

Monkeypox Treatment ID Providers CUIMC Training

Updated: 7/29/2022



Monkeypox Treatment

- Supportive care
 - **Most patients fully recover**
 - Symptomatic treatment
- Antiviral medications
 - Cidofovir
 - Brincidofovir
 - Trifluridine (eye disease)
 - Tecovirimat (EA-IND)
- Vaccine immune globulin (IND)
 - Consider for patients ineligible for vaccination for PEP



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- **Proctitis**
 - Stool softeners
 - Lidocaine gel
 - Anti-inflammatory (if not bleeding)
 - Sitz Baths
 - Avoid opioids if possible

- **Genital Lesions**
 - Frequent bathing
 - Keep it dry
 - Change clothes frequently

- **Oropharyngeal lesions**
 - Magic mouthwash

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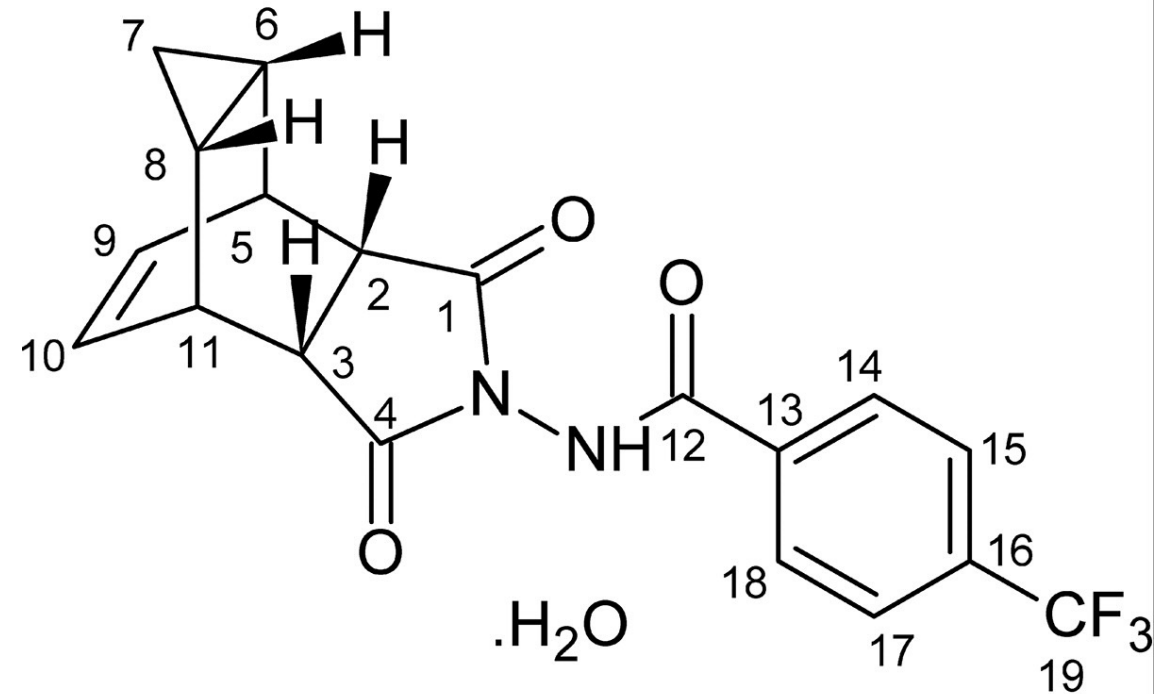
- **Severe disease**
 - Sepsis
 - Hospitalization
 - Evidence of viremia
 - Lesion location/type (e.g areas at risk of scarring or stricture)
 - Eye
 - Mouth/Pharynx
 - Rectum
 - Urethra
 - Vagina

- **Illness complication**
 - Secondary bacterial infection
 - Proctitis with tenesmus
 - Uncontrolled pain
 - Rectal bleeding
 - Gastroenteritis
 - Pneumonia
 - Encephalitis

- **At high risk for severe disease**
 - HIV with high VL or low CD4
 - Severe immunocompromise
 - Age < 8
 - Pregnant/breastfeeding
 - Significant active exfoliative dermatologic conditions
 - Increased risk for stricture/fisula (e.g IBD)

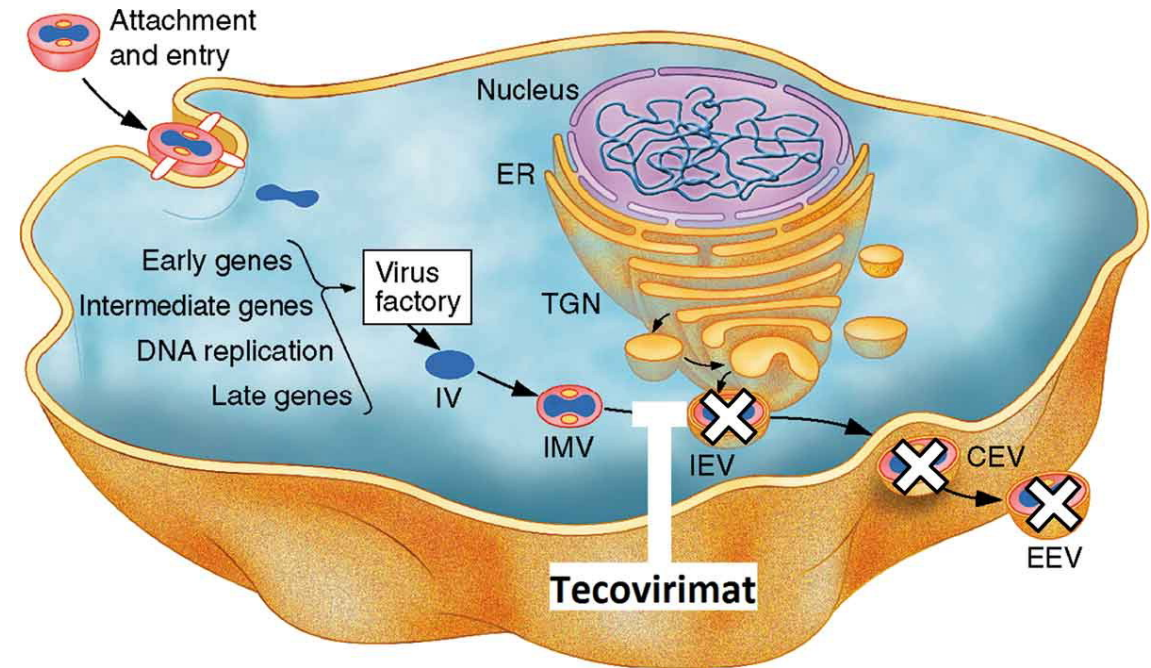
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Tecovirimat

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Oral Tecovirimat for the Treatment of Smallpox

Douglas W. Grosenbach, Ph.D., Kady Honeychurch, Ph.D., Eric A. Rose, M.D., Jarasvech Chinsangaram, D.V.M., Ph.D., Annie Frimm, B.S., Biswajit Maiti, Ph.D., Candace Lovejoy, B.S., Ingrid Meara, M.S., Paul Long, B.S., and Dennis E. Hruby, Ph.D.

Table 3. Adverse Events That Occurred or Worsened during Receipt of Tecovirimat or Placebo in the Overall Summary Safety Population.

Type of Event*	Placebo (N=90)		Tecovirimat (N=359)		Total (N=449)	
	No. of Participants (%)	No. of Events	No. of Participants (%)	No. of Events	No. of Participants (%)	No. of Events
Any event	30 (33.3)	68	134 (37.3)	318	164 (36.5)	386
Event related to the trial agent	15 (16.7)	32	71 (19.8)	176	86 (19.2)	208
Event leading to discontinuation of trial agent	2 (2.2)	3	6 (1.7)	16	8 (1.8)	19
Serious events and events leading to death	0	0	1 (0.3)†	1	1 (0.2)	1

Tecovirimat

Clinical features and management of human monkeypox: a retrospective observational study in the UK



Hugh Adler, Susan Gould, Paul Hine, Luke B Snell, Waison Wong, Catherine F Houlihan, Jane C Osborne, Tommy Rampling, Mike BJ Beadsworth, Christopher JA Duncan, Jake Dunning, Tom E Fletcher, Ewan R Hunter, Michael Jacobs, Saye H Khoo, William Newsholme, David Porter, Robert J Porter, Libuše Ratcliffe, Matthias L Schmid, Malcolm G Semple, Anne J Tunbridge, Tom Wingfield*, Nicholas M Price* on behalf of the NHS England High Consequence Infectious Diseases (Airborne) Network†

Summary

Background Cases of human monkeypox are rarely seen outside of west and central Africa. There are few data regarding viral kinetics or the duration of viral shedding and no licensed treatments. Two oral drugs, brincidofovir and tecovirimat, have been approved for treatment of smallpox and have demonstrated efficacy against monkeypox in animals. Our aim was to describe the longitudinal clinical course of monkeypox in a high-income setting, coupled with viral dynamics, and any adverse events related to novel antiviral therapies.

Methods In this retrospective observational study, we report the clinical features, longitudinal virological findings, and response to off-label antivirals in seven patients with monkeypox who were diagnosed in the UK between 2018 and 2021, identified through retrospective case-note review. This study included all patients who were managed in dedicated high consequence infectious diseases (HCID) centres in Liverpool, London, and Newcastle, coordinated via a national HCID network.

Findings We reviewed all cases since the inception of the HCID (airborne) network between Aug 15, 2018, and Sept 10, 2021, identifying seven patients. Of the seven patients, four were men and three were women. Three acquired monkeypox in the UK: one patient was a health-care worker who acquired the virus nosocomially, and one patient who acquired the virus abroad transmitted it to an adult and child within their household cluster. Notable disease features included viraemia, prolonged monkeypox virus DNA detection in upper respiratory tract swabs, reactive low mood, and one patient had a monkeypox virus PCR-positive deep tissue abscess. Five patients spent more than 3 weeks (range 22–39 days) in isolation due to prolonged PCR positivity. Three patients were treated with brincidofovir (200 mg once a week orally), all of whom developed elevated liver enzymes resulting in cessation of therapy. One patient was treated with tecovirimat (600 mg twice daily for 2 weeks orally), experienced no adverse effects, and had a shorter duration of viral shedding and illness (10 days hospitalisation) compared with the other six patients. One patient experienced a mild relapse 6 weeks after hospital discharge.

Lancet Infect Dis 2022

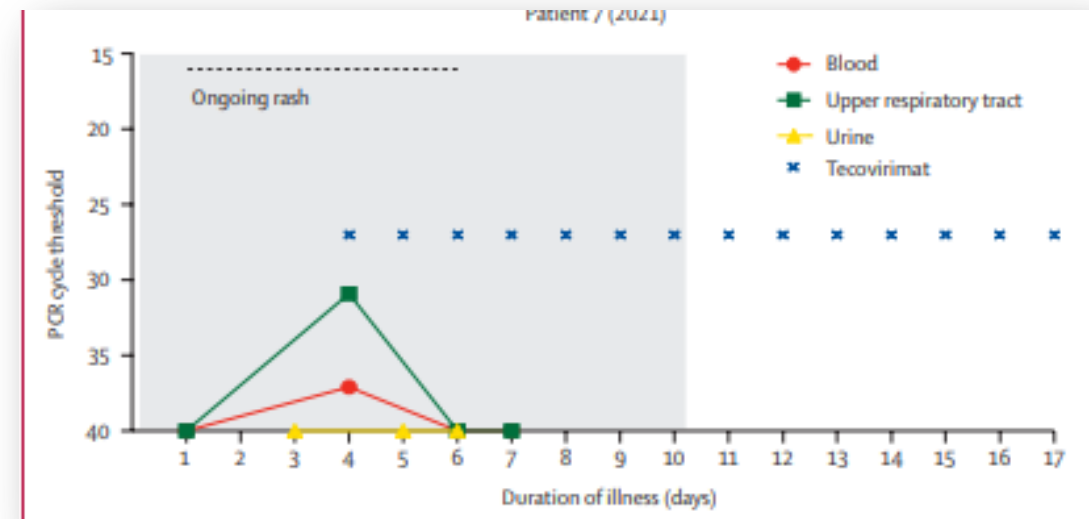
Published Online
May 24, 2022
[https://doi.org/10.1016/S1473-3099\(22\)00228-6](https://doi.org/10.1016/S1473-3099(22)00228-6)

This online publication has been corrected. The corrected version first appeared at [thelancet.com/infection](https://www.thelancet.com/infection) on May 26, 2022

*Contributed equally
†Members are listed in the appendix

Tropical and Infectious Disease Unit, Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK (H Adler PhD, S Gould MRCP, P Hine MRCP, M BJ Beadsworth MD, T E Fletcher PhD, Prof S H Khoo MD, L Ratcliffe MRCP, T Wingfield PhD); Department of Clinical Sciences, Liverpool School of Tropical Medicine, Liverpool, UK (H Adler, S Gould, P Hine, M BJ Beadsworth,

- One patient was treated with tecovirimat and experienced no adverse effects, and had a shorter duration of viral shedding and illness



Current Indications for Treatment - Severe Disease

- **Severe disease**

- Sepsis
- Hospitalization
- Evidence of viremia
- Lesion location/type (e.g areas at risk of scarring or stricture)
 - Eye
 - Mouth/Pharynx
 - Rectum
 - Urethra
 - Vagina

- **Illness complication**

- Secondary bacterial infection
- Proctitis with tenesmus
- Uncontrolled pain
- Rectal bleeding
- Gastroenteritis
- Pneumonia
- Encephalitis

- **At high risk for severe disease**

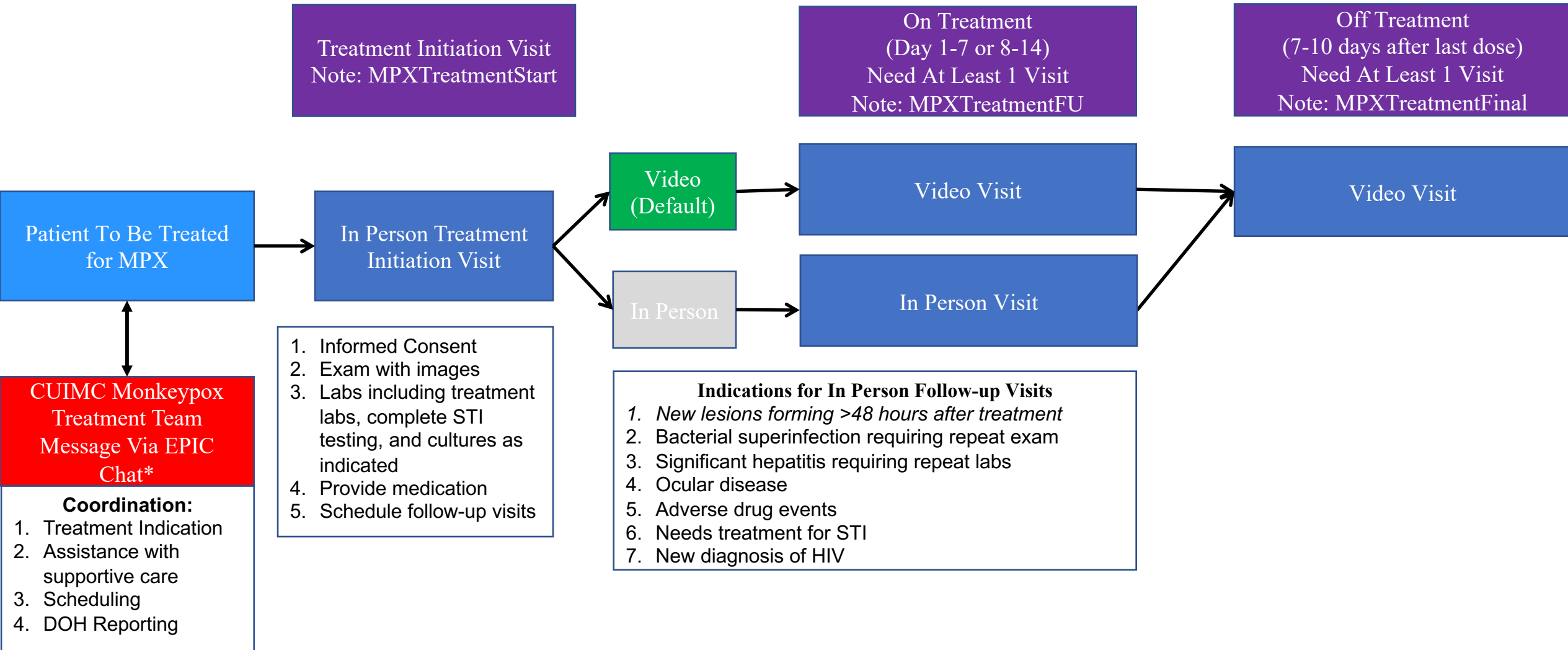
- HIV with high VL or low CD4
- Severe immunocompromise
- Age < 8
- Pregnant/breastfeeding
- Significant active exfoliative dermatologic conditions
- Increased risk for stricture/fisulta (e.g IBD)

Current Treatment Process for Monkeypox

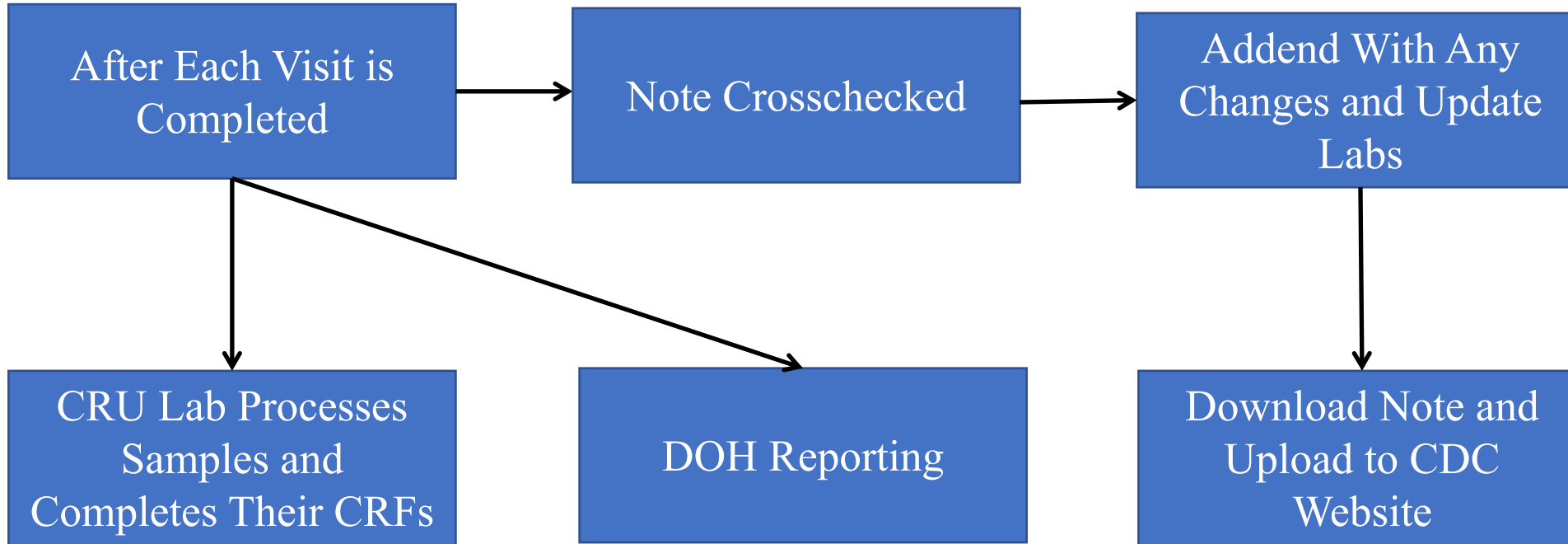
- Treatment **only for indications**
- Note = Case Report Form For CDC
- Needs to include
 - CDC Required Questions
 - Exam
 - Labs
 - Photos
- Please complete all fields
- Each patient needs a minimum of 3 notes
- **Treatment start**
 - MPXTREATMENTSTART
- **On Treatment**
 - MPXTREATMENTFU
- **Off Treatment**
 - MPXTREATMENTFINAL



Outpatient Treatment Pathway



Additional Management By Treatment Team



MPX Treatment Initiation

1. Informed Consent
2. Order medication from research pharmacy
 - Need weight
3. Exam with images
4. Labs including treatment labs and complete STI testing
5. Finish MPXTreatmentStart note
6. Schedule follow-up

MPXTREATMENTSTART

Demographics and Eligibility

Required by CDC:

Sex assigned at birth: ***

(Choices: M, F)

Gender identity: ***

(Choices: M, F, Transgender male, Transgender female, other, unknown)

Race: ***

(Choices: AA/Black, Asian, White, American Indian or Alaskan Native, Native Hawaiian or Other Pacific Islander, Other)

Ethnicity: ***

(Choices: Hispanic/Not Hispanic)

CDC Eligibility criteria:

Does the patient have laboratory confirmed orthopoxvirus infection? : {Yes No:20284}

Has the orthopoxvirus species been confirmed: No

Indication for treatment: ***

(Choices: Risk of severe outcome due to immunosuppression, Lesions in sensitive anatomical areas (please list area), pain (please list location of pain), other (please specify details))

This evaluation is being completed in the *** setting

Choices: inpatient, inpatient-icu, outpatient

If inpatient, date of admission: ***

- 1) Willing to sign informed consent: Yes
- 2) Accepts Tecovirimat treatment: Yes
- 3) Known allergy to tecovirimat or excipients of tecovirimat: No
- 4) For IV only: Cr Cl < 30ml/min: No

- Sex/Gender/Race/Ethnicity
 - Please choose from CDC choices
- Eligibility criteria
 - If choose yes document whether the patient has a positive test or this is presumed infection
 - Indication for treatment
 - Setting of treatment (inpatient, ICU, outpatient)
 - Eligibility criteria is “pre-filled” but should review

MPXTREATMENTSTART

Monkeypox Specific History

HPI

(including day by day timeline from prodrome to present)

Monkeypox Specific History

Date of illness onset: ***

Date of exposure if known): ***

Date of smallpox vaccination (and type):

If ACAM 2000 was there a documented vaccine take:

Presenting Signs and Symptoms:

Number of lesions (<10, 10-100, >100): ***

Size of maximal lesion (in mm): ***

Percent of body affected: ***

(Using rule of 9's with any part with at least one lesion counting)

Risk Factors:

Immunocompromised: ***

Immunocompromising medication: ***

Travel History:***

Example HPI

HPI

(including day by day timeline from prodrome to present)

First symptoms: 6/18 – 6/20, felt like he had some allergy symptoms took allergy medications and felt better (rapid COVID negative)

First lesion: Friday 6/25 just 3 skin lesions at this time (dorsal shaft of penis, inguinal, suprapubic, R inguinal LAD)

Monday 6/27 flu like symptoms, body aches, joint symptoms, SOB, swabs done and 6/30 testing returned positive. Noticed some early irritation with urination.

6/28 102.1, lasted about 48 hours, worst pain, discharge, blood tinged

6/29 felt better, fatigue, brain fog for next couple of days

6/30 test returned positive, spoke with contact tracer

7/1 – 3 lesions in groin started to become really inflamed, used mupirocin (did not help may have spread viral particles), developed a macular rash in groin area, spread to chest, arms, back, buttocks and still there

7/2 – 7/3 – New lesions on arms, near original three lesions, possibly on forehead and nose, continued to have extremely painful discharge

7/4 - Referred from DOH for treatment, slight improvement, rash less intense than previous, maybe receded a little bit, but R antecubital is still pretty bad and most significant issue is pain with urination.

Patient presents today for TPOXX evaluation.

MPXTREATMENTSTART

Basic History

Past Medical History
@PMH@

Medication History
@CMED@

Surgical History
@PSH@

Immunization History
@IMMHIST@

Family History
@FAMHX@

Social History
@SOCH@
Gender of sex partners: ***
Top/Bottom/Verse: ***
Partners in past month: ***
Condoms (% of time): ***

Allergies
@ALLERGY@

Updated in EPIC and Mark Reviewed

The screenshot shows the EPIC interface for a patient visit on 7/18/2022 with Jason E Zucker, MD for FOLLOW UP CUIMC. The top navigation bar includes tabs for Chart Review, Immunizations, Synopsis, Visit Data, Screenings, Plan, Wrap-Up, and iNYP. Below this, a secondary navigation bar highlights 'Care Everywhere' and includes tabs for Allergies, Verify Rx Benefits, Medication, Answer Qnrs, SOGI, History, and Goals. The 'History' section is expanded, showing 'Medical History' and 'Surgical History' with 'Mark as Reviewed' buttons. Purple arrows point from the 'Updated in EPIC and Mark Reviewed' header to the 'Visit Data' tab, the 'Care Everywhere' tab, and the 'Mark as Reviewed' buttons.

MPXTREATMENTSTART

Basic History

Past Medical History

@PMH@

Medication History

@CMED@

Surgical History

@PSH@

Immunization History

@IMMHIST@

Family History

@FAMHX@

Social History

@SOCH@

Gender of sex partners: ***

Top/Bottom/Verse: ***

Partners in past month: ***

Condoms (% of time): ***

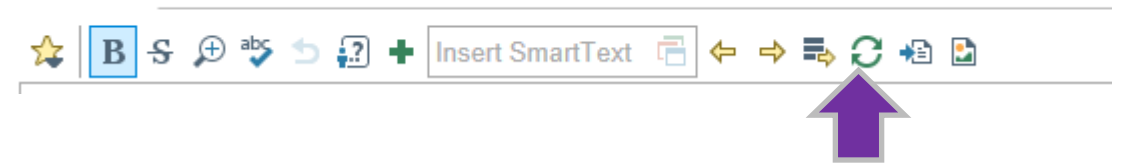
Allergies

@ALLERGY@

Updated in EPIC and Mark Reviewed

- Refresh once it's updated

Summary:



MPXTREATMENTSTART

Basic History

Vital Signs:

@VS@

@PHYSEXAMBYAGE@

Distribution of Lesions:

Left

<input type="checkbox"/> scalp	<input type="checkbox"/> face	<input type="checkbox"/> mouth	<input type="checkbox"/> oral mucosa
<input type="checkbox"/> throat	<input type="checkbox"/> eye	<input type="checkbox"/> hand	<input type="checkbox"/> arm
<input type="checkbox"/> trunk	<input type="checkbox"/> abdomen	<input type="checkbox"/> buttock	<input type="checkbox"/> genitals
<input type="checkbox"/> anus	<input type="checkbox"/> thigh	<input type="checkbox"/> calf	<input type="checkbox"/> foot
<input type="checkbox"/> Other			

Right

<input type="checkbox"/> scalp	<input type="checkbox"/> face	<input type="checkbox"/> mouth	<input type="checkbox"/> oral mucosa
<input type="checkbox"/> throat	<input type="checkbox"/> eye	<input type="checkbox"/> hand	<input type="checkbox"/> arm
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<input type="checkbox"/> anus	<input type="checkbox"/> thigh	<input type="checkbox"/> calf	<input type="checkbox"/> foot
<input type="checkbox"/> Other			

Lesion photos in Epic (Y/N): {Yes No:20284}

Images inserted at bottom of the note: {Yes No:20284}

Add X's For Distribution of Lesions

Example:

Distribution of Lesions:

Left

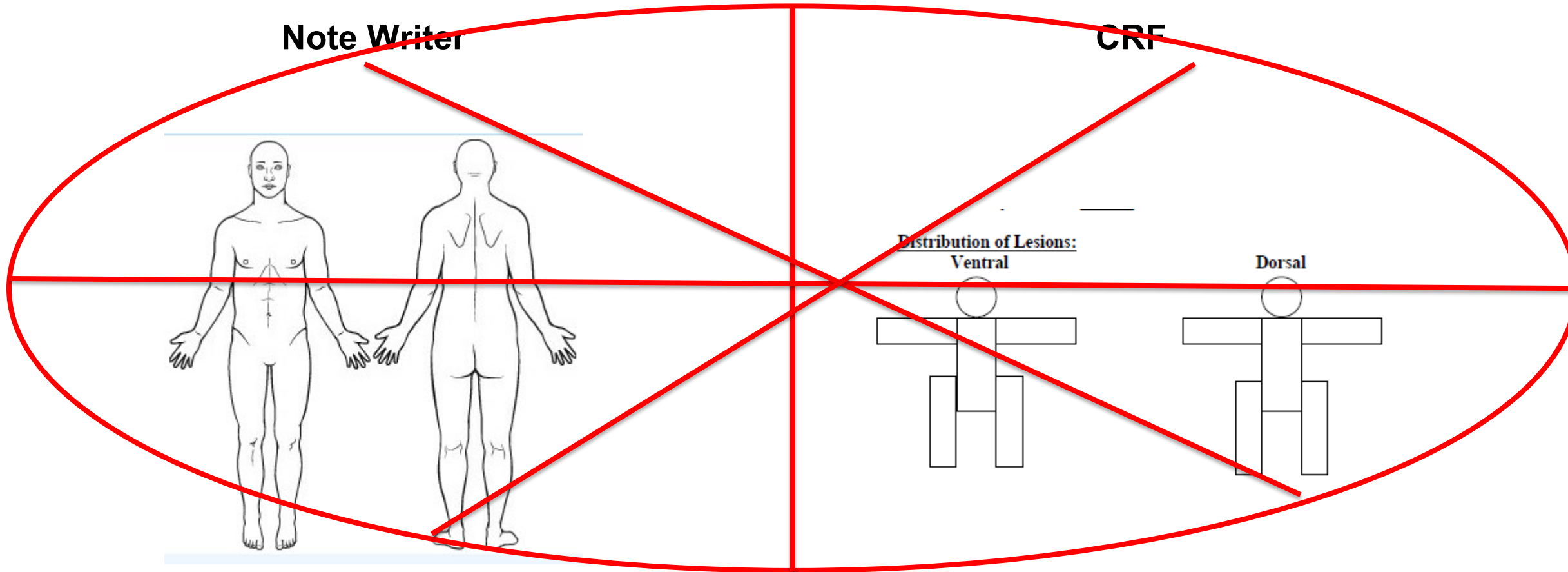
<input checked="" type="checkbox"/> scalp	<input type="checkbox"/> face	<input type="checkbox"/> mouth	<input type="checkbox"/> oral mucosa
<input checked="" type="checkbox"/> throat	<input checked="" type="checkbox"/> eye	<input checked="" type="checkbox"/> hand	<input type="checkbox"/> arm
<input type="checkbox"/> trunk	<input type="checkbox"/> abdomen	<input type="checkbox"/> buttock	<input type="checkbox"/> genitals
<input type="checkbox"/> anus	<input type="checkbox"/> thigh	<input checked="" type="checkbox"/> calf	<input type="checkbox"/> foot
<input type="checkbox"/> Other			

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<input type="checkbox"/> throat	<input type="checkbox"/> eye	<input type="checkbox"/> hand	<input type="checkbox"/> arm
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<input type="checkbox"/> anus	<input checked="" type="checkbox"/> thigh	<input type="checkbox"/> calf	<input type="checkbox"/> foot
<input type="checkbox"/> Other			

Only need to use Note Writer to document lesions if patient refuses photos

MPXTREATMENTSTART



Only need to use Note Writer to document lesions if patient refuses photos

MPXTREATMENTSTART

Local Labs

Laboratory

BMP:

@BRIEFLAB(NA,CL,BUN,K,CO2,CREATININE,GLUs)@

CBC:

@BRIEFLAB(WBC,RBC,HGB,CRIT,MCV,MCH,MCHC,RDW,PLT,MPV,NEUTP,LYMPH P,MONOP,EOSP,BASOP,NEUT,LYMPH,MONO,EOS,BASO,RETIC,MANDIFF,LUC,LU CP)@

LFTs:

@BRIEFLAB(TP,SGPT,SGOT,ALK,ALB,DBILI,TBILI)@

UA

@BRIEFLAB(UCOLOR,UAPPEAR,SGUR,PHUR,PROTUR,GLUUR,UKETONE,UBILI,UBLOOD,UROBILINOGEN,NIUR,LEUEU,SQUAMOUSEC,SQUAMOUSECH,SPERMUR,WBCUR,WBCUR H,RBCUR,RBCURH,UREC,UTEC,TRICHOMONAS,BACTUR,BACTERIAUR)@

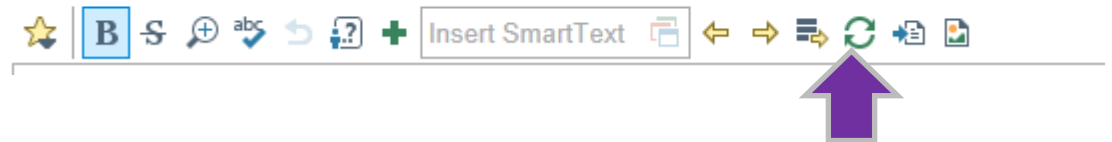
STI Testing:

(If previously completed please document date and results)

- HIV -
- Hep C -
- 3 site GC/CT -
- RPR -
- HSV/VZV -
- Bacterial Culture -

- Won't be complete until hours later or next day, may need to addend and refresh your note to update

Summary:



- **Ensure that complete STI testing is performed recently due to high rates of co-infection**

MPXTREATMENTSTART

CDC Labs

CDC Labs:

Immunochemistry collected: {Yes (Default)/No:51158}

Lesion swab collected: {Yes (Default)/No:51158}

Lesion swab collected from: ***

- When you communicate with the MPX Trt Team we will bring you a kit with the tubes needed and swabs

MPXTREATMENTSTART

Plan

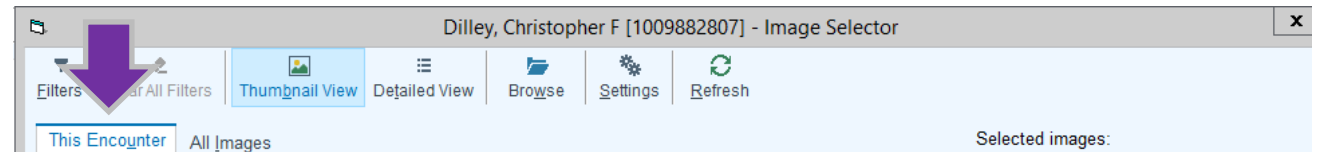
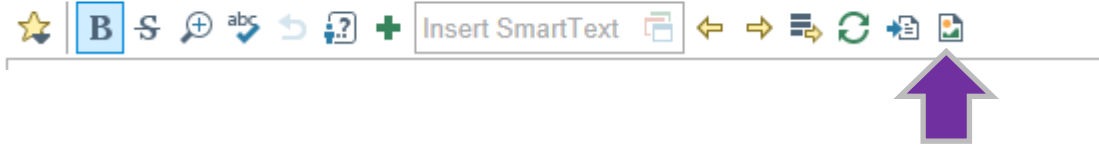
- - Document
 - TPOXX
 - Superinfection/Antibiotics
 - Labs performed
 - Supportive care provided
 - Counseling provided
 - Follow-up

MPXTREATMENTSTART

Clinical Images Taken at Today's Visit:

Clinical Images Taken at Today's Visit:

Summary:



- Can select all and insert

MPXTREATMENTFU and MPXTREATMENTFINAL

Visit type: ****
(In person or Video)

This is an infectious disease consult for @PATPREFNAME@, who is a @AGE@
@GENDERID@ on therapy for Monkeypox.

➤ Document visit type

MPXTREATMENTFU and MPXTREATMENTFINAL

HPI

HPI

New lesions after 48 hours of therapy? {YES/NO:12384:::1}
If yes please includes dates and locations:

Signs/symptoms first started to improve on treatment day #

Describe the improvements if any:

CDC Treatment Questions:

Treatment drug: Tecoviramat

Treatment dose: 600mg

Treatment frequency: ***

Day/Time first dose taken: ***

Most recent dose taken (day/time) ***

Number of days on therapy: ***

Number of doses taken so far: ***

Did patient consume a meal containing about 600 calories and 25 grams of fat when taking most recent dose of tecoviramat? {YES/NO:12384:::1} -

Was oral tecoviramat given via nasogastric (NG) tube?: No

Has the patient missed any doses? {YES/NO:12384:::1}

Has the patient had any serious adverse events? {YES/NO:12384:::1}

Has the patient been hospitalized since starting Tecoviramat? {YES/NO:12384:::1}

MPXTREATMENTFU and MPXTREATMENTFINAL

Basic History and ROS

Past Medical History
@PMH@

Medication History
@CMED@

Allergies
@ALLERGY@

ROS
@ROSBYAGE@

Updated in EPIC and Mark Reviewed

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MPXTREATMENTFU and MPXTREATMENTFINAL

ROS and Exam

Vital Signs:

@VS@

@PHYSEXAMBYAGE@

Distribution of Lesions:

Left

<input type="checkbox"/> scalp	<input type="checkbox"/> face	<input type="checkbox"/> mouth	<input type="checkbox"/> oral mucosa
<input type="checkbox"/> throat	<input type="checkbox"/> eye	<input type="checkbox"/> hand	<input type="checkbox"/> arm
<input type="checkbox"/> trunk	<input type="checkbox"/> abdomen	<input type="checkbox"/> buttock	<input type="checkbox"/> genitals
<input type="checkbox"/> anus	<input type="checkbox"/> thigh	<input type="checkbox"/> calf	<input type="checkbox"/> foot
<input type="checkbox"/> Other			

Right

<input type="checkbox"/> scalp	<input type="checkbox"/> face	<input type="checkbox"/> mouth	<input type="checkbox"/> oral mucosa
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<input type="checkbox"/> anus	<input type="checkbox"/> thigh	<input type="checkbox"/> calf	<input type="checkbox"/> foot
<input type="checkbox"/> Other			

Lesion photos in Epic: {YES/NO:12384:::1}:

Monkeypox Specific Exam

Approximate number of lesions: ***

Size of maximal lesion (in mm): ***

Percent of body affected: ***

(Using rule of 9's with any part with at least one lesion counting)

Has there been a change in the size or stage of healing of lesions (describe)? ***

Has there been a change in other clinical signs/symptoms (describe)? ***



MPXTREATMENTFU and MPXTREATMENTFINAL

Local Labs

Laboratory

BMP:

@BRIEFLAB(NA,CL,BUN,K,CO2,CREATININE,GLUs)@

CBC:

@BRIEFLAB(WBC,RBC,HGB,CRIT,MCV,MCH,MCHC,RDW,PLT,MPV,NEUTP,LYMPHP,MONOP,EOSP,BASOP,NEUT,LYMPH,MONO,EOS,BASO,RETIC,MANDIFF,LUC,LUCP)@

LFTs:

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UA

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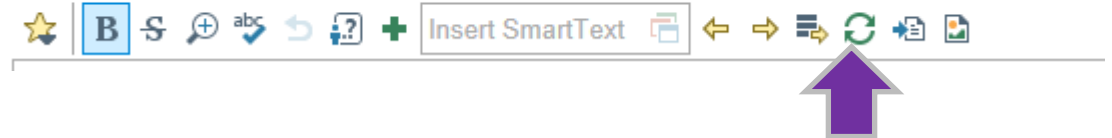
STI Testing:

- HIV -
- Hep C -
- 3 site GC/CT -
- RPR -
- HSV/VZV -
- Culture -

Only send what is clinically indicated

- Won't be complete until hours later or next day, may need to addend and refresh your note to update

Summary:



- Ensure that complete STI testing is performed recently due to high rates of co-infection

MPXTREATMENTFU and MPXTREATMENTFINAL

CDC Labs

CDC Labs (For in-person visits only):

Immunochemistry collected: {Yes (Default)/No:51158}

PK collected: {Yes (Default)/No:51158}

Lesion swab collected: {Yes (Default)/No:51158}

Where was lesions swab sent from:

- Immunochemistry is a large tiger top SST 8.5ml tube you can get from the research unit
- PK (EDTA 6mL) Goes on ice
- Swabs are sent in dry blue top tubes (like we did when we started testing)
 - Please document location

MPXTREATMENTFU and MPXTREATMENTFINAL

Plan

- - Document
 - TPOXX
 - Superinfection/Antibiotics
 - Labs performed
 - Supportive care provided
 - Counseling provided
 - Follow-up
 - CDC Outcomes

CDC Monkeypox Outcomes:

All lesions crusted and healed with new layer of skin?

Evidence of scarring or depigmentation?

Strictures in the genital region?

Overall outcome:

(Please choose from:

- 1) Recovered from orthopoxvirus infection without sequelae
- 2) Recovered from orthopoxvirus infection with sequelae (please describe)
- 3) Not recovered from orthopoxvirus infection (e.g., persistence of residual lesions)
- 4) Death (please provide details)

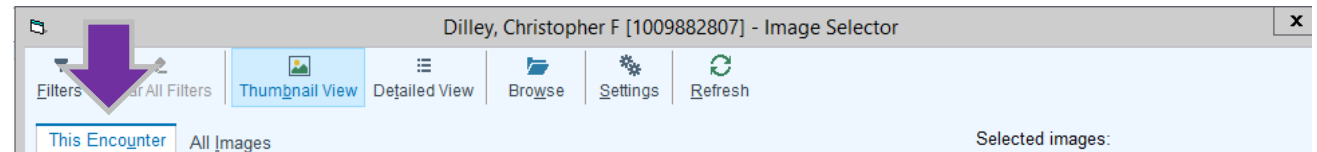
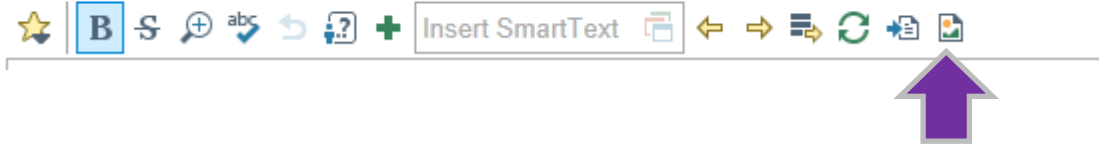


MPXTREATMENTFU and MPXTREATMENTFINAL

Clinical Images Taken at Today's Visit:

Clinical Images Taken at Today's Visit:

Summary:



- Can select all and insert

Contributors

Monkeypox Treatment Team

- Magda Sobieszczyk
- Jason Zucker
- Brett Gray
- Arianna Pazmino
- Mascha Elskamp
- Orlando Rosario
- Jacob McClean
- Clare Delaurentis
- Michelle Chang
- Lawrence Purpura
- Jon Kirschner

HP6/VC4

- Matt Scherer
- Peter Gordon
- Susan Olender
- Caroline Carnevale
- Maria Espinal

IP&C

- Yoko Furuya
- Tina Wang

Providers

- **All of the providers who have seen and treated MPX patients (more than I can list here!)**