TITLE: Implementation of a standardized process for outpatient COVID-19 treatments at a

 Veterans Affairs (VA) hospital

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BACKGROUND/PURPOSE: Multiple pharmacologic agents have recently been introduced into healthcare systems for the treatment of mild-to-moderate symptomatic COVID-19 infection in patients at high risk for severe disease in the ambulatory setting. With challenges such as product availability, coordination of timely dispensing and administration, and many patient-specific factors to consider prior to selecting the most appropriate therapy, it is imperative that healthcare professionals collaborate to provide high quality care to patients in an efficient way. This project aims to analyze the newly-implemented treatment process utilized at VA Connecticut (VACT) to effectively allocate the available supplies of molnupiravir, nirmatrelvir/ritonavir (Paxlovid), remdesivir, and sotrovimab.

METHODS: This evaluation was approved by the VACT Institutional Review Board as a quality improvement project. Veterans considered for outpatient treatments for mild-to-moderate symptomatic COVID-19 infection at VACT between January 11, 2022 and March 11, 2022 were included in this retrospective chart review. Inclusion was determined based on the submission of a COVID-19 treatment eligibility note in the patient chart by a provider. Patient eligibility requests for COVID-19 outpatient therapy were reviewed by clinical pharmacists to determine which treatment options were available and most appropriate for each patient based upon a comprehensive review of patient factors including vaccination status, risk for disease progression, recent bloodwork, and presence of potential drug interactions with concomitant medications. Implementation of this process aligned with the most updated COVID-19 treatment guidelines. Prioritization of therapy was determined utilizing the National Institute of Health and Center for Disease Control tier system based on risk for disease complications as well as a site-specific algorithm considering supply. Patient demographics and treatment-related information were collected from the electronic health record. Outcome measurements collected included adverse drug reactions (ADRs) within 7 days of initiation of COVID-19 treatment, hospitalization for COVID-19 within 30 days of treatment initiation, and death within 30 days of treatment initiation. Data was analyzed to assess for trends in patient characteristics and utilization of the available therapies with a focus on patient safety as well as treatment process evaluation.

RESULTS: The study population (n=128) consisted of primarily older males with multiple medical conditions increasing risk for progression and complications related to COVID-19 infection. On average, patients were evaluated at 4.1 ± 3.5 days since symptom onset with 93% of participants being fully vaccinated against COVID-19. Of the included 128 patients formally considered for outpatient treatment over a span of two months, 73 patients were treated. Approximately two-thirds of those patients received remdesivir (36%) or Paxlovid (31%), while the remainder received molnupiravir (19%) or sotrovimab (14%). Of those who did not receive treatment (n=55), the primary causes were attributed to being outside the therapeutic window of treatment (32.7%), patient declination (29.1%), and symptom improvement (20%). Within 7 days of treatment initiation three adverse drug reactions were reported by patients. One COVID-19-related hospitalization and one death occurred in the patient population within 30 days of initiating outpatient treatment. During the study period 21 clinical pharmacists were involved in the assessment, selection, and coordination of outpatient COVID-19 treatment for patients, and every patient appropriate for treatment upon submission of the eligibility note who consented to receiving treatment did so in a timely manner.

CONCLUSION: This evaluation demonstrates how implementation of a standardized process with pharmacist-based patient assessment provided safe and effective selection and allocation of outpatient treatments for COVID-19 infection. While complex and fluid, this process highlights the importance of timely collaboration between healthcare professionals and patients with a focus on updated evidence-based recommendations, product availability, and patient-specific factors. In considering sustaining this process moving forward, ongoing communication of updates, effective delegation of responsibilities, and growing comfortability with the multi-step process will be essential. Furthermore, the proactive utilization of pharmacists in this process can likely be expanded to many scenarios outside of the COVID-19 pandemic.