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Removing Barriers to Tecovirimat for Mpox-infected Individuals via Novel Models of Care Delivery

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Background

Problem Statement:

During the 2022 mpox outbreak, the CDC's expanded access Investigational New Drug (IND) protocol created a practical barrier to the outpatient provision of tecovirimat. We rapidly implemented a tecovirimat prescription program for individuals infected with mpox to improves access to care.

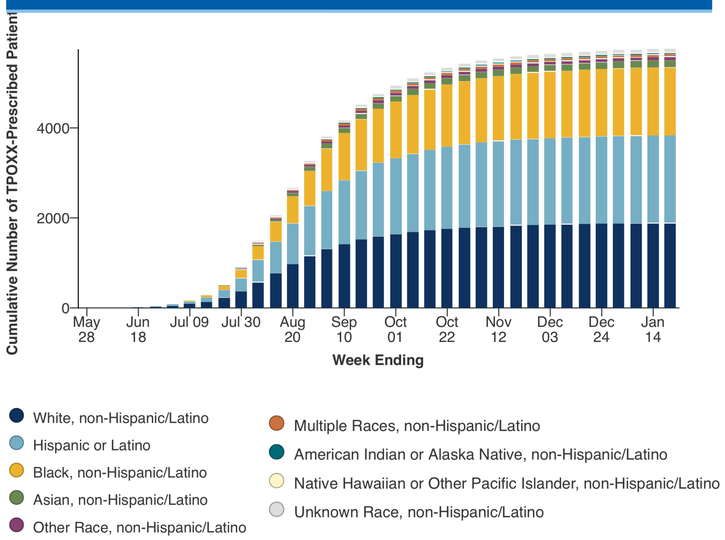
Project AIM:

Primary aim: describe how we rapidly implemented a program for increasing tecovirimat distribution in a metropolitan area.

Secondary aims: describe the patient population who received tecovirimat as treatment for mpox at our clinic and analyze several clinically relevant time intervals along the continuum of care delivery.

Baseline Metrics

Cumulative Number of TPOXX-prescribed Patients Reported to CDC: Race/Ethnicity by Week



Source: Centers for Disease Control and Prevention. *Demographics of Patients Receiving TPOXX for Treatment of Mpox*. Retreived April 23, 2023 from https://www.cdc.gov/poxvirus/mpox/response/2022/demographics-TPOXX.html

Methods & Interventions

- A tecovirimat referral line was created and staffed by a physician assistant trained in the CDC mpox IND protocol.
- Overseen by Infectious Diseases faculty, the PA assessed the referred individuals via telemedicine appointments, managed all IND paperwork, then prescribed and arranged for home delivery of tecovirimat.
- The primary measures of program success were the time interval from referral to the mpox clinic to the initial visit with the mpox clinic PA and the time between that initial visit and the receipt of tecovirimat.

Results

Descriptive Statistics of Individuals Seen in Tecovirimat Clinic by HIV History

Patients seen in Tecovirimat clinic	Patients with Known HIV	Patients without Known HIV
Age, years, mean (SD)	40.7 (8.8)	34.0 (8.7)
Gender, N (%)		
Female	1 (10%)	1 (4%)
Male	9 (90%)	24 (96%)
Race, N (%)		
Black/African American	5 (50%)	12 (48%)
White	3 (30%)	8 (32%)
Hispanic	2 (20%)	4 (16%)
Native American	0 (0%)	1 (4%)
Involvement of Anatomic Areas that May Result in Serious Sequelae, N (%)	8 (80%)	17 (68%)
At High Risk For Progression, N (%)	10 (100%)	10 (40%)
Patients who completed the course, N (%)	5 (50%)	11 44%)
Side Effects to Tecovirimat Requiring Discontinuation, N (%)	0 (0%)	1 (4%)

- Patient demographics were notable for sex (94.3% male), race (48.6% Black, 31.4% White, 17.1% Hispanic), and HIV-positivity (28.6%).
- The mean time from symptom onset to tecovirimat receipt was 10.17 days.
- Within this overall timeframe, once individuals were seen in the mpox clinic, care was delivered with minimal delay: days from referral to first mpox provider visit (mean 1.03) and from first mpox provider visit to receiving tecovirimat (mean 0.22).
- Of the 29 patients who met treatment criteria, 17 were prescribed tecovirimat, of which 16 completed treatment.

Intervals for Significant Time Points Along Treatment Timeline

Time Intervals	Median (IQR)	Mean	SD	Variance
Days from symptom onset to first being seen by non-tecovirimat prescriber	3 (2,6)	4.51	3.86	14.90
Days from first seen to referral	4 (2,6)	4.86	3.55	12.60
Days from referral to being seen by tecovirimat prescriber	0 (0,1)	1.03	1.90	3.61
Days from tecovirimat prescription to receiving tecovirimat	0 (0,1)	0.22	0.43	0.18
Total days from symptom onset to receiving tecovirimat	9.5 (6,14)	10.17	4.33	18.73

Challenges and Lessons Learned

- Identifying high-risk patients, many of which already have difficulty accessing medical care and maintaining follow up at baseline.
- Formulating and implementing a stream-lined prescription program while overcoming the practical barrier of IND protocol, which included many complex logistical steps.
- Establishing a lead provider involved collaborating and coordinating amongst the infectious disease division.
- Educating community providers about the availability of our program for referral as well as ancillary medical staff at the institution level.

Future Directions

Our care model can serve as a guide not only for tecovirimat procurement, but also for future INDs and other outpatient medications during infection outbreaks, limiting barriers to necessary medication delivery and reducing infection burden amongst the community at large.

Linkage to Healthcare Disparities

- Infectious diseases have long been a source of social stigma throughout history and their burden is associated with lower socioeconomic status.
- Stigma has been shown to be independently associated with increased time from symptom onset to presentation for care.
- Our outreach to community providers attempted to connect these at-risk populations not already in established care to our clinic, reducing disparities in therapeutic delivery.
- The observed delay between symptom onset and referral could be attributed, in part, to stigma surrounding mpox.