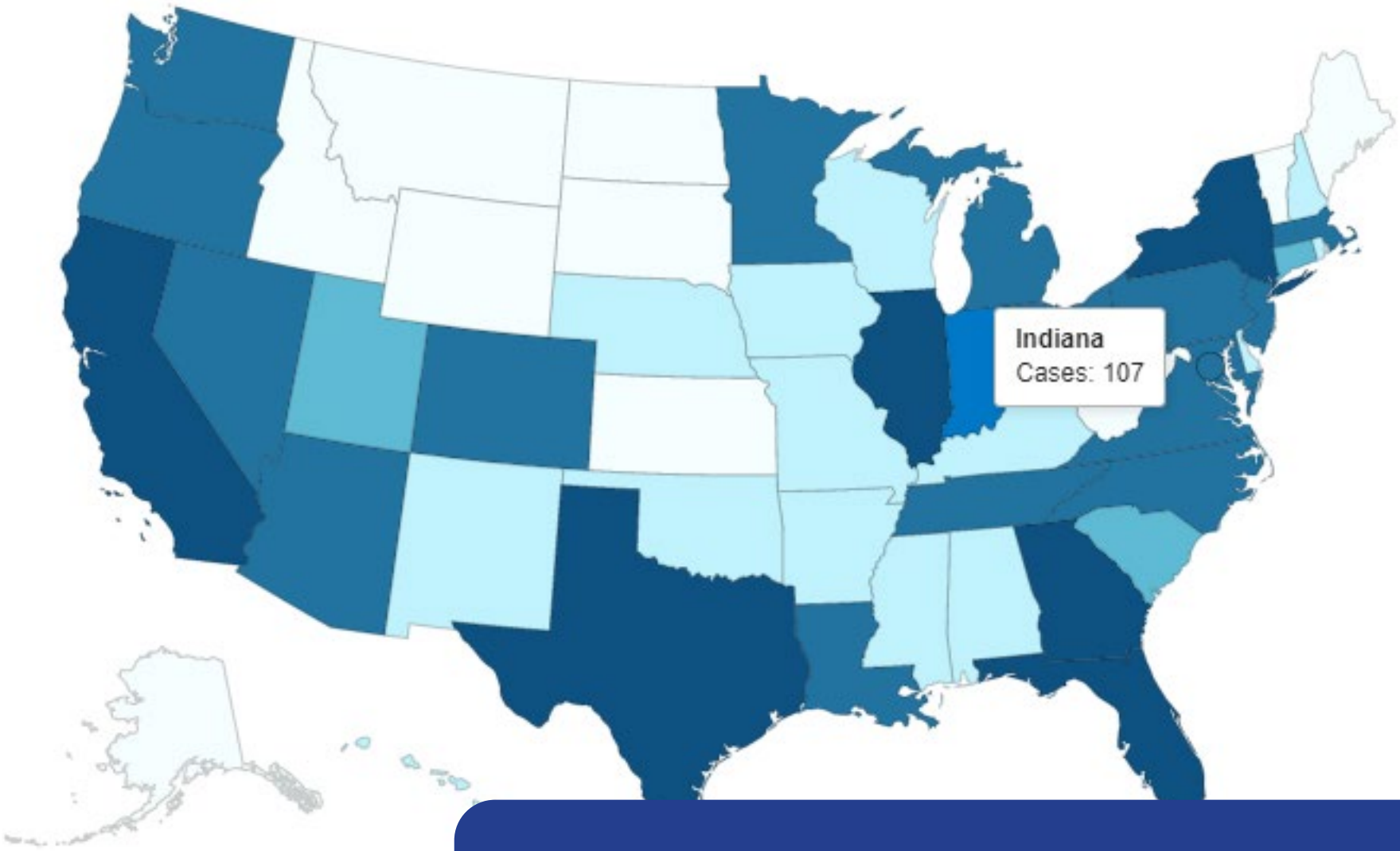
MONKEYPOX AND COVID-19 UPDATES

SHIREESHA VUPPALANCHI, M.D.
MEDICAL DIRECTOR

8/25/22



Monkeypox Outbreak

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Monkeypox Case Counts

- 2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC
  - As of Aug. 23: 15,909 Total confirmed monkeypox/ orthopoxvirus cases
- 2022 Monkeypox Outbreak Global Map | Monkeypox | Poxvirus | CDC
  - As of Aug. 23, confirmed global cases: 44,503
- Number of cases in IN: 134

Key messages from CDC

- In the current monkeypox outbreak, the virus is spreading primarily through close personal contact. This may include contact with infectious lesions or respiratory secretions via close, sustained skin-to-skin contact that occurs during sex.
- The current outbreak has led to questions about whether monkeypox is a sexually transmitted infection (STI). Monkeypox can more accurately be described as “sexually transmissible.” In other words, sex is just one of the ways that monkeypox can be spread.
- Vaccination is an important tool in preventing the spread of monkeypox. But given the current limited supply of vaccines, consider temporarily changing some behaviors that may increase risk of being exposed. These temporary changes will help slow the spread of monkeypox until the vaccine supply is adequate.
- Reducing or avoiding behaviors that increase the risk of monkeypox exposure is also important between first and second shots of the vaccine. Protection will be highest two weeks after second dose of the vaccine.

Transmission

- Close Contact: direct skin-to-skin contact with monkeypox rash, scabs, or body fluids from a person with monkeypox. Touching objects, fabrics (clothing, bedding, or towels), and surfaces that have been used by someone with monkeypox. Contact with respiratory secretions.
- Intimate contact: such as oral, anal, and vaginal sex or touching the genitals or anus of a person with monkeypox. Hugging, massage, and kissing. Prolonged face-to-face contact. Touching fabrics and objects during sex that were used by a person with monkeypox and that have not been disinfected, such as bedding, towels, fetish gear, and sex toys.
- A pregnant person can spread the virus to their fetus through the placenta.
- It's also possible for people to get monkeypox from infected animals, either by being scratched or bitten by the animal or by preparing or eating meat or using products from an infected animal.
- A case of monkeypox in a traveler who returned from the United Kingdom to the United States who did not report recent sexual contact, but was in crowded events Early Release - Human Monkeypox without Viral Prodrome or Sexual Exposure, California, USA, 2022 - Volume 28, Number 10—October 2022 - Emerging Infectious Diseases journal – CDC

Should people be concerned about crowded events?

- People can get monkeypox if they have close, skin-to-skin contact with someone who has monkeypox. Early indications are that events with activities in which people engage in close, sustained skin-to-skin contact have resulted in cases of monkeypox.
- If you plan to attend an event, consider how much close, personal, skin-to-skin contact is likely to occur there. Frequently Asked Questions | Monkeypox | Poxvirus | CDC

Infection Control: Healthcare Settings

- A patient with suspected or confirmed monkeypox infection should be placed in a single-person room; **special air handling is not required**. The door should be kept closed (if safe to do so). The patient should have a dedicated bathroom. Transport and movement of the patient outside of the room should be limited to medically essential purposes. Patients transported outside of their room should use well-fitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown.
- Intubation, extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room.
- PPE used by healthcare personnel who enter the patient's room should include: **Gown, gloves, eye protection** (i.e., goggles or a face shield that covers the front and sides of the face) **and NIOSH-approved particulate respirator equipped with N95 filters or higher**
- Standard cleaning and disinfection procedures should be performed using an EPA-registered hospital-grade disinfectant with an emerging viral pathogen claim. Products with Emerging Viral Pathogens claims may be found on EPA's List Q

Visiting someone with monkeypox

- Visitors to patients with monkeypox infection should be limited to those essential for the patient's care and wellbeing (e.g., parents of a child, spouse)
- Decisions about who might visit, including whether the visitor stays or sleeps in the room with the patient, typically take into consideration the patient's age, the patient's ability to advocate for themselves, ability of the visitor to adhere to infection prevention and control recommendations, whether the visitor already had higher risk exposure to the patient, and other aspects
- In general, visitors with contagious diseases should not be visiting patients in healthcare settings to minimize the risk of transmission to others

Exposure

- In general, patients in healthcare facilities who have had a monkeypox virus exposure and are asymptomatic do not need to be isolated, but they should be monitored
- Monitoring should include assessing the patient for signs and symptoms of monkeypox, including a thorough skin exam, at least daily, for 21 days after their last exposure
- Asymptomatic HCP with exposures to monkeypox virus do not need to be excluded from work, but should be monitored (e.g., at least a daily assessment conducted by the exposed HCP for signs and symptoms of monkeypox infection) for 21 days after their last exposure

Risk assessment if exposed in healthcare setting

Risk level of exposure	Exposure characteristics	Recommendations	
		Monitoring	PEP¶
Higher	Unprotected contact between an exposed individual's broken skin or mucous membranes and the skin lesions or bodily fluids from a patient with monkeypox (e.g., inadvertent splashes of patient saliva to the eyes or mouth of a person), or soiled materials (e.g., linens, clothing) -OR-	Yes	Recommended
	Being inside the patient's room or within 6 feet of a patient with monkeypox during any medical procedures that may create aerosols from oral secretions (e.g., cardiopulmonary resuscitation, intubation), or activities that may resuspend dried exudates (e.g., shaking of soiled linens), without wearing a NIOSH-approved particulate respirator with N95 filters or higher and eye protection		
	Being within 6 feet for a total of 3 hours or more		

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Infection Control: Healthcare Settings | Monkeypox | Poxvirus | CDC

Risk assessment if exposed in healthcare setting

Risk level of exposure	Exposure characteristics	Recommendations	
		Monitoring	PEP¶
Intermediate	Being within 6 feet for a total of 3 hours or more (cumulative) of an unmasked patient with monkeypox without wearing a facemask or respirator -OR-	Yes	Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks of transmission or severe disease ¶¶
	Unprotected contact between an exposed individual's intact skin and the skin lesions or bodily fluids from a patient with monkeypox, or soiled materials (e.g., linens, clothing) -OR-		
	Activities resulting in contact between an exposed individual's clothing and the patient with monkeypox's skin lesions or bodily fluids, or their soiled materials (e.g., during turning, bathing, or assisting with transfer) while not wearing a gown		
Lower	Entry into the contaminated room or patient care area of a patient with monkeypox without wearing all recommended PPE, and in the absence of any exposures above	Yes	None
No Risk	No contact with the patient with monkeypox, their contaminated materials, nor entry into the contaminated patient room or care area	No	None

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Infection Control: Healthcare Settings | Monkeypox | Poxvirus | CDC

NDC 50632-001-02

Smallpox and Monkeypox Vaccine, Live, Non-replicating

JYNNEOS®

Suspension for subcutaneous injection

Contains 20 single-dose 0.5 mL vials

BAVARIAN NO

Vaccination

Indiana Department of Health

Who Can Get Vaccinated?

[Vaccination Strategies | Monkeypox | Poxvirus | CDC]

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Table 1. Vaccination Strategies Used in the 2022 U.S. Monkeypox Outbreak

Strategy	Definition	Criteria
Post-Exposure Prophylaxis (PEP)	Vaccination **after known exposure** to monkeypox	• People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment
Expanded Post-Exposure Prophylaxis (PEP++)	Vaccination **after known or presumed** exposure to monkeypox	Any of the following: • People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment • People who are aware that a recent sex partner within the past 14 days was diagnosed with monkeypox • Certain gay, bisexual, or other men who have sex with men, or transgender people, who have had any of the following within the past 14 days: sex with multiple partners (or group sex); sex at a commercial sex venue; or sex in association with an event, venue, or defined geographic area where monkeypox transmission is occurring
Pre-Exposure Prophylaxis (PrEP)	Vaccination **before exposure** to monkeypox	• People in certain occupational risk groups*

*People at risk for occupational exposure to orthopoxviruses include research laboratory workers performing diagnostic testing for *Monkeypox virus,* and members of health care worker response teams designated by appropriate public health and antiterror authorities (see ACIP recommendations).

Vaccination schedule

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

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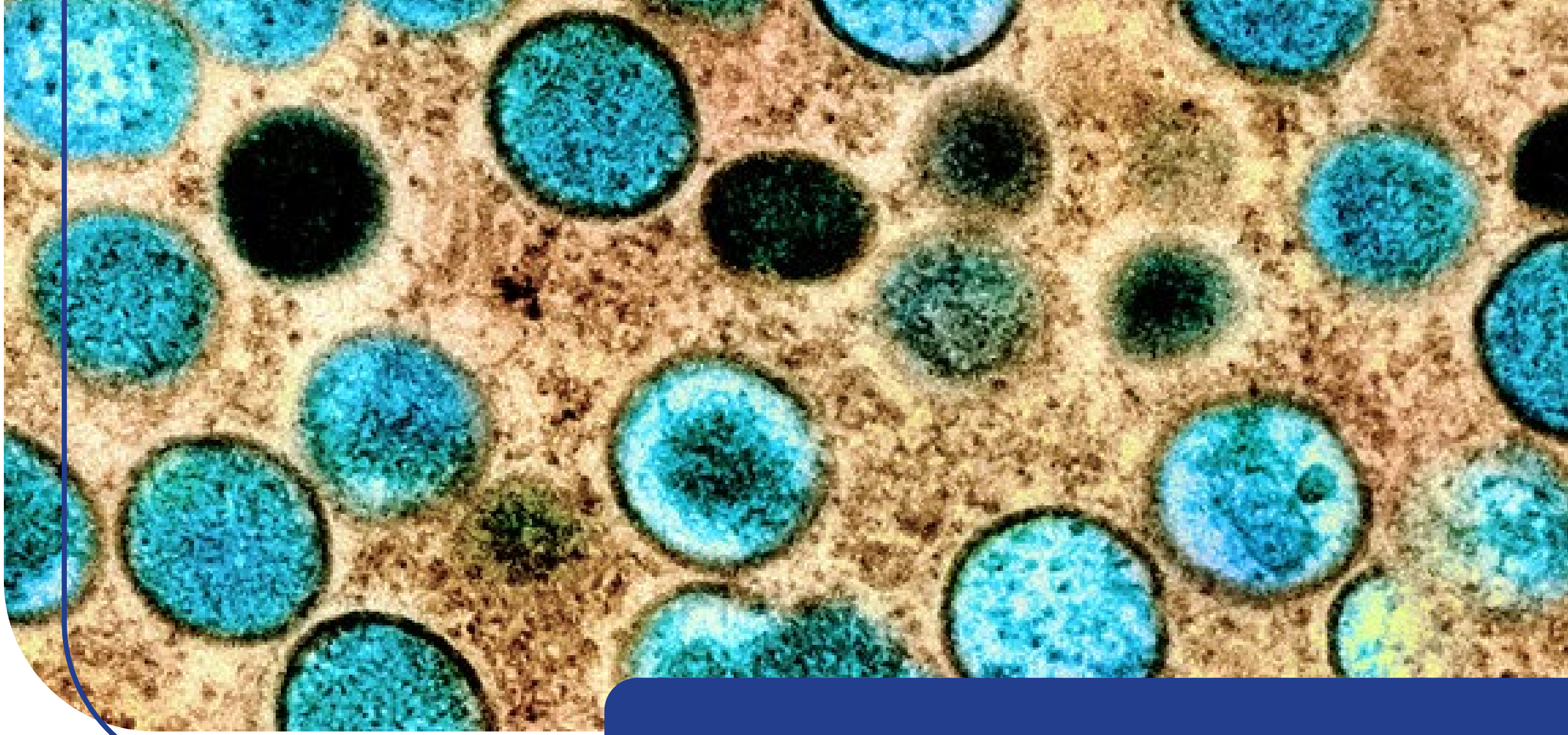

Testing

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Testing Reminders

- The public health response to monkeypox depends on timely and comprehensive laboratory testing and reporting of those results
- Tests should be performed on persons for whom monkeypox is suspected based on clinical presentation and epidemiologic criteria
- Positive diagnostic results from testing of skin lesion material for *Orthopoxvirus* or *Monkeypox virus* DNA in persons without epidemiologic criteria or known risk factors should be verified through repeat testing and/or confirmatory testing

Reminders for Consideration

- CDC will be updating website specimen collection instructions — **advise that lesions not be unroofed or lanced to avoid needlesticks — if swabbed vigorously, tests give good CT values**
- 75% of lesions are found in anogenital region, 40% of mucosal surfaces of genitals/oropharynx, need to also consider other STI when evaluating these lesions
- NOTE: MPX lesions **hurt** — if no pain when collecting, consider alternate diagnosis. Example syphilis
- Monkeypox can co-occur with other STI, including HIV
- Monkeypox rash can be confused with other STI.
- Rash in mucosa is reported to be very painful with monkeypox, even if it doesn't look bad

Testing Reminders

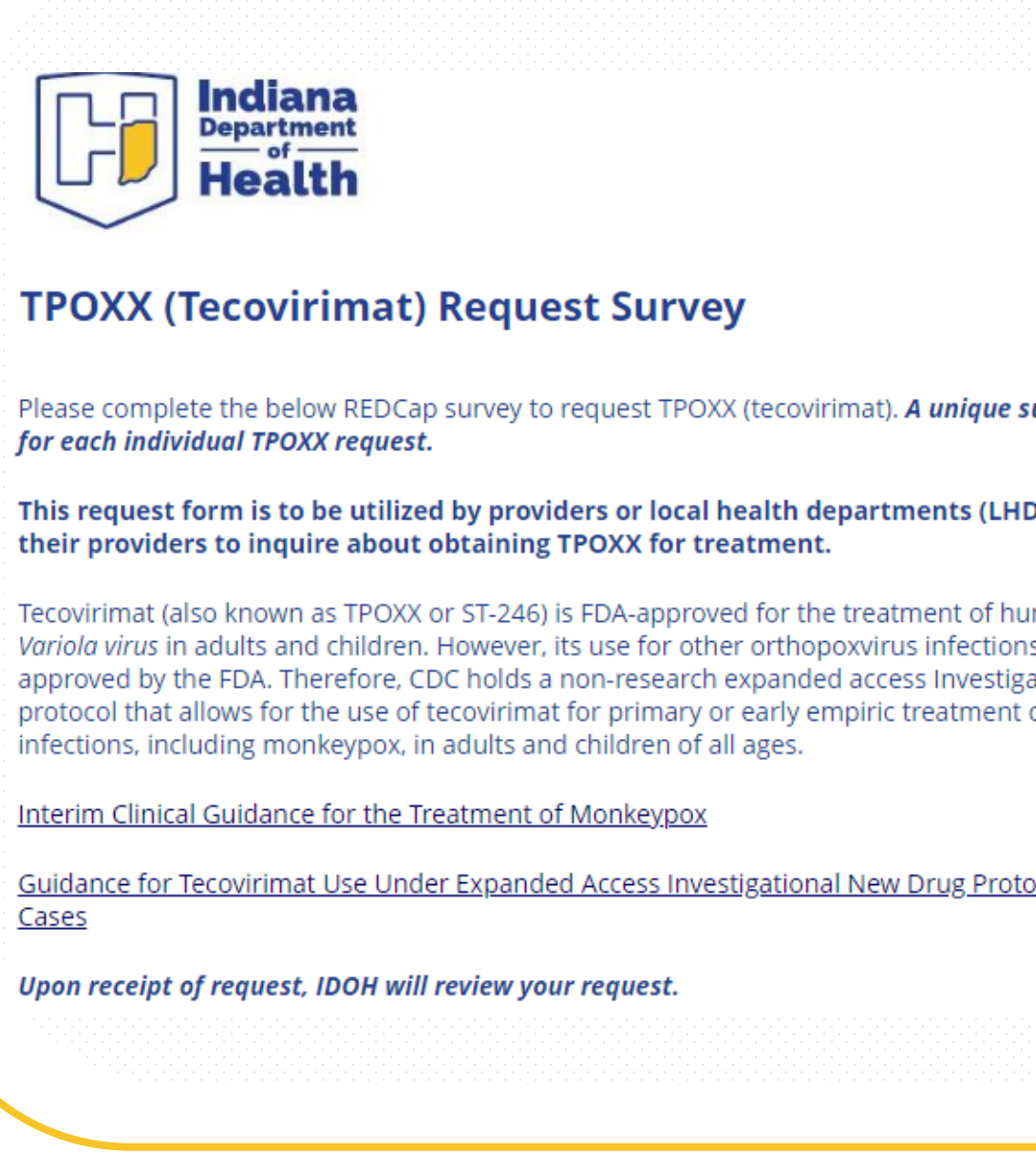
- Any provider can order tests
- **Several commercial labs are now testing for orthopox virus which detects monkeypox. Please work with your lab staff to send specimen to these commercial labs: Aegis Science, ARUP, Labcorp, Mayo Clinic Laboratories, Quest Diagnostics and Sonic Healthcare.**
- **Results will be transmitted to the IDOH. Prior IDOH authorization is not required to submit specimens to commercial laboratories.**
- If you are unable to submit to one of these five labs, complete a Monkeypox Specimen Authorization Request for testing through the Indiana Department of Health (IDOH)
- **Negative pressure room is not needed**

Treatment

Indiana Department of Health

How do I order TPOXX?

- For patients with **probable** or confirmed monkeypox
- **This request form is to be utilized by providers or local health departments (LHDs) only.** Patients should contact their providers to inquire about obtaining TPOXX for treatment.
- A unique survey entry must be completed for each individual TPOXX request.



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TPOXX (Tecovirimat) Request Survey

Please complete the below REDCap survey to request TPOXX (tecovirimat). ***A unique su***
for each individual TPOXX request.

This request form is to be utilized by providers or local health departments (LHD
their providers to inquire about obtaining TPOXX for treatment.

Tecovirimat (also known as TPOXX or ST-246) is FDA-approved for the treatment of hu
Variola virus in adults and children. However, its use for other orthopoxvirus infections
approved by the FDA. Therefore, CDC holds a non-research expanded access Investiga
protocol that allows for the use of tecovirimat for primary or early empiric treatment o
infections, including monkeypox, in adults and children of all ages.

Interim Clinical Guidance for the Treatment of Monkeypox

Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Proto
Cases

Upon receipt of request, IDOH will review your request.

Indiana Department of Health

https://redcap.isdh.in.gov/surveys/?s=3REN7J3XRDE3FTTJ

Considerations for TPOXX treatment

- **With severe disease** (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- **Who are at high risk of severe disease**:
- People with immunocompromising conditions (e.g., HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component)
- Pediatric populations, particularly patients younger than 8 years of age

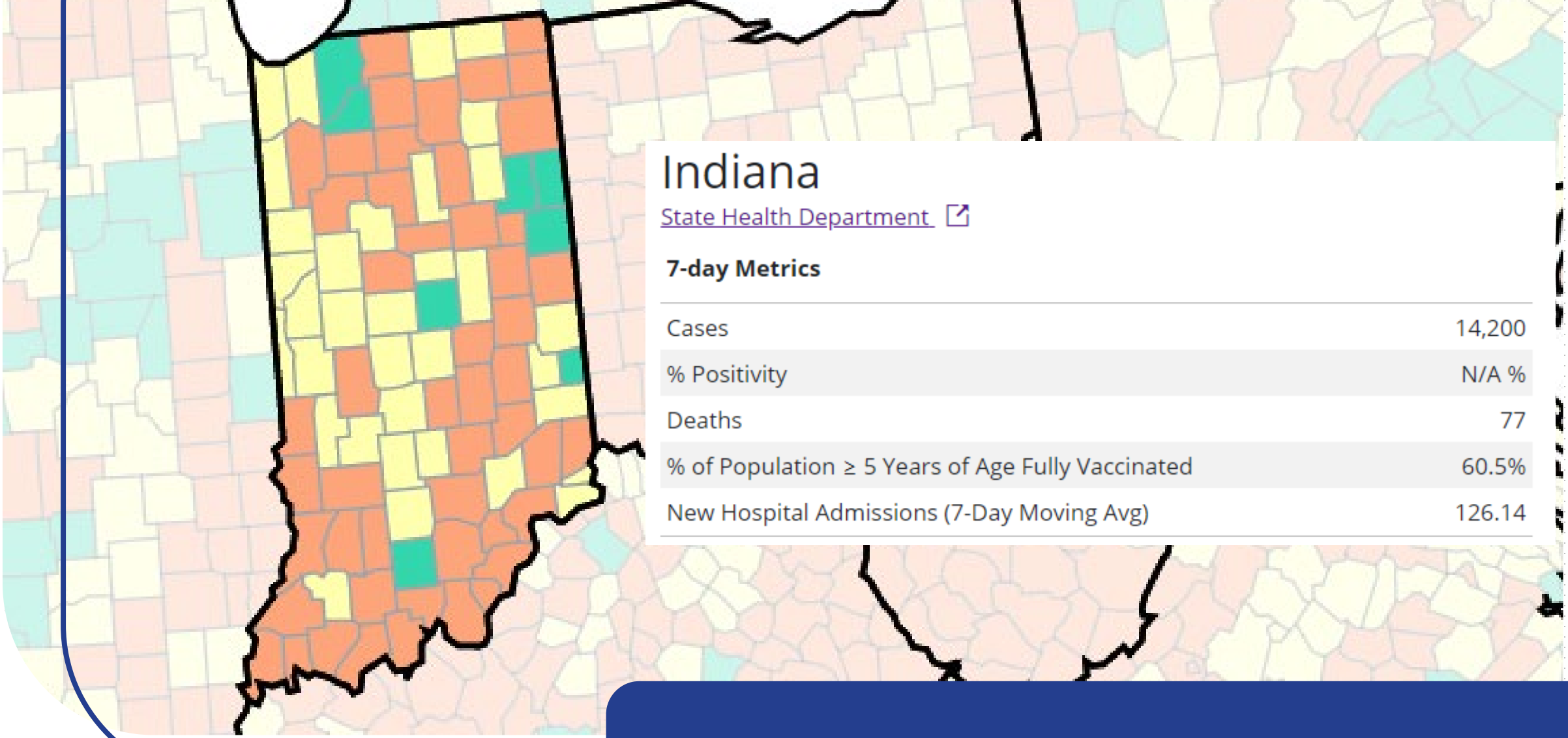
Considerations for TPOXX treatment

- Pregnant or breastfeeding women
- People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions (e.g., eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease [keratosis follicularis])
- People with one or more complication (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)
- With aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where Monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)

Vaccinia Immune Globulin Intravenous (VIGIV)

- At this time, VIGIV is not pre-positioned within states. It is available for request from the Strategic National Stockpile (SNS), through coordination with state health departments, if providers identify eligible patients meeting criteria.
- VIGIV is under either an EA-IND or single-patient IND depending on the use. CDC holds an intermediate size patient population EA-IND for use of VIGIV for treatment of orthopoxvirus infection. The process for access to and use of VIGIV by hospitals/facilities is similar to the EA-IND for TPOXX. Please see attached for the VIGIV EA-IND protocol packet and FDA Form 1572.
- VIGIV for post-exposure prophylaxis or early empiric treatment of monkeypox is under a single-patient IND requiring FDA authorization prior to administration. Please see attached email for further information regarding the process.

https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html#anchor_1655488307086



Indiana

State Health Department

7-day Metrics

Cases	14,200
% Positivity	N/A %
Deaths	77
% of Population ≥ 5 Years of Age Fully Vaccinated	60.5%
New Hospital Admissions (7-Day Moving Avg)	126.14

COVID-19 Update

Indiana Department of Health

CDC MMWR: Kaiser Permanente Southern California Paxlovid and Hospitalizations

June 24, 2022 – CDC Morbidity and Mortality Weekly Report (MMWR) COVID-19-related hospital admissions and emergency department (ED) encounters after Paxlovid treatment. Kaiser Permanente Southern California, December 23, 2021 - May 21, 2022

Demographics:

- 5,287 patients ≥ 12 years received 5-day Paxlovid treatment.
- Median age was 61.
- 92% had received at least one COVID-19 vaccine dose; 72.5% received at least 3 doses, 8% unvaccinated.

Key Findings:

- 6 hospitalizations and 39 ED encounters related to SARS-CoV-2 infection.
- Hospitalizations and ED encounters for COVID-19 related illness 5-15 days after Paxlovid dispensation occurred **<1%** of all patients.
- When administered as an early-stage treatment, Paxlovid might prevent COVID-19–related hospitalization among persons with mild to moderate COVID-19 cases who are at risk for progression to severe disease.

For more information see, Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment — California, December 2021–May 2022 https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm?s_cid=mm7125e2_w

Paxlovid: Clinical Trial and Observational Data

- The benefit of a 5-day treatment course of Paxlovid was demonstrated in the clinical trial that supported the EUA. This study showed that among non-hospitalized, unvaccinated patients at high risk of progression to severe disease, treatment with **Paxlovid reduced the risk of hospitalization or death by 88%.**

- Observational data, including vaccinated patients, from Israel[1], United States[2], and Hong Kong[3] is consistent with benefit in high-risk patients:
  - **67% reduction in hospitalizations and 81% reduction in deaths compared to the untreated** for patients over 65[1]
  - **45% reduction in hospitalization and greater reductions for obese or unvaccinated patients** among adult patients[2]
  - **75% reduction in death compared to non-users**[3].

References:
- [1]Ronza Najjar-Debbiny et al. *Clinical Infectious Diseases*, 2022;, ciac443, https://doi.org/10.1093/cid/ciac443
- [2]Scott Dryden-Peterson et al. medRxiv 2022.06.14.22276393; doi: https://doi.org/10.1101/2022.06.14.22276393
- [3]Carlos K.H. et al. medRxiv 2022.05.19.22275291; doi: https://doi.org/10.1101/2022.05.19.22275291

https://www.idsociety.org/globalassets/idsa/multimedia/clinician-call-slides--qa/8-06-22-clinician-call.pdf

Additional information

Indiana Department of Health

Monkeypox website

- Monkeypox.health.in.gov
- Section for the public and clinicians
- Watch here for updates

Information for the Public

CDC Monkeypox Website
Press Release: Health department provides monkeypox update (7/29/2
Monkeypox Fact Sheet - CDC
Social Gatherings, Safer Sex and Monkeypox - CDC

Frequently Asked Questions

What are the signs and symptoms of monkeypox?

I was exposed, when should I expect to see symptoms?

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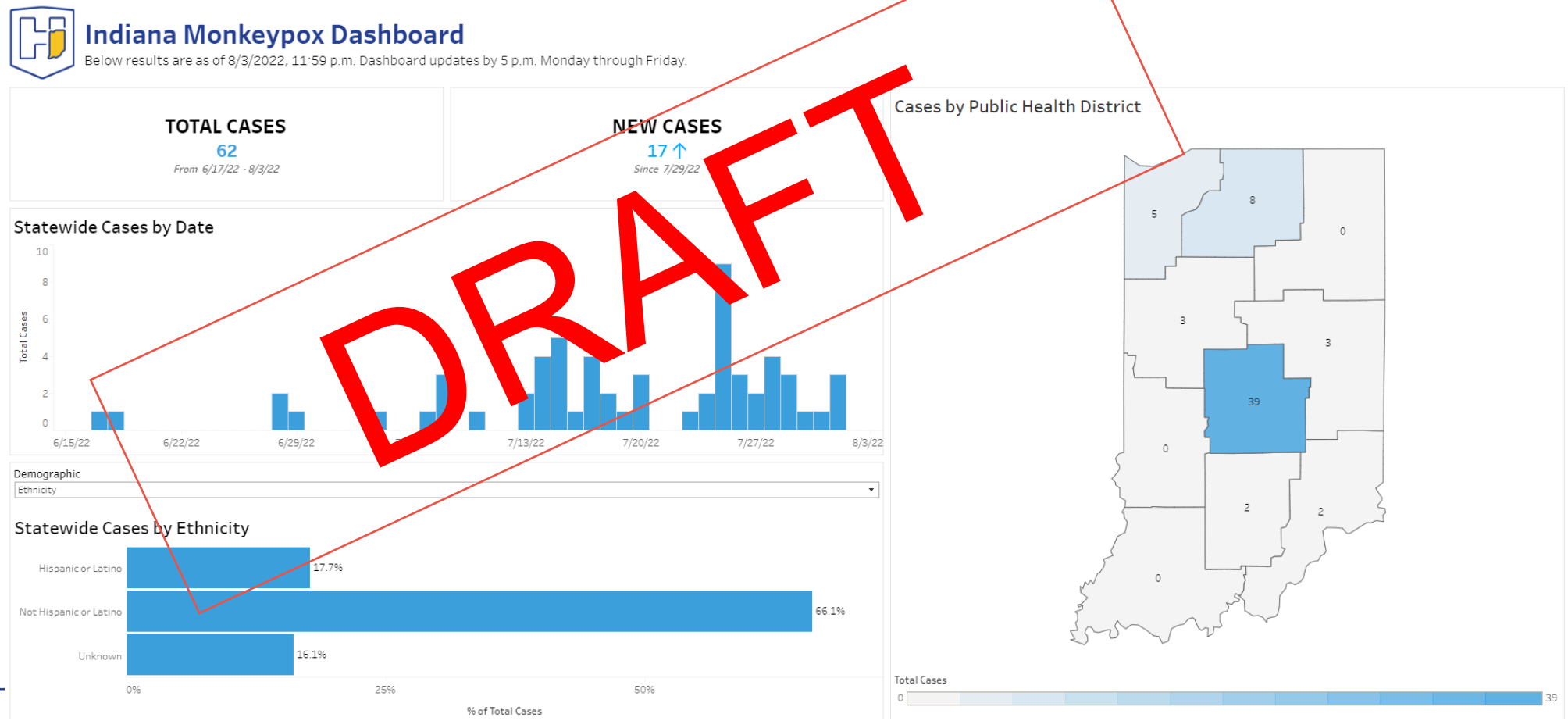
Dashboard: Coming soon

Will update by 5 p.m. daily Monday through Friday



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Intradermal Regimen: Resources

- JYNNEOS Vaccine Guidance (CDC)
- JYNNEOS Intradermal Administration
- JYNNEOS Cheat Sheet
- JYNNEOS Healthcare Provider Fact Sheet
- JYNNEOS Storage and Handling
- VIDEO: How to administer a JYNNEOS vaccine intradermally

Tests submitted to IDOH

- The Indiana Department of Health Laboratory (IDOHL) has encountered a discrepancy in our monkeypox testing process.
  - Therefore, we have made the decision to temporarily suspend monkeypox testing at the IDOH lab while we work to reconcile this issue with our federal partners.
  - In the meantime, we have partnered with an outside lab to ensure specimens you send to IDOHL are processed in a timely manner without interruption.
- We encourage you to send specimens to the list of commercial labs that are now testing for orthopox and/or monkeypox specifically (see previous slide)
- If you are unable to utilize a commercial lab (not connected or the patient is uninsured/underinsured and payment is a concern) than you can continue to send specimens to IDOHL as usual.
  - Note that there is one temporary change to specimen submission**. Please place two dry swabs in the same tube (not one swab in two separate tubes).**
  - Specimens sent to IDOHL will still be processed at no charge, and turn-around time is estimated to be 2-5 days.
  - These specimens will be routed to ARUP Laboratories in coordination with IU Health Pathology Lab. Updated specimen submission guidelines are posted online. Results will still be available through NBS and through LimsNet.

Testing Guidance

- Please ensure that your organization has a plan in progress for ordering and maintaining a supply of monkeypox testing, storage, and shipping materials. IDOH will only provide small numbers of testing supplies in emergencies.
- Please remember to complete the REDCap form to determine if the specimen is authorized for testing via the online REDCap form, found at www.monkeypox.health.in.gov. This form needs to be filled out even if the specimen has been verbally authorized by an IDOH epidemiologist.
- We encourage providers to use a dry, synthetic swab with a stiff shaft when swabbing a lesion. The stiff shaft will help ensure that the provider collects sufficient viral DNA when vigorously swabbing the lesion.
- When submitting a specimen to the IDOH Laboratory, **please double-check** that the following items **match EXACTLY** on each set of containers, prior to shipping to IDOHL:
    - Full patient name
    - Patient date of birth
    - Date of specimen collection
    - Location of the swabbed lesion (i.e., left forearm)
    - C-number generated from LimsNet

  If any of these patient identifiers do not match the corresponding LimsNet submission and/or other containers from the same lesion, the specimen will be cancelled, and new samples will be requested.

NOTE: As a final reminder, all monkeypox specimens must arrive at the laboratory **cold or frozen**. Specimens arriving at room temperature or warm will not be processed at our laboratory.

Tecovirimat information for clinicians

- Indications:

Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC

- Protocol:

Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC

- Oral TPOXX is preferred over IV

How to obtain TPOXX

- TPOXX is available through the Strategic National Stockpile and is pre-positioned throughout the state.
- **This request form is to be utilized by providers or local health departments (LHDs) only.** Patients should contact their providers to inquire about obtaining TPOXX for treatment.
- For urgent clinical situations after hours, providers may contact the CDC Emergency Operations Center (770-488-7100) for clinical consultation on patient cases.
- **Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent**.
- Forms requested under the EA-IND can be returned to CDC **after** treatment begins. Please return completed forms to CDC via encrypted email (regaffairs@cdc.gov) or uploading to secure ShareFile (please zip multiple files and use filenames with patient initials, patient age, hospital/facility name, state, tecovirimat start date, and file contents [e.g., 1572, CV, Patient Intake Form]). Personally identifiable information should not be emailed without encryption.

Required for TPOXX administration

Informed Consent Form English [268 KB, 6 pages] | Spanish [335 KB, 6 pages]: Obtain prior to treatment.

- Alternative Short Form Consent [134 KB, 3 pages] and Written Summary [317 KB, 5 pages] that can be used to obtain informed consent

- **Patient Intake Form [338 KB, 2 pages]:** Baseline assessment.
- **FDA Form 1572 [1 MB, 2 pages]:** One signed 1572 per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
- **Serious Adverse Events:** Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [956 KB, 5 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

Questions?

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THANK YOU!

Indiana Department of Health