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The Development of a Novel Outpatient Infusion Therapy Center for Treatment of COVID-19 in a Rural Healthcare System

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Abstract

Therapeutic interventions to manage symptoms of COVID-19 are continually evolving and being used in a variety of settings. In an attempt to reduce the potential for a high influx of hospital admissions for COVID-19 and mitigate the advancement of COVID-19 disease in infected patients, an outpatient therapy clinic for infusion therapy was established. The focus of the current paper is to outline the development of the outpatient treatment center, provide a detailed summary of workflow and discuss operational challenges and directions for the future.

Keywords

COVID-19, pandemic, outpatient therapy, coronavirus, monoclonal antibodies

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has placed tremendous burden on healthcare systems across the United States. During the fall of 2020, the United States (US) was facing a third wave of COVID-19 as a result of widespread community transition. Subsequently, all-time highs for daily positive tests, positivity rates, hospitalizations, and deaths occurred in November—December of 2020. Across the US, Midwestern states were among some of the hardest hit during the third wave as community transmission appeared to traverse from coastal regions inward throughout the year. Until vaccine deployment is more widely available, experimental pharmacological therapies are being explored for rapid deployment in the treatment of COVID-19 in an effort to reduce the need for hospitalization and prevent the progression of disease.

Multiple pharmacological therapies are currently being utilized to treat patients. Remdesivir, a nucleotide prodrug designed to inhibit viral RNA-dependent RNA polymerases, is one such investigational drug being used as an early therapeutic for moderate to severe COVID-19 infection with varying degrees of efficacy.[1-3] These preliminary findings were used to support the approval of Emergency Use Authorization (EUA) by the US Food and Drug Administration for patients with severe COVID-19. Recently, spike protein monoclonal antibody treatments (Casirivimab/Imdevimab and Bamlinivimab) also received EUA from the US FDA for treatment of mild to moderate COVID-19 in the outpatient setting for adults, to prevent progressing to severe COVID-19 requiring hospitalization.[4] While clinical trials examining the safety and effectiveness of these therapeutic agents are currently underway, the EUA's have allowed for their rapid utilization in outpatient and inpatient settings, albeit in a limited capacity per each state's predetermined allotment. As a detailed summary of the multiple pharmacologic treatments currently being explored for COVID-19 is

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beyond the scope of the current article, interested readers are directed to recently published reviews on the topic for more information.[5-8]

Until COVID-19 vaccines become more widely available, healthcare systems are faced with unprecedented challenges in their efforts to manage patient care for their local community members, while being forced to make difficult decisions regarding the need for evolving admission criteria, treatment of COVID-19 patients and critical care management. To address this need, a rural healthcare system in the upper Midwest region in the US developed an outpatient therapy infusion clinic for the treatment of patients with COVID-19. The focus of the current paper is to outline the development of a COVID Outpatient Treatment Center, provide a detailed summary of the workflow, discuss operational challenges and summarize directions for the future.

Development of Outpatient Treatment Center

Planning

In November of 2020, an interdisciplinary team of hospital administrators, nursing, physicians, and support services were in communication with state officials to discuss the process of safely delivering therapeutics for COVID-19 in an outpatient setting. An internal COVID Outpatient Infusion Center Team was assigned to the development of the appropriate infrastructure, procurement of resources, workflow, and execution of the team's plans. Administrators made the swift decision to reconfigure a portion of an ambulatory facility to be used as a COVID Outpatient Treatment Center for patients who had recently tested positive for COVID-19.

Logistics

The COVID Outpatient Treatment Center Team identified multiple infusion rooms in an infusion center of a clinic to be used for the outpatient therapy. Due to the infectious nature of COVID-19, it was determined that a space with a separate entrance would be ideal and patients needed to be treated in an isolated space; therefore, each room was isolated and kept separate from other outpatient and inpatient care areas. The unit was stocked with personal protective equipment (PPE), which included isolation gowns, surgical masks, gloves, and face shields, intravenous pumps and supplies. Implementing a new service required new scheduling, documentation, and ordering procedures. Clinical Informatics Specialists were assigned to assist with electronic health record changes needed to support new ordering, consenting, scheduling, and documentation of workflows for this unique service. In addition, Scheduling and Registration staff were educated on the new workflows. Operational and Nursing leadership were a consistent seven-day per week presence, providing oversight and support as these new workflows were operationalized and refined.

Staffing

Nurse staffing was established based on the following factors: expected state allocation of treatments, seven-day per week infusion schedule, space capacity, and projected volume of outpatient infusions. The Infusion Center staff did not originally have capacity to absorb this added volume so nurses were reassigned from other clinical departments to work in this unit for a defined period of time (block schedule assignment). In addition, registered nurses (RNs) were identified to support the front-end work of contacting eligible infusion patients, provide patient education and facilitate the ordering and scheduling process for those who agreed to the treatment. Nurse Education and Clinical Nurse Specialist experts were deployed to the COVID Outpatient Infusion Center to train nurses in intravenous therapy skills, appropriate PPE usage and safe transfusion these new drugs. This also included training to care for pediatric patients.

Workflow

This rural healthcare system is part of a larger medical system whose process was deployed to help identify eligible patients for the infusion therapies. Briefly, following a positive test, a time point of Day 0 was established for each patient, which set in motion a timeline and subsequent window of opportunity for the patient to receive the treatment. An internal scoring system with evolving algorithms developed from a centralized process out of Mayo Clinic, was used to stratify patient risk for severe COVID-19 outcomes, accounting for specified confounding risk factors and comorbidities. Eligible patients were then contacted by nursing staff who informed the patient of the treatment, discussed treatment procedures, potential for adverse events and obtained informed consent, if the patient agreed to receive the treatment. The scheduling of infusions was only done with a 2 day advance, to account for changes in patient outcomes, disease severity, evolving positive patient case counts, and availability of therapies.

Upon arrival, patients were given a phone number to call when they arrived in the parking lot and educated to report worsening symptoms, if applicable. Patients were then checked-in at an isolated entrance to the clinic facility to protect patients and staff from potential exposure. All nursing staff were equipped with full PPE and escorted patients to a private room. Nurses then registered the patients, took vital signs (blood pressure, pulse oxygen saturation, pulse, and respirations) to ensure patients were

physiologically stable prior to receiving the infusion. An intravenous (IV) catheter was then placed to be used for to receiving infusion. In parallel, the pharmacy was notified of patient arrival and began preparing the drug to standardize appropriate dose and to ensure confirmation of patient arrival prior to preparing the drug. The patient was continually monitored for changes in vitals, IV discomfort, and adverse events. The total infusion time averaged 30 to 60 min while the total visit time for the patient was approximately 3 h. Following completion of the infusion, patients had the IV removed and remained in the clinic for 60 min to allow for a brief monitoring period prior to being discharged pending any complications. At the time of article submission, 332 patients total had received a monoclonal antibody infusion (Bamlanivimab, n = 232; Casirivmab/Imdevimab, n = 100) and 58 patients have received treatment with Remdesivir at the COVID Outpatient Treatment Center.

Challenges

An initial challenge to the development of the COVID Outpatient Treatment Center was staffing the facility. Nursing staff from other departments had to be reallocated to the outpatient COVID-19 therapy clinic. Meeting the demand of the evolving need of fluctuating patient volumes conflated by the pressing window of opportunity for successful treatment was a substantial logistical challenge that required constant surveillance and modification. The management of patients who were out of network was also a challenge as they had to be registered ahead of time to create a medical registration number prior to scheduling. This also created a challenge when providing patients with follow up care instructions or monitoring. An ongoing challenge has been the unpredictability of our monoclonal antibody allocation from the state each week, which at times has limited the number of patients that could be offered this treatment.

Directions for the Future

The COVID Outpatient Treatment Center Team believes this outpatient therapy will likely be in need for several months and therefore there are continual planning meetings to help improve the efficiency of the workflow, accommodate a larger patient volume, and improve resources. Furthermore, patient outcomes and metrics are being recorded to help determine the most effective course of therapy as the need for this treatment is on the rise until widespread vaccination becomes available during 2021. Long term observational studies and randomized controlled trials are warranted to further examine the efficacy and safety of pharmacological therapeutic interventions for COVID-19.

Declaration of Conflicting Interests

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