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Brief Report

Standing-up COVID-19 monoclonal antibody infusion centers: Infection prevention and control

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This paper describes the creation of outpatient monoclonal antibody (mAb) infusion centers for COVID-19 patients in a large academic medical center. It shows how the early and consistent partnership between infection prevention and the clinical and operational teams to establish and implement policies and procedures led to efficient and safe workflows.

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BACKGROUND

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. By the spring/summer of 2020, cases of COVID-19 were overwhelming many medical systems throughout the United States and the world. Monoclonal antibody therapy is effective at reducing viral load, preventing hospitalization, and reducing the severity of COVID-19.¹ On November 9, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for a monoclonal antibody (mAb) product to treat mild/moderate COVID-19 infection confirmed by direct SARS-CoV-2 viral testing in non-hospitalized adults and specific pediatric patients who are high risk for progressing to severe COVID-19 and/or hospitalization.^{2,3} The Infection Prevention team and infusion clinic managers at a major academic medical center were tasked with quickly setting up an area to provide these infusions while protecting the healthcare personnel (HCP) and patients in the clinic. Here we summarize infection prevention interventions, mitigation strategies, and lessons learned while operationalizing outpatient administration of monoclonal antibody therapy amidst a global pandemic.

METHODS

After clinic walkthroughs and multidisciplinary meetings with clinic leadership, ancillary services, and Infection Prevention, guidance for the safe care of COVID-19 patients in the infusion clinic was developed. Designs from the existing inpatient COVID-19 containment units were adapted for use at the clinic. Discussions at multidisciplinary meetings and physical walkthroughs of the selected space resulted in developing the interventions shown in Table 1. Tape placed on the floor demarcated the patient care area from the nonpatient care areas. Infection Prevention, along with clinic leadership, developed a system to safely bring COVID-19 patients into the infusion area. The center is located at the back of a larger medical office building with an entrance at the back of the building. Parking spaces were designated for COVID-19 infusion patients, who were instructed to call upon arrival to the clinic and wait in their car until the clinic was ready to see them. HCP escorted the patient directly from the door to the infusion clinic. The patient remained masked during the entire visit and was escorted out of the building following treatment.

A freestanding outpatient infusion center was chosen as the location for mAb treatment. The clinic (Fig 1) had nine infusion chairs separated by privacy curtains in an open area surrounding a centralized nursing station and pharmacy. Due to space constraints and the inability to relocate all non-COVID-19 patient infusions, the clinic continued to provide services to non-COVID-19 patients. COVID-19 and non-COVID-19 patients would not be treated in the clinic at the same time. Infection Prevention recommended that COVID-19 patients be seen in the afternoons, leaving the morning reserved for

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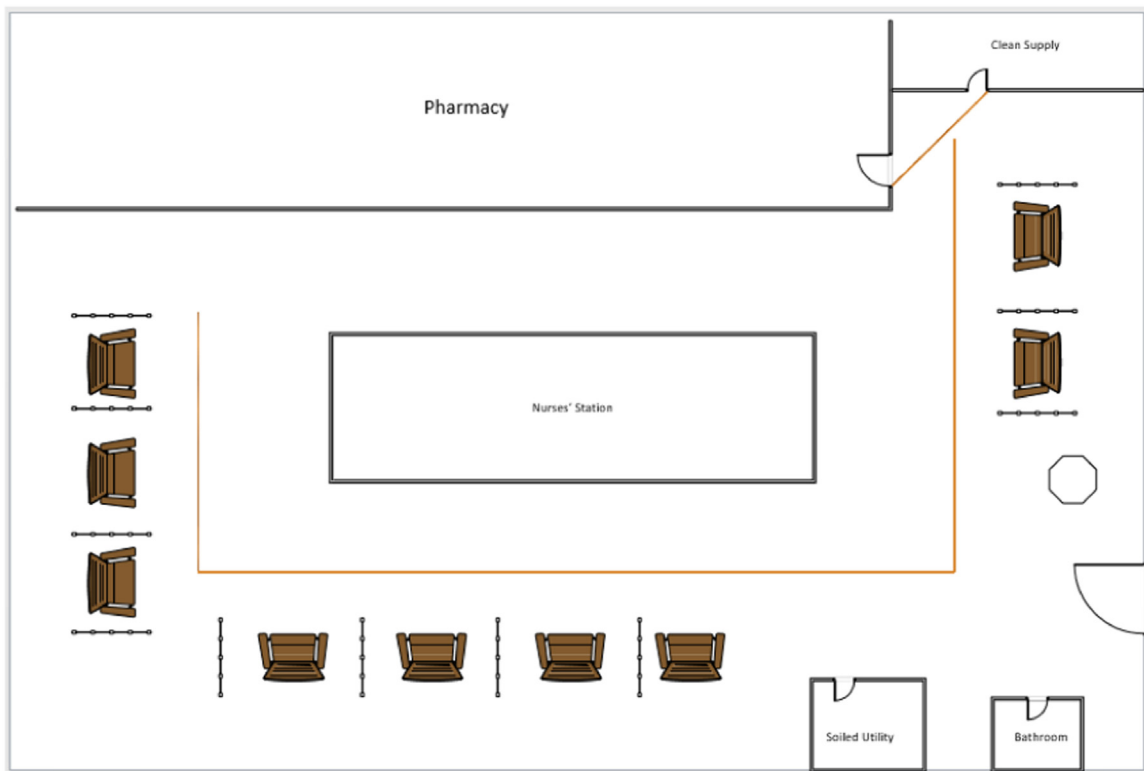
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Table 1
Infection prevention recommendations

Infusion Unit considerations	Infection prevention recommendations
Space <ul style="list-style-type: none"> • Appointment Times • Waiting Area • Entrance and Exit 	Dedicated space for only COVID-19 patients <ul style="list-style-type: none"> • Non-COVID-19 patient seen in morning; COVID-19 patients seen in afternoon • No waiting areas to be used; patients wait in their car • Dedicated entrance and exit; patients enter the building when HCP call their phone and escort the patient to the infusion area
PPE <ul style="list-style-type: none"> • HCP entering the infusion unit • HCP entering designated patient care area • HCP moving between patients • Leaving patient care area • Leaving infusion unit 	
Cleaning and Disinfection	Dedicated PPE cart at the entrance of the infusion area for donning/doffing PPE <ul style="list-style-type: none"> • Don N95 and eye protection • Don N95, eye protection, disposable isolation gown, and gloves
	<ul style="list-style-type: none"> • Change gloves between patients while performing hand hygiene in between • Doff gown and gloves • Doff N95 and eye protection, don new procedure mask for movement in building
	Infusion chairs and equipment wiped down between patients with an EPA* registered disinfectant Environmental Services(ES) personnel will enter the clinic area 1 h after the last patient is seen for cleaning and disinfection of the clinic <ul style="list-style-type: none"> • ES personnel will wear a procedure mask, eye protection, gown and gloves for cleaning and disinfection

*Environmental Protection Agency



Legend




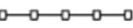
-  Infusion Chair
-  Tape
-  PPE Cart
-  Curtains

Figure 1. Clinic infusion area diagram.

non-COVID-19 patients. This allowed adequate time for aerosols to settle prior to thoroughly cleaning and disinfecting the area for non-COVID-19 patients the next morning.

After the adult infusion area was set up, a second location was set up for pediatric mAb infusions, utilizing the same processes as the adult infusion area. A walkthrough with Infection Prevention and clinic leadership was conducted prior to opening the space for use. The pediatric area has two airborne isolation infection rooms (AIIR), and infusion chairs separated by curtains. The AIIRs are prioritized for use over the curtained spaces.

RESULTS

Signage denoting Personal Protective Equipment (PPE) required to enter the area and proper donning and doffing procedures were created and placed at the entrance to the clinic. All HCP who entered the area donned an N95 respirator and eye protection at the entrance to the clinic. HCP who crossed the tape into the patient care area also donned an isolation gown and gloves, in addition to the N95 and eye protection. The HCP wore the same isolation gown between patients but changed gloves between each patient encounter. HCP ultimately wore two pairs of gloves on each hand. The HCP would remove the outer gloves after patient care, perform hand hygiene with an alcohol-based hand rub, and don a new pair of gloves on top of dry inner gloves before moving to the next patient. When HCP exited the patient care area, they doffed the gown and gloves and performed hand hygiene. N95 and eye protection were worn for the duration the HCP was in the clinic. If the HCP left the clinic for a break, they doffed and disinfected their eye protection, then doffed and discarded their N95. Disinfected eye protection was placed in a clean dry area to be used when the employee returned to the area. A new N95 was donned each time the HCP entered the infusion clinic.

Throughout the pandemic, Infection Prevention and Occupational Health Services tracked all COVID-19 HCP infections and performed contact tracing to determine if they were occupational or community-acquired. From November 2020 until November 9, 2021, 1,861 unique patient administrations of mAb treatment were given at the adult and pediatric locations. During this same time period, 1,097 HCP tested positive for COVID in the organization, and through contact tracing and HCP interviews it was determined that no patient-to-provider COVID-19 transmissions were observed in the mAb infusion clinic.

DISCUSSION

Utilizing an organized and practical method of creating an area specifically for treating COVID-19 patients streamlined care of the patient, while preventing transmission of COVID-19 from patients-to-providers. Feedback obtained from infusion clinic HCPs identified valuable lessons learned, and led to the implementation of improved workflows, especially around safe PPE practices. For example, infusion clinic nurses promptly provided feedback on the need for the ability to move quickly from patient to patient, which resulted in revised, more efficient processes. The feedback and standard workflows proved valuable when in September 2021 the adult clinic expanded into a larger space due to increased demand caused by the Delta variant surge and the FDA issued an EUA for MAB post-exposure prophylaxis in certain adult and pediatric patients. As the volume of patients began to decrease, the original clinic space was used again for treatment of COVID patients. In order to continue to treat non-COVID patients requiring infusions, infusion appointments for COVID patients have been standardized to 2-3 afternoons per week. If volume for infusions increases again, this model allows for flexibility to utilize other spaces as needed.

CONCLUSIONS

The creation of an outpatient infusion center to treat patients with highly communicable diseases, such as COVID-19 had not previously been done at our organization. Our planning and implementation allowed monoclonal antibody treatment of COVID-19 to a high volume of patients, while maintaining the safety of our staff, as demonstrated by lack of COVID-19 transmission.

References

1. Chen P, Nirula A, Heller B, et al. SARS-CoV-2 neutralizing antibody LY-CoV555 in outpatients with Covid-19. *N Engl J Med*. 2020;384:229–237.
2. FDA Authorizes REGEN-COV Monoclonal Antibody Therapy for Post-exposure Prophylaxis (prevention) for COVID-19. FDA. [online] (2021). Accessed July 13, 2021. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-mono-clonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19>.
3. FDA Authorizes Bamlanivimab and Etesevimab Monoclonal Antibody Therapy for Post-exposure Prophylaxis (prevention) for COVID-19. FDA. [online] (2021). Accessed July 13, 2021. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-bamlanivimab-and-etesevimab-mono-clonal-antibody-therapy-post-exposure-prophylaxis>.