Pharmacist outreach program for COVID-19 monoclonal antibody distribution

Deaths in the United States attributed to coronavirus disease 2019 (COVID-19) have recently surpassed 500,000, and vaccines are actively being distributed and administered, which promises to mitigate the number of future hospitalizations and deaths. However, the development and rollout of effective therapeutic agents for COVID-19, particularly ones that could be given early in the disease course to reduce potential for severe disease, were initially elusive. The announcement of emergency use authorization (EUA) for the first COVID-19 monoclonal antibody (mAb) product, bamlanivimab, which helped to fill this niche, also created many logistical and ethical challenges for hospitals in the midst of many other competing priorities brought on by the COVID-19 pandemic.

This was exacerbated by the compressed timeline of the rollout, which included release of data from the BLAZE-1 clinical trial establishing bamlanivimab efficacy in reducing hospitalizations for high-risk patients on October 28, 2020, issuance of the initial EUA on November 9, 2020, and initial allocations for bamlanivimab authorized from the US Department of Health and Human Services for delivery on November 16, 2020. Details regarding the necessary logistical and clinical questions for therapy administration were slowly coming into focus over this 2-week period, and it became immediately clear that a multidisciplinary team would be required to achieve an optimal administration process on a short timeline. Because of these barriers, many institutions across the United States demonstrated slow adoption in offering bamlanivimab to patients in their communities. Recognizing the potential key benefit of mAb therapy in mitigating hospitalizations among high-risk patients before vaccine uptake, Nebraska Medicine drew on prior pandemic planning expertise and assembled a multidisciplinary team to prioritize and operationalize the offering and administration of bamlanivimab to our patients. Team members included physicians, pharmacists, nurses, attorneys, risk management personnel, ethicists, informaticists, and quality improvement personnel who worked together to overcome various challenges and quickly implemented a process for local allocation and administration of COVID-19 mAb treatment. Key objectives identified by the team included efficient identification of newly diagnosed patients with COVID-19 meeting EUA high-risk criteria, ensuring a randomized allocation system was designed in the event that need exceeded supply, providing access to mAb therapies for underserved communities in our area, and creating a safe environment for mAb administration for both patients and staff.

Process design. The first challenge to overcome was addressing the logistics of safely and efficiently administering outpatient infusions to SARS-CoV-2–positive patients. Nebraska Medicine lacked preexisting personnel and equipment to provide infusions in a space not already dedicated to infusion care, particularly one separate from patients in the emergency department or who were immunocompromised. Therefore, we decided to repurpose 1 of our 3 oncology-based infusion centers solely for the purpose of administering mAb infusions. All of the patients originally scheduled in this infusion center were rescheduled to 1 of the other 2 locations to avoid the infection control challenges associated with having both patient populations in the same center. This led to notable impacts such as increased workload for providers and patient relations personnel in communicating the reasons behind introducing a new and significant logistical hurdle for these patients. It also necessitated increased staffing and infusion capacity in the other centers that absorbed the transferred patients. Lost revenue attributed to this temporary transformation was estimated at around $1 million across all 3 centers.

The next challenge was the need to create a criteria-based algorithm to identify patients who would likely derive the most benefit from therapy based on the BLAZE-1 trial population. The organization’s infectious diseases pharmacy specialists and providers drafted a weighted, point-based scoring system, which was then translated into the electronic health record (EHR), to identify patients with newly positive assays for SARS-CoV-2 (Table 1). The list automatically screened for EUA inclusion criteria and prioritized patients on the basis of their assigned weighted score. Patients with the highest scores were prioritized for outreach first. An analysis performed before deploying the algorithm suggested that patients eligible for therapy might exceed the medication therapy initially available, so a randomization process was also developed. The finalized tool provided a platform for the outreach team to quickly identify and offer time-sensitive therapy based on established criteria applied to all SARS-CoV-2–positive patients, ensuring a process of equitable inclusion and distribution. The tool additionally allowed for broad inclusion of eligible patients in our system and was not dependent on individual provider awareness of therapy or advocacy to have patients included.

With a suitable infusion location identified and an automated method to screen and detect potential candidates for therapy established, the focus transitioned to identifying
Once the order was placed by the ordering provider, the infusion center staff were responsible for scheduling the infusion to be given within 24 hours. If the patient accepted therapy, the pharmacist entered a prebuilt order for casirivimab/imdevimab. They then provided instructions for quarantine. When a patient tested positive for COVID-19, the outreach pharmacist communicated the results and asked additional screening questions to verify patient eligibility. Because of the time-sensitive nature of administration, patients were provided up to 24 hours to accept or decline therapy. The team used EHR tools to document their communications with patients; that data then automatically populated the allocation list and was subsequently available for reporting. If the patient had not previously received the results of their COVID-19 test, the outreach pharmacist communicated the results and provided instructions for quarantine. When a patient accepted therapy, the pharmacist entered a prebuilt order for infusion therapy and routed notification to infusion center staff for scheduling. The infusion center staff were responsible for scheduling the infusion to be given within 24 hours and, when necessary, facilitated transportation for patients in need through the social work department.

During the next phase of the infusion outreach program (Figure 1, phase 2), 2 additional requests were presented to the team for integration into the program. The first concerned how the organization could extend the infusion therapy to underserved patients cared for at 2 federally qualified health centers (FQHCs). The team was able to work with the FQHCs to ensure that pharmacists would provide consistent information to patients on EUA details and administration costs. Although the report logic was built to include only qualified patients, pharmacists asked additional screening questions to verify patient eligibility. Because of the time-sensitive nature of administration, patients were provided up to 24 hours to accept or decline therapy. The team used EHR tools to document their communications with patients; that data then automatically populated the allocation list and was subsequently available for reporting. If the patient had not previously received the results of their COVID-19 test, the outreach pharmacist communicated the results and provided instructions for quarantine. When a patient accepted therapy, the pharmacist entered a prebuilt order for infusion therapy and routed notification to infusion center staff for scheduling. The infusion center staff were responsible for scheduling the infusion to be given within 24 hours and, when necessary, facilitated transportation for patients in need through the social work department.


team members available to provide patient outreach and offer therapy. Physicians, nurse practitioners, physician assistants, and nursing case managers could have been tasked with reviewing patient eligibility for EUA medications and arranging subsequent follow-up. These groups were already stretched secondary to a combination of high patient volumes, alternative assignments, and reduced staff availability as a result of quarantine requirements. Pharmacists are highly trained and have scope of practice to develop and communicate medication therapies to patients. COVID-19 mAb therapy is particularly time sensitive, and, given already strained resources, a separate pharmacist outreach team could position the project for success. Therefore, we identified pharmacist resources comprising members from clinical pharmacy leadership, antimicrobial stewardship, patient-centered medical home (PCMH), and emergency department pharmacy to provide uniform patient outreach and education.

Given the pace at which bamlanivimab received authorization and arrived onsite, there were many primary and specialty care providers without proper education on this product. Furthermore, some providers, such as emergency medicine or community partner providers, were not well positioned to serve as the ordering provider for the infusion therapy. A provider champion volunteered to serve as the “per-protocol” provider for mAb therapies to streamline the ordering process of this medication and ensure that therapy was ordered as soon as possible following a positive SARS-CoV-2 assay.

Workflow process. A workflow process map for delivering COVID-19 mAb therapy was developed (Figure 1). The workflow commenced with a pharmacy manager running a daily report identifying all EUA-eligible patients. On the basis of allocation score, a list of patients requiring outreach for the offer of mAb therapy was built and access was given to the team contacting the patients. Pharmacists from 2 groups formed the outreach team: pharmacists working in PCMH clinics contacted patients tested at primary care and immediate care clinics or at preprocedural testing stations, while emergency department pharmacists contacted patients tested through the emergency department or employee health. The outreach team followed a standardized script to ensure that pharmacists would provide consistent information to patients on EUA details and administration costs. Although the report logic was built to include only qualified patients, pharmacists asked additional screening questions to verify patient eligibility. Because of the time-sensitive nature of administration, patients were provided up to 24 hours to accept or decline therapy. The team used EHR tools to document their communications with patients; that data then automatically populated the allocation list and was subsequently available for reporting. If the patient had not previously received the results of their COVID-19 test, the outreach pharmacist communicated the results and provided instructions for quarantine. When a patient accepted therapy, the pharmacist entered a prebuilt order for infusion therapy and routed notification to infusion center staff for scheduling. The infusion center staff were responsible for scheduling the infusion to be given within 24 hours and, when necessary, facilitated transportation for patients in need through the social work department.

During the next phase of the infusion outreach program (Figure 1, phase 2), 2 additional requests were presented to the team for integration into the program. The first concerned how the organization could extend the infusion therapy to underserved patients cared for at 2 federally qualified health centers (FQHCs) in the community that lacked the personnel and physical location to appropriately administer COVID-19 mAb infusions themselves. This partnership advanced the team’s goal of ensuring equitable access to therapy and allowed the organization to fill an important need for community partners. The team was able to work with the FQHCs and determine a workflow to support patients from these clinics receiving an infusion at our site. Adjustments to the informatics workflows embedded in the EHR allowed for a seamless transition to begin offering outreach for patients already identified by the FQHCs as meeting EUA criteria.

Second, there was a need to integrate an additional EUA-approved mAb, casirivimab/imdevimab, into the allocation process. From a clinical outcomes perspective, the 2 EUA
antibody products were considered interchangeable. In Nebraska, there was a limited supply of early allocations of each product; therefore, the decision was made, by state health authorities, to keep inventory of both products at all allocated sites to allow for flexibility in the event of a temporary shortage of either product. EHR resources were updated for inclusion of casirivimab/imdevimab, and patients were then randomized to receive either product when both bamlanivimab and casirivimab/imdevimab were available. The outreach list identified to the pharmacist which product was being offered to each patient to allow appropriate education.

By the beginning of the third week of this process, the team recognized a need to further refine the list of eligible patients designated by the EHR logic. The outreach team discovered that many patients on the outreach list were not appropriate candidates for therapy because of extended time from COVID-19 symptom onset. In an effort to better capture this missing information in the identification algorithm, the order for the SARS-CoV-2 assay was updated to include required questions for providers to input the presence of symptoms and, if these were present, the date of symptom onset. This key information was then evaluated in the EHR criteria-based algorithm to appropriately narrow the daily outreach list and position the outreach team for additional efficiency. Refining this process allowed our organization to better evaluate expansion with other community partners and allowed staff to focus on the patients for whom therapy was most appropriate according to EUA criteria. A later modification allowing patients with positive SARS-CoV-2 assays from outside laboratories was incorporated and communicated to providers in our organization (Figure 1, phase 3). This process required the provider to document the assay result and EUA criteria in the EHR before contacting the outreach team for addition of the patient to the outreach list.

Early internal data from this effort have suggested that patients accepting therapy may have had a decreased rate of emergency department visits and/or hospitalizations. The pharmacists conducting the outreach were well positioned to review all medication- and EUA-related questions with the patients. The call volume and workload were higher.
when community percent positivity rates were greater than 20% and, as expected, have decreased as the percent positivity rate has decreased over time. Active outreach efforts to facilitate mAb therapy for all qualifying patients (“push”) resulted in a significantly larger number of infusions administered than at peer institutions that relied on individual provider awareness and advocacy to educate and order mAb therapy for their patients (“pull”). The average acceptance rate for antibody therapy has been consistently around 50%. This rate has remained constant even with increased public awareness coupled with increased comfort of the outreach pharmacists with the scripting and common patient questions about mAb therapy.

**Concluding remarks.** The combined efforts of a multidisciplinary team led to an innovative approach that ensured that all eligible patients tested at this organization were offered the opportunity to receive mAb therapy for early mild to moderate COVID-19 disease. This program alleviated initial concerns such as emergency department administration of infusions or infection control issues with mixing patients in areas caring for noninfected patients. Additionally, this process ensured that patients were grouped in cohorts and system burden was reduced. Multidisciplinary collaboration is critical to the development of innovative practices, especially during periods of unknowns and frequent change. Pharmacists’ skill sets proved valuable to this effort throughout procedure development and execution. Our multidisciplinary team feedback on this process has been favorable, and the team has been agile and maintained the ability to pivot when workflow adjustments have been required. The greatest success of this outreach methodology has been in the sustained, timely offering and subsequent administration of mAb therapy to all eligible patients in our system with early symptomatic COVID-19 disease.

1. Food and Drug Administration. Fact sheet for health care providers: emergency use authorization (EUA) of bamlanivimab. Published February 2021. Accessed February 23, 2021. https://www.fda.gov/media/143603/download

2. Chen P, Nirula A, Heller B, et al. SARS-CoV-2 neutralizing antibody LY-CoV555 in outpatients with Covid-19. *N Engl J Med.* 2021;384(3):229-237.

3. Food and Drug Administration. Fact sheet for health care providers: emergency use authorization (EUA) of Regen-Cov (casirivimab with imdevimab). Published February 2021.

4. Weinreich DM, Sivapalasingam S, Norton T, et al. Regn-Cov2, a neutralizing antibody cocktail, in outpatients with Covid-19. *N Engl J Med.* 2021;384(3):238-251.

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