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MAYO CLINIC

A Framework for Outpatient Infusion of Antispike Monoclonal Antibodies to High-Risk Patients with Mild-to-Moderate Coronavirus Disease-19: The Mayo Clinic Model

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Abstract

The administration of spike monoclonal antibody treatment to patients with mild to moderate COVID-19 is very challenging. This article summarizes essential components and processes in establishing an effective spike monoclonal antibody infusion program. Rapid identification of a

Mayo Clin Proc. ■ May 2021;96(5):1250-1261 ■ https://doi.org/10.1016/j.mayocp.2021.03.010
www.mayoclinicproceedings.org ■

dedicated physical infrastructure was essential to circumvent the logistical challenges of caring for infectious patients while maintaining compliance with regulations and ensuring the safety of our personnel and other patients. Our partnerships and collaborations among multiple different specialties and disciplines enabled contributions from personnel with specific expertise in medicine, nursing, pharmacy, infection prevention and control, electronic health record (EHR) informatics, compliance, legal, medical ethics, engineering, administration, and other critical areas. Clear communication and a culture in which all roles are welcomed at the planning and operational tables are critical to the rapid development and refinement needed to adapt and thrive in providing this time-sensitive beneficial therapy. Our partnerships with leaders and providers outside our institutions, including those who care for underserved populations, have promoted equity in the access of monoclonal antibodies in our regions. Strong support from institutional leadership facilitated expedited action when needed, from a physical, personnel, and system infrastructure standpoint. Our ongoing real-time assessment and monitoring of our clinical program allowed us to improve and optimize our processes to ensure that the needs of our patients with COVID-19 in the outpatient setting are met.

 ■ Mayo Clin Proc. 2021;96(5):1250-1261

The neutralizing antispike monoclonal antibodies against SARS-CoV-2—bamlanivimab, casirivimab-imdevimab, and bamlanivimab-etesevimab—are available under separate emergency use authorizations (EUAs) by the US Food and Drug Administration (FDA) for early outpatient treatment of mild-to-moderate coronavirus-19 disease (COVID-19) in patients at increased risk of clinical progression and hospitalization.[1-3] However, the administration of antispike monoclonal antibodies in the outpatient setting has challenged health care facilities already overwhelmed with the surging number of patients with COVID-19 in the hospital, maintenance of testing sites, and the development and rollout of vaccination programs.[4] Health care providers are hesitant to prescribe these monoclonal antibodies, as medical society guidelines from the National Institutes of Health (NIH),[5] Infectious Disease Society of America (IDSA),[6] and Pediatric Infectious Diseases Society (PIDS)[7] have not endorsed their routine use because of modest efficacy demonstrated in clinical trials. Furthermore, patients are either unaware of the availability of these products (and do not actively seek out treatment) or are concerned about its investigational nature. Moreover, the logistical challenges of administering outpatient monoclonal antibody infusions to contagious patients with COVID-19 have curtailed their widespread use. As such, a dedicated facility that can serve the needs of these patients while adhering to infection prevention and control (IPAC) policies to limit potential exposures to medical personnel and the community is vital.

Addressing these unique challenges, Mayo Clinic developed a dedicated clinical program for safely administering antispike monoclonal antibodies to patients. The multidisciplinary program started to administer these therapies as soon as the first shipment of bamlanivimab arrived at its facilities on November 19, 2020. By February 19, 2021, Mayo Clinic had infused antispike monoclonal antibodies to more than 4100 patients across its sites in Arizona, Florida, Minnesota, and Wisconsin.

In this report, we describe our framework for the successful implementation of this program. The essential components are listed in the Table, and the details of our processes that incorporate these components are shown in Figure 1. We hope that our processes can serve as a model for the creation of dedicated infusion therapy practices for patients with COVID-19 and other potentially infectious pathogens. The lessons we learned can guide others in developing similar programs within their health care institutions.

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TABLE. Components of an Effective Antispike Monoclonal Antibody Infusion Program for High-Risk Patients With Mild COVID-19 in the Outpatient Setting

Public health concern	Patients	Providers and health care personnel	Pharmacy	Physical space and electronic infrastructure	Processes and procedures
A pandemic of a highly infectious pathogen (SARS-coronavirus-2)	High-risk adults:	COVID-19 frontline care team	Bamlanivimab	Dedicated and separate from traditional infusion units that care for patients without COVID-19	Rapid patient identification and referrals
	65 years and older	Family medicine	Casirivimab and imdevimab	Designated parking spaces for patients; patients escorted from and to their vehicles	Equitable and fair allocation of drug upon review of eligibility criteria
	Diabetes mellitus	Infectious diseases	Bamlanivimab and etesevimab	Immediate check in and intake process	Patient education, assessment of disease severity and consenting
	Chronic kidney disease	Internal medicine	Emergency support medications (for infusion related reactions, anaphylaxis, hypersensitivity)	Infection Prevention and Control	Scheduling for infusion as soon as possible and within 10 days of onset of symptoms
	Immunocompromised condition	Pediatrics and adolescent medicine		Compliance with regulations	Symptom severity screen before monoclonal antibody infusion; clinical monitoring
	Immunosuppressive drugs	Primary care providers		Electronic heart records	Follow up mechanism, including call-back number for reporting of adverse effects
	Body mass index ≥35	Nursing		Monoclonal Antibody Treatment Registry	Real-time and systematic review of outcomes
	At least 55 years of age and hypertension, cardiac disease, or chronic lung disease	Pharmacy			
	Adolescents 12 to 17 years of age with high-risk characteristics[a]	Infection Prevention and Control			
		Healthcare Administration			
		Compliance			
		Legal			
		Medical Ethics			
		Management Engineering and Consulting			

Continued on next page

TABLE. Continued

Public health concern	Patients	Providers and health care personnel	Pharmacy	Physical space and electronic infrastructure	Processes and procedures
		Clinical and Nursing Informatics Information Technology Facilities			

[a]High risk adolescents included patients with any of the following underlying conditions: poorly controlled type 1 diabetes mellitus (most recent hemoglobin [Hb] A1C >8%) or type 2 diabetes mellitus; end-stage renal disease receiving dialysis (peritoneal or hemodialysis); allogeneic stem cell transplant within the previous 3 months; solid organ transplant within the previous 3 months or currently receiving treatment for rejection; high-risk acute lymphoblastic leukemia with receipt of induction or consolidation chemotherapy during the previous 4 weeks; acute myeloid leukemia with receipt of any chemotherapy during the previous 4 weeks; primary or acquired immunodeficiency with significant cellular immunodeficiency; receipt of immunosuppression with biologic agents such as tumor necrosis factor-alpha (TNF-α) antagonists (eg, adalimumab, certolizumab, infliximab, etanercept, and golimumab), anti–B-lymphocyte monoclonal antibodies (eg, rituximab), anti–T-lymphocyte monoclonal antibodies (eg, alemtuzumab); or daily corticosteroid therapy at a dose ≥20 mg (or >2 mg/kg per day for patients weighing <10 kg) of prednisone or equivalent for ≥14 days; severe obesity, defined as at or above 120% of the 95th percentile; sickle cell disease with ≥1 hospitalization for a sickle cell disease-related complication in the previous 3 years; chronic lung disease requiring daytime home supplemental oxygen or ventilation; severe asthma or poorly controlled asthma; neuromuscular disease with home respiratory support (continuous positive airway pressure, bilevel positive airway pressure, oxygen, cough assist); heart failure and currently listed for cardiac transplant; congenital heart disease with single-ventricle physiology and heart failure, defined as a systemic ventricle ejection fraction <30%, or the presence of protein-losing enteropathy or plastic bronchitis.

A PANDEMIC CALLS FOR INNOVATIVE CLINICAL PRACTICES

SARS-CoV-2 is a highly infectious viral pathogen, associated with a clinical spectrum ranging from asymptomatic infection to severe and critical COVID-19.[8] Since it was first reported as an outbreak of a potentially fatal pneumonia in China in December 2019, there have been major efforts in the development of therapeutics for its clinical management. The nucleoside analogue, remdesivir, was the first antiviral drug approved by the US FDA for treatment of severe COVID-19 in the hospital.[9] Convalescent plasma containing high concentrations of neutralizing antibodies against SARS-CoV-2 was granted EUA by the FDA for hospitalized patients with COVID-19.[10,11] The immunomodulatory dexamethasone has been shown to reduce overall mortality and emerged as a standard treatment of hospitalized patients who require oxygen supplementation from severe and critical COVID-19.[12] All these therapies are approved or authorized for use only in hospitalized patients with severe or critical COVID-19.

The majority of patients with SARS-CoV-2 infection develop mild-to-moderate COVID-19 that is best managed in the outpatient setting.[8,13] As there is, at present, no FDA-approved virus-directed therapy for these patients, symptomatic treatment—using over-the-counter antipyretics and analgesics—is recommended.[14] Moreover, these patients are advised to stay home and remain in isolation to reduce transmission of the virus in the community or health care setting.[8,13] The Mayo Clinic virtual telemedicine practice, through Remote Monitoring Program by our COVID-19 Frontline Care Team (CFCT) and Pediatric COVID-19 Care Team (PCCT), has ensured that high-risk patients with mild-to-moderate COVID-19 are monitored remotely for signs and symptoms that would warrant escalation of medical care to the hospital setting.[14,15]

NOVEL PHARMACEUTICAL THERAPIES EMERGE TO PREVENT CLINICAL PROGRESSION OF DISEASE AND HOSPITALIZATION

The US FDA has issued separate EUAs to 3 neutralizing monoclonal antibody

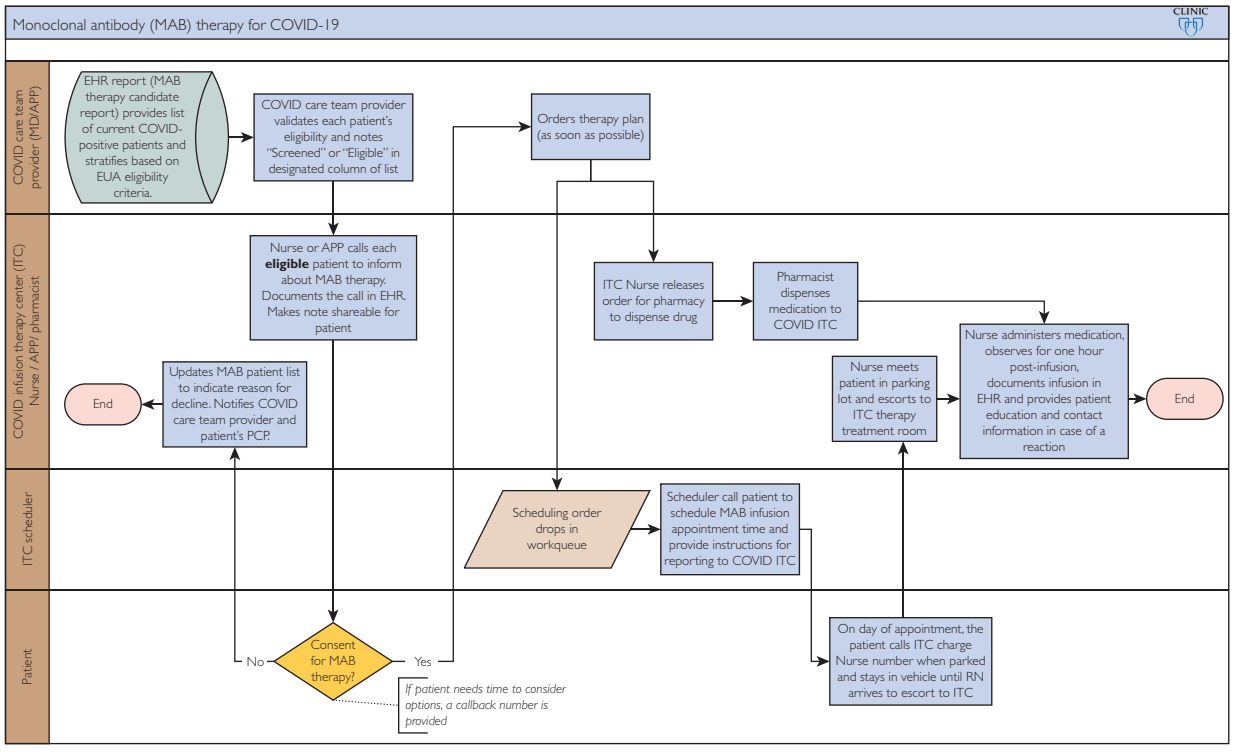

FIGURE 1. Interaction among practice providers, patients, and other personnel in the workflow of allocation, education, consenting, infusion, and monitoring for spike monoclonal antibody therapies for mild-to-moderate COVID-19.

preparations— bamlanivimab, casirivimab-imdevimab, and bamlanivimab-etesevimab—for early treatment of high-risk patients with mild-to-moderate COVID-19 in the outpatient setting.[1-3] The EUAs are based on preliminary data from early-phase clinical trials that separately compared the monoclonal antibodies with placebo and showed reductions in viral load and, potentially, the need for hospitalizations or emergency department visits.

In an interim analysis of a phase 2 trial that randomized 452 patients to receive intravenous infusions of bamlanivimab (of varying doses) vs placebo, the percentage of patients who required hospitalization or emergency department visits by day 29 was lower (1.6% of 309 patients) in the bamlanivimab cohort compared with placebo (6.3% of 143 patients).[2] In a post hoc analysis among high-risk patients (≥65 years of age or body mass index [BMI] ≥35), hospitalization rate was lower (4% of 95 patients) in the bamlanivimab group compared with placebo (15% of 48 patients).[2] In a subsequent analysis of this ongoing clinical trial, the patients who received the combination of balmanivimab and etesevimab had significant reductions in viral load compared with those who received bamlanivimab monotherapy.[3] In an interim analysis of a phase 1 to 2 trial of 275 patients, the use of casirivimab and imdevimab was also associated with reduction in viral load, especially among patients with high initial viral load and negative SARS-CoV-2 serology.[1] In the seronegative population, the rate of hospitalization was reduced from 15% (among placebo group) to 6% (among those who received casirivimab and imdevimab), although this difference was not statistically significant.[1]

The US FDA granted EUA for bamlanivimab (700-mg dose) on November 9, 2020, casirivimab (1200-mg dose)-imdevimab (1200-mg dose) combination on November 21, 2020, and bamlanivimab (700-mg dose)-etesevimab (1400-mg dose) combination on February 9, 2021, for early treatment of high-risk patients with mild-to-moderate

Mayo Clin Proc. ■ May 2021;96(5):1250-1261 ■ https://doi.org/10.1016/j.mayocp.2021.03.010
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COVID-19 in the outpatient setting. Subsequently, the US government distributed monoclonal antibodies to the states that are tasked with allocation and distribution to health care facilities within their jurisdictions. However, there have been many factors that markedly limited the widespread use of these products (as discussed throughout this article), resulting in a large stockpile of unused monoclonal antibody supplies.

Because spike monoclonal antibody therapies are given intravenously, they require eligible patients to leave the confines of their home quarantine to receive infusions in health care facilities. The infusions may also be provided in long-term care facilities and nursing homes that are able to administer the drugs.

BUILDING THE PHYSICAL AND ELECTRONIC INFRASTRUCTURE FOR SAFE INFUSIONS

Most health care systems, including Mayo Clinic, did not have dedicated infusion facilities serving COVID-19 patients who needed parenteral medications in the outpatient setting. Our existing infusion therapy center (ITC) is generally used by high-risk and immunocompromised patients for infusions of antimicrobials, other monoclonal antibodies, other parenteral medications, and blood products. Because patients who use existing ITC are predisposed to develop severe, critical, and potentially fatal COVID-19, it is essential that they be protected from potential exposures to patients with COVID-19.

Encouraged by the promising preliminary results of spike monoclonal antibodies and their potential to reduce hospitalizations, the Mayo Clinic Healthcare Incident Command System (HICS) prioritized the rapid establishment of COVID-19 outpatient infusion facilities that are physically separate from non–COVID-19 clinical areas; HICS is a leadership team, which is activated only when an emergency situation surpasses (or anticipated to surpass) the normal operating capabilities of the institution or departments. In this situation, the surge in the number of cases of COVID-19 in our communities is straining our hospital resources and capacity. This HICS-prioritized pandemic initiative allowed us to rapidly realign our resources leading to the development of dedicated infusion centers across the diverse locations of Mayo Clinic, including sites in Arizona and Florida and multiple facilities in Minnesota and Wisconsin. This allowed our program to expand beyond geographical limitations, incorporate diverse regions, and extend the ability to reach a large number of eligible patients.

Existing clinical-care units were repurposed into infusion facilities ensuring compliance with regulatory requirements. Consultation with IPAC and strict implementation of their policies was critically important in establishing the COVID-19–dedicated outpatient ITC to minimize potential exposure to staff and other patients. Certain Mayo Clinic infusion facilities were temporarily designated as hospital outpatient practices under a waiver available through the Public Health Emergency provisions. Providers are available onsite or in close proximity to infusion centers to provide support in cases of adverse reactions or medical emergencies. Clinical and Nursing Informatics facilitated the change management process to ensure that each of the new infusion facilities' workflows and electronic health record (EHR) tools were standardized across multiple sites.

Because of the prolonged infusion and monitoring period required during each monoclonal antibody infusion appointment, we anticipated that 1 room could accommodate up to 4 infusion time slots per day (for example, 3-hour appointments for a 12-hour day). In Rochester, Minnesota, we dedicated 16 rooms to provide between 48 and 60 appointments per day, depending on the demand and staffing capabilities. These infusion units also serve patients with COVID-19 who require other parenteral therapies such as antibiotics, intravenous fluids, and blood products. The Rochester, Minnesota, site has the largest infusion capacity in the midwest practice and serves as a default alternate infusion center for residents in the southeast Minnesota region when other locations in the region have reached full capacity.

All our infusion units operate daily, including weekends and holidays. To accommodate the increase in demand, our community practices in Mayo Clinic Health Systems

(MCHS) have increased their infusion capacity by expanding their physical space or extending their hours of operation. Our ITC in MCHS Eau Claire expanded to a rural critical access facility in Barron to accommodate the surge in demand in the northwest Wisconsin region. Mobile infusion units were created to serve frail residents in nursing homes and long-term care facilities in the midwest region.[16] Our program in Arizona used a mobile research unit van for infusing monoclonal antibodies while work was ongoing to expand the program into a larger 10-bay COVID-19 unit with an infusion capacity of up to 50 patients per day.

The Mayo Clinic Pharmaceutical Formulary subcommittee expedited the addition of bamlanivimab, casirivimab-imdevimab, and bamlanivimab-etesevimab to our institutional formulary as a Tier 2 restricted injectable product. Clinical and nursing informatics and information technology (IT) analysts rapidly developed electronic order sets for these monoclonal antibodies. Information technology teams leveraged the EHR to create an algorithm to automatically identify patients with new diagnoses of COVID-19 (based on testing) who fulfill the criteria for allocation. Electronic health record experts assisted the monoclonal antibody team by integrating a documentation field for date of onset of symptoms in the COVID-19 intake call for testing to populate the algorithm for our allocation process. This was helpful in our clinical review of patients, especially for those who are new to our health system, with incomplete medical records. Electronic health record experts also developed a monoclonal antibody treatment registry for all patients who are eligible, infused, or who declined infusions. This facilitated the task of reporting our data to our state departments and assisted in real-time review to optimize our processes for patient education and consenting, improve the logistics of our program, and assess clinical outcomes.

IDENTIFYING PATIENT POPULATIONS AT HIGH RISK OF CLINICAL PROGRESSION AND HOSPITALIZATION

Per the FDA EUAs, bamlanivimab, casirivimab-imdevimab, and bamlanivimab-etesevimab may only be given for emergency use to a select group of high-risk individuals.[17] These include patients who are 65 years of age and older; have diabetes; have BMIs greater than or equal to 35; have chronic kidney disease; or those with compromised immune systems, either from disease or from use of immunosuppressive agents. Patients 55 years and older may also be eligible if they have hypertension, cardiovascular disease, chronic obstructive pulmonary disease, or other chronic respiratory disease. Children 12 years of age and older and weighing at least 40 kg are eligible if they meet criteria (Table). Our partnership with EHR informatics afforded us the ability to screen and identify eligible patients quickly, based on the EUAs and state guidance.

Identifying high-risk patients quickly is critical to offer them infusion of the monoclonal antibodies as early as possible and within 10 days of onset of symptoms. Data suggest that monoclonal antibodies are more efficacious if given before the development of endogenous antibodies.[1] However, we learned that patients are often unaware of these therapies, and, accordingly, they do not actively seek treatment. For high-risk patients who are aware of these treatments, many decline infusions during the early course of their illnesses when they only experience minimal symptoms. However, by the time patients experience significant increases in symptom burden, they may no longer be eligible for infusion based on clinical-severity criteria. Some patients voiced concern about the investigational status of monoclonal antibodies, the potential for drug—drug interactions, or cost of treatment, whereas others refused the therapies because their local providers are skeptical to recommend them owing to limited efficacy data.

Recognizing these concerns and the time-sensitive nature of these therapies, our program has proactively sought eligible patients as soon as they test positive for COVID-19. At the start of the pandemic, Mayo Clinic instituted a centralized process in which positive SARS-CoV-2 polymerase chain reaction results are reported via EHR to CFCT and PCCT. The CFCT and PCCT contacts, risk stratifies, and

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enrolls patients to a nurse-led monitoring program that assesses for warning signals while patients are advised to remain in home isolation.[14,15] Our monoclonal antibody team partners with the CFCT and PCCT programs and complements their process by developing a daily report of patients with COVID-19 who fulfill eligibility criteria for monoclonal antibodies. A referral program was also developed to consider patients who may not have been tested in our clinical laboratories and those who do not receive medical care at our facilities, including underserved and underrepresented populations in our communities.

For all identified and referred patients, comorbidities and patient characteristics are reviewed and verified by the monoclonal antibody treatment team (MATRx). All eligible patients are contacted for education, discussion, and consenting for monoclonal antibody infusion (Supplemental Materials A and B, available online at http://www.mayoclinicproceedings.org). Although all patients meeting eligibility and allocation criteria are offered infusions, those with multiple comorbidities are prioritized for contacting because of their greater perceived risk for progression of disease.

PARTNERSHIPS WITH PROVIDERS AND HEALTH CARE PROFESSIONALS

A multidisciplinary MATRx team was created to tap into the clinical and administrative expertise of multiple providers and health care personnel (Table). Many members are also part of the CFCT, which ensured coordination between monitoring and treatment groups.[14,15] The MATRx clinical team developed the process of drug allocation, based on guidance from the FDA and our states' Departments of Health and Human Services, with input from medical ethics and legal colleagues to ensure a fair and equitable process. Since the start of our program, the MATRx team convenes daily to review and discuss the list of patients with COVID-19 and allocate the medications to eligible patients across our sites. During this meeting, the multidisciplinary team also discusses issues that emerged and optimizes our processes of program implementation.

We developed partnerships with clinical-practice providers and teams through education on antispike monoclonal antibodies and the eligibility criteria for infusion. Some providers have expressed hesitancy in advocating proactively for use in their patients because of lack of solid clinical data and the statements of caution from NIH, IDSA and PIDS.[5-7] Our MATRx team developed education materials on monoclonal antibodies that were disseminated through electronic mail communication, virtual practice meeting updates, electronic bulletins, and the Ask Mayo Expert online clinical reference and decision-making platform. Our MATRx team also communicated our real-world outcomes, with updates provided to institutional leadership and local providers through grand rounds and clinical-practice forums.

We developed partnerships with leaders and providers who practice outside our walls. This includes community and county hospitals, nursing homes, assisted-living communities and long-term care facilities, and those who care for underserved and underrepresented populations. Because patients tested at other facilities are not automatically pulled into our daily report, we developed a pathway for external providers to refer their patients to our program. Self-referred patients are considered. This was especially important in regions that lacked other health systems performing monoclonal antibody infusions, as it created a pathway for patients in those regions to receive treatment that was otherwise unavailable to them. Our MATRx clinical review team quickly screens all patient and provider referrals, verifies medical information, and determines eligibility based on the FDA EUA criteria.

Our provider and nursing teams contact all patients identified as eligible to provide education about monoclonal antibodies, inform about the process of infusions, and obtain verbal consent for infusion (Figure 1, Supplemental Materials A and B). Language interpreters are available to assist patients or their legally authorized representatives. Our team emphasizes to the patients that monoclonal antibody therapies are free of charge and that we have a pathway to assist uninsured

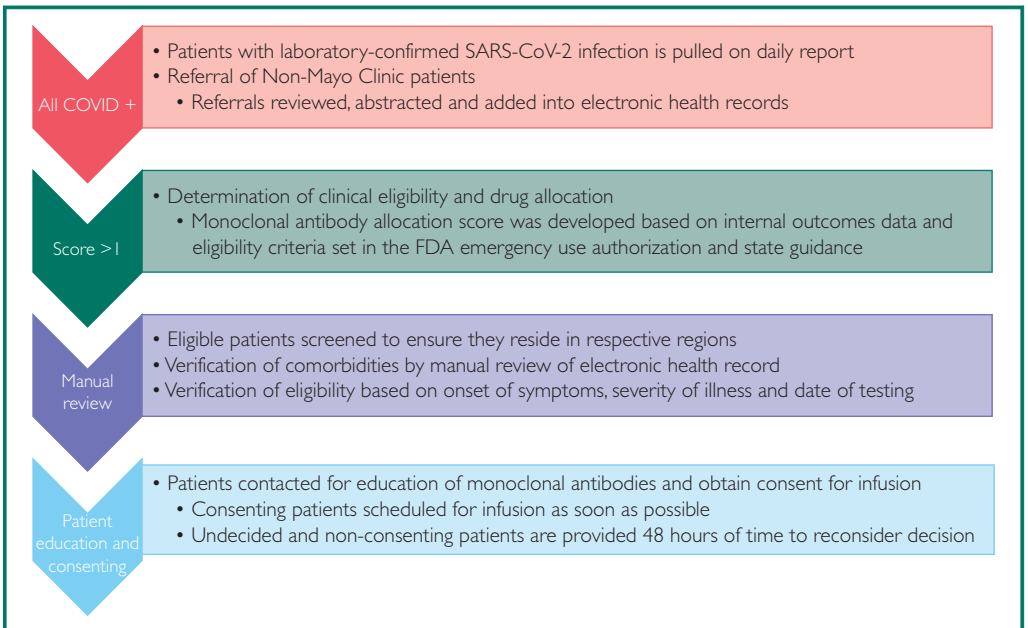

FIGURE 2. Simplified workflow for patient identification, clinical evaluation, and monoclonal antibody allocation to high-risk patients with mild-to-moderate COVID-19.

and underinsured patients. This standardized education and consenting process lasts an average of 20 minutes per patient. Those who are undecided are encouraged to discuss with family members and their physicians and then get re-evaluated as soon as a decision is made. Our nursing and provider teams gathered reasons why patients were declining monoclonal antibody infusions. Based on the information gathered, we developed education materials, including a video (Supplemental Material B), to facilitate patient education by our nursing team about monoclonal antibodies, the potential benefits and adverse effects, cost concerns, and its investigational nature. These education materials help patients with their decisions, and some who initially decline eventually agreed to receive these therapies in several instances.

Our MATRx team obtains and documents verbal consent for monoclonal antibody infusion, using a standardized script and documentation tool developed based on FDA-provided medication information and EUA requirements. This document is continually updated to address areas of patient concerns and incorporate lessons learned with our process. The most up-to-date version of the patient education script is available in Supplemental Material A. The use of a standardized script ensures that every patient receives the same information across the Mayo Clinic. Once patients or their legally authorized representatives verbalize consent, they are scheduled for infusions as soon as possible at the nearest infusion facility. Same-day schedule for infusion is preferred. All education resources, patient-education videos, documentation of the consenting process, and standard messaging are shared with patients through their online portals to allow them the ability to refer back to our guidance should questions arise. A callback number to the consenting team is also provided in case patients have additional questions.

Our ITC has well-established processes in providing medications to patients outside the hospital. We partner with ITC leaders, providers, nurses, and pharmacists to help implement our outpatient monoclonal antibody infusions. We leverage inpatient pharmacies to prepare the monoclonal antibodies for all patients scheduled for infusion each day. At some locations, logistical barriers had to be overcome, as the COVID-19 infusion centers are not physically connected to the hospital

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pharmacy. In these situations, our pharmacy team prepares the medications for same-day delivery to our infusion facilities, and having an efficient drug delivery service allows us to accommodate patients who are scheduled for infusion within hours of consenting. Upon patient arrival, but before infusion, our nursing team screens patients to ensure that they still have mild-to-moderate symptoms of COVID-19. If they have worsened clinically (eg, if they now require oxygen supplementation), the infusions are cancelled, and patients are directed to receive further care at our emergency department. For patients who are still eligible for the infusion, our nurses monitor them for adverse effects during—and for 1 hour after—completion of therapy. The infusion unit is stocked with medications that can be used to address potential hypersensitivity and other adverse events.

Our infusion therapy team, which consists of nursing and desk operations, is critical in ensuring adherence to IPAC policies and practices. Personal protective equipment—including gowns, masks, and gloves—was used by all staff members who were in direct contact with patients. We have no report of staff exposure by strictly adhering to IPAC procedures. Upon arrival to the infusion center, patients call desk personnel, who will escort them from their vehicle directly to the infusion units to prevent them from lingering in hospital and clinic premises, minimizing the potential for exposure of other patients, visitors, and health care personnel. Patients are required to wear face masks at all times. After their infusion appointments, patients are escorted back out of the building to their private transportation. The use of public transportation was specifically discouraged. For many patients who are residents of nursing homes and long-term care facilities that do not have the ability to provide infusions, or are unable to safely travel to our infusion centers, our mobile therapy team travels to infuse them at their facilities.[16] Supported by physician leaders, our infusion therapy team serves as a contact for patients to report any problems after they leave the infusion centers. Adverse events are reported to the FDA electronically by physician leaders, using the MedWatch form. Patients enrolled in the remote monitoring program and the CFCT nursing program continue to be monitored through telemedicine.

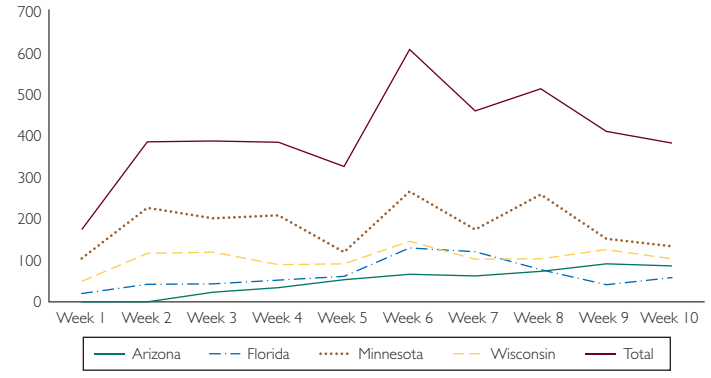

FIGURE 3. Weekly number of antispike monoclonal antibody infusions during the first 10 weeks of the Mayo Clinic Monoclonal Antibody Program across geographically diverse COVID-19–dedicated outpatient infusion centers.

OPTIMIZING PROCESSES AND MEASURING OUTCOMES

The interplay among various components of the monoclonal antibody allocation and administration workflow is depicted in Figures 1 and 2. Adjustments to this workflow were made across our infusion sites, based on federal, state, and local regulations. A monoclonal antibody treatment registry of all screened and infused patients with COVID-19 serves our aim to examine and refine our clinical program continually, improve the quality of care we provide, and assess our outcomes. Continuous quality improvement, using a Plan-Do-Study-Act framework, is used to provide assessment of the process and target improvement interventions. The daily MATRx meeting facilitates efficient communication among relevant stakeholders. This provides a platform to review eligibility and patient-infusion volumes, provide feedback on process updates, and identify topics that require escalation to senior leadership.

Figure 3 shows the total number of monoclonal antibody infusions across our

regions through January 31, 2021. By February 19, 2021, our monoclonal antibody treatment registry included more than 4100 patients who have received infusions. We are working to assess the clinical outcomes of patients with COVID-19 in terms of the rates of hospitalization, adverse drug effects, number of hospital-free and intensive care unit-free days, and mortality. Our preliminary data are promising. In addition, the infusions are well tolerated, with minimal adverse effects. We are planning on reporting our collective experience and contribute evidence to the potential efficacy and safety of monoclonal antibody infusions in COVID-19.

CONCLUSION

This article summarizes the essential components and processes of an effective spike monoclonal antibody infusion program for patients with mild-to-moderate COVID-19 in the outpatient setting. Rapid designation of a dedicated physical infrastructure was essential to circumvent the logistical challenges of caring for infectious patients while maintaining compliance with regulations and ensuring the safety of our personnel and other patients. This was made possible by the willingness of other clinical-care areas to relocate and disrupt their practices to prioritize this need. Our partnerships and collaborations among multiple different specialties and disciplines ensured contributions from personnel with specific expertise in medicine, nursing, pharmacy, IPAC, EHR informatics, compliance, legal, medical ethics, engineering, administration, and other critical areas. Clear communication and a culture in which all roles are welcomed at the planning and operational tables are critical to the rapid development and refinement needed to adapt and thrive in providing this time-sensitive beneficial therapy. Our partnerships with leaders and providers outside our walls, including those who care for underserved and underrepresented populations, promote equity in the access to the monoclonal antibodies in our regions. Strong support from institutional leadership facilitated the expedited action when needed, prioritizing physical, personnel, and system infrastructure support. Our real-time assessment and monitoring of our clinical program allows us to improve and optimize our processes to ensure that the needs of our patients with COVID-19 in the outpatient setting are satisfactorily met.

ACKNOWLEDGMENTS

The authors would like to express appreciation to all the patients and their legally authorized representatives for trusting us with their medical care; our nurses and providers who contacted our patients and provided education; our desk operations who assisted in the care of our patients; and our personnel who transported medications to our off-site infusion units and safely transported our mobile infusion teams to nursing homes and long-term care facilities. The authors also thank information technology experts who rapidly built our monoclonal antibody treatment registry and our algorithm for allocation. Finally, the authors thank Kelly J. Sullivan, MS; David A. Ring, MBA; and Tarin A. Casadonte, MS, of the Department of Management Engineering and Consulting in Eau Claire and La Crosse, Wisconsin, and Jacksonville, Florida, respectively.

SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at http://www.mayoclinicproceedings.org. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: **CFCT** = COVID-19 Frontline Care Team; **COVID-19** = coronavirus disease-19; **EHR** = electronic health records; **EUA** = emergency use authorization; **FDA** = Food and Drug Administration; **HICS** = Healthcare Incident Command System; **IDSA** = Infectious Diseases Society of America; **IPAC** = Infection Prevention and Control; **ITC** = Infusion Therapy Center; **MATRx** = monoclonal antibody treatment team; **NIH** = National Institutes of Health; **PCCT** = pediatric COVID-19 care team; **SARS-CoV-2** = severe acute respiratory syndrome coronavirus-2

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Grant Support: Dr Razonable has received a Mayo Clinic Research award.

Potential Competing Interests: The authors report no competing interests.

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