Centers for Disease Control and Prevention

Mpox

Mpox Home

Clinician Fact Sheet: Virologic and Immunologic Characteristics of Severe Mpox in Persons with Advanced HIV (VIRISMAP)

Updated April 20, 2023

People with advanced HIV who contract mpox are at risk of severe illness and death. The extent to which the pathology of mpox in patients with advanced HIV is driven by mpox viral effects versus a dysregulated immune response – and potentially immune reconstitution inflammatory syndrome (IRIS) – is unclear. CDC is collaborating with the National Institutes of Health (NIH) to study the extent of mpox viral spread and immunologic markers in people with advanced HIV.

Findings from this study will enhance knowledge of mpox pathogenesis in severely immunocompromised people, which can inform treatment and prevention of severe illness and deaths associated with mpox in people with advanced HIV. The study will include people living in the United States who are at least 18 years old and who have HIV with CD4 count < 200 cells/mL and are hospitalized with probable or confirmed mpox.

Presentation for the Study

For more information, see the Virologic and Immunologic Characteristics of Severe Mpox among Persons with Advanced HIV Presentation [600 KB, 28 pages].

Study Objectives

- Describe the relationship between the immunologic response and the persistence and replication competence of mpox virus at rash lesions, in blood, in tissue, and at mucosal sites over the course of severe mpox illness among patients with advanced HIV.
- Describe the association between clinical outcomes and virologic and immunologic parameters among patients with severe mpox and advanced HIV.
- Survey for emergence of antiviral drug resistance among mpox virus isolates collected over time during severe mpox illness among patients with advanced HIV.
- Characterize the effects of antivirals to treat mpox and/or HIV infection on virologic and immunologic parameters among patients with severe mpox and advanced HIV.

Design

Prospective cohort study.

Population, Sample Size, and Timeline

Convenience sampling will be used to select 85 participants aged ≥ 18 years who are hospitalized in the United States with probable/confirmed mpox and HIV with CD4 count < 200 cells/mL. The study will launch in March 2023 and run for 18 months.

Collaborators

1. Laboratories: CDC, NIH, and Karius Laboratories
2. Clinicians at clinical sites from which participants will be recruited.

Collaborators will be included in group authorship (VIRISMAP study team) on publications resulting from this work.

Participant Recruitment

Individuals must meet all the following inclusion criteria to be eligible to participate:

- Age ≥18 years; AND
- HIV infection with CD4 count < 200 cells/mL; AND
- Probable or confirmed mpox (does NOT need to be a new diagnosis); AND
- Hospitalized while symptomatic from mpox, for reasons other than (or in addition to) infection prevention and control

Visit Schedule

For hospitalized participants, the collaborating clinical team will perform the visits at each of the following routine and sentinel time points:

- Routine visits
  - Enrollment
  - Every 4 weeks while hospitalized; OR
  - Every one week while in intensive care
  - Resume two weeks after study visit
- Sentinel events
  - Two weeks after antiretroviral therapy (ART) initiation
  - One week after vaccinia immune globulin intravenous (VIGIV) administration
  - Surgery under general anesthesia related to mpox-associated complication
  - Admission to ICU from non-ICU
  - Hospital discharge
  - Death

Sample Collection

Lesion swabs, mucosal swabs, and blood samples will be collected at each visit including enrollment. Tissue samples might be collected ante-mortem (per clinical discretion and after obtaining patient consent) and/or post-mortem (if permission for autopsy).

Data Collection

While the participant is hospitalized, data collection (includes participant background and physical exam data) will occur until any one of the four events occurs:

- 16 weeks since enrollment
- Recovery from mpox
- Death
- Voluntary withdrawal.

Estimated time burden of collection of clinical data and samples, per participant, in minutes.

Data and Sample Collection	Participant	Clinician
Clinical Data		
Enrollment	60	60
Visit*	45	90
Lab Sample Collection		
Lesion swabs*	15	20
Blood samples*	15	30
Total time (minutes)*	**135**	**200**

*We estimate an average of 3 visits per participant; times provided are totals for 3 visits

Ethical Considerations and Approval

CDC holds a single research Institutional Review Board determination, which may be used by collaborating sites through reliance agreements (though sites may seek independent IRB determination if desired). Specific methods of informed consent will be provided per site institutional policies and preference. Risks are minimal and are those associated with routine blood draws. There is no financial compensation for participation in the study, but findings may inform the care of future patients.

Resources/Tasks Covered by CDC/NIH

- IRB determination
- Project packets including clinical research forms to be filled
- Sample collection packets including all collection tubes
- Sample shipping costs
- Lab testing beyond routine clinical testing per project objectives (e.g., virologic and immunologic assessments at CDC and NIH)
- Input of all study data to database
- Analysis and interpretation of study results
- Fees associated with publishing and presenting findings

Resources/Tasks that Will Need to be Covered by Sites

- IRB review – each site will need to review CDC IRB determination
- Informed consent – to be completed by clinical site staff upon enrollment
- Sample collection – blood and lesion samples to be collected at each visit
- Physical exam data – symptom and physical exam data, and documentation on paper forms, to be performed at each visit

- Sample preparation – to be performed at site lab, for shipping to collaborating labs

Interested in participating?

Clinicians and sites are welcome to express interest in participating and to reach out with questions by emailing poxvirus@cdc.gov!

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