In November 2020, monoclonal antibody infusions became the first available treatment for outpatients with Covid-19. The logistics of administering the drug, however, necessitated novel approaches to health care delivery to maximize the effectiveness in Geisinger’s patient community. To overcome these challenges, Geisinger quickly set up a process to identify the patients at highest risk and to proactively reach out to them for treatment scheduling. For most patients, an ambulatory clinic was the appropriate setting for infusions. For patients living in a skilled nursing facility or a residential facility for the developmentally disabled, Geisinger deployed mobile units to deliver care treatment to them. Additionally, to serve imprisoned patients, the health system arranged for secure access to select ambulatory clinics at designated times. Using this agile approach, nearly 3,000 patients have been treated by Geisinger since monoclonal antibody treatments were first granted Emergency Use Authorization by the FDA. In this article, the authors describe how Geisinger designed and executed this innovative approach to care delivery.
acquisition, needed administration resources, documentation, and data collection for outcome measurement tracking. The group identified priority action items, which included:

- Drug acquisition
- Patient management, including proactive identification and outreach
- Clinic scheduling and operations
- Alternative settings or methods
- Documentation
- Marketing and provider education/outreach
- Data and outcome tracking

By November 11, 2020, the team was huddling daily to work through operational specifics and assign leads to each priority item. The team included physician leadership from community practice and infection control, administrative and nursing leads from quality and outpatient services, pharmacists, electronic health record (EHR) informaticians, and personnel from scheduling services, finance, and reporting systems. Given the rapid cycle improvement and timeliness, we determined that we wanted to be up and running within 2 weeks of the initial meeting on the basis of drug availability. Senior leadership hand selected the multidisciplinary team members from thought leaders across the enterprise with the ability to drive change quickly and efficiently.

Indeed, through these efforts, on November 23, 2020, our first patient received mAb treatment at a local skilled nursing facility, and 2 weeks later, we opened three repurposed Geisinger facility–owned regional outpatient clinic sites. As of April 2022, mAb treatments have been administered in 10 ambulatory infusion locations, 16 skilled nursing facilities, and other community facilities, including developmental disability residential facilities; we also arranged to provide care to imprisoned patients at one secure outpatient setting.

Demographics and comorbidity burden for the first 2,007 patients treated (through February 15, 2022) were tracked and are summarized in Table 1 along with our overall Covid-19–positive population from that period and a propensity-matched cohort of controls.

**Drug Acquisition**

Geisinger relied on the Commonwealth of Pennsylvania’s distribution process to acquire the mAb treatment. Both the distribution process and the system utilization were unknown at the onset. The Geisinger pharmacy team took the lead in obtaining the medication and in developing
and coordinating the distribution plan for use across the system service area, which encompasses approximately 1 million people in northeast Pennsylvania. As the situation evolved, Geisinger began acquiring the medications through its primary wholesaler, which improved the communication and access to distribution information. Our pharmacy team continued to order, store, distribute, and prepare the medications.

**Table 1. Covid-19–Positive Patients at Geisinger Between November 15, 2020, and February 15, 2022**

| Patient Demographics                  | Case (N = 2,007) | Control (N = 2,007) | All Covid-19–Positive Patients (N = 91,417) |
|---------------------------------------|-----------------|---------------------|---------------------------------------------|
| Age (years)                           |                 |                     |                                             |
| Mean (SD)                             | 58.3 (16.4)     | 58.5 (16.4)         | 38.0 (21.7)                                 |
| Median (minimum, maximum)             | 60.0 (18.0, 103)| 60.0 (2.00, 101)   | 37.0 (0, 105)                               |
| Sex, No. (%)                          |                 |                     |                                             |
| Female                                | 1,130 (56.3)    | 1,130 (56.3)        | 50,368 (55.1)                               |
| Male                                  | 877 (43.7)      | 877 (43.7)          | 41,049 (44.9)                               |
| Race, No. (%)                         |                 |                     |                                             |
| Black or African American             | 25 (1.2)        | 25 (1.2)            | 4,537 (5.0)                                 |
| Other                                 | 8 (0.4)         | 8 (0.4)             | 3,417 (3.7)                                 |
| White                                 | 1,974 (98.4)    | 1,974 (98.4)        | 83,463 (91.3)                               |
| Ethnicity, No. (%)                    |                 |                     |                                             |
| Hispanic or Latino                    | 39 (1.9)        | 64 (3.2)            | 7,180 (7.9)                                 |
| Not Hispanic or Latino                | 1,950 (97.2)    | 1,918 (95.6)        | 82,346 (90.1)                               |
| Unknown                               | 18 (0.9)        | 25 (1.2)            | 1,891 (2.1)                                 |
| Charlson Comorbidity Index            |                 |                     |                                             |
| Mean (SD)                             | 3.54 (3.04)     | 3.31 (3.00)         | 1.38 (2.27)                                 |
| Median (minimum, maximum)             | 3.00 (0, 19.0)  | 3.00 (0, 19.0)      | 0 (0, 21.0)                                 |
| Elixhauser Index (van Walraven)       |                 |                     |                                             |
| Mean (SD)                             | 4.84 (9.39)     | 3.71 (8.87)         | 1.44 (6.28)                                 |
| Median (minimum, maximum)             | 2.00 (−14.0, 60.0) | 0 (−14.0, 47.0) | 0 (−18.0, 60.0)                             |

*SD = standard deviation. The case population was only a part of the overall eligible population. Source: The authors*  

and coordinating the distribution plan for use across the system service area, which encompasses approximately 1 million people in northeast Pennsylvania. As the situation evolved, Geisinger began acquiring the medications through its primary wholesaler, which improved the communication and access to distribution information. Our pharmacy team continued to order, store, distribute, and prepare the medications.

“The drug was delivered by mobile paramedics who then began the process of intravenous line insertion. Of the 2,007 patients reviewed in this article, 203 (10.11%) were treated in this manner directly at their residential skilled nursing facility.”

Antibody preparation required careful and specific steps per manufacturer recommendations, so the overall preparation and management were limited to three separate inpatient pharmacy
locations across the service area. Order sets were developed within the EHR to facilitate the ordering process and to ensure consistency in the order, monitoring, and documentation of the antibody products. As additional mAb treatments received EUA, they were included in Geisinger’s process. We adopted all authorized mAb treatments and determined which mAb would be used on the basis of recommendations from the FDA and the Centers for Disease Control and Prevention, as well as data from Geisinger’s virology group, including the identification of the predominant variant of coronavirus in our community.

**Patient Management**

Our goal was to treat as many patients as possible, especially those at the highest risk of developing severe Covid-19. As such, a pool for eligibility was established through the analytic team, which ran daily reports based on electronic medical record documentation to identify patients with a positive Covid-19 laboratory test who also met the clinical high-risk criteria defined in the EUA. These criteria included but were not limited to patients with a body mass index of 35 kg/m² or higher, chronic kidney disease, diabetes, or immunosuppressive disease; those currently prescribed immunosuppressive medications; or those 65 years of age or older. All outpatients with a positive test for severe acute respiratory syndrome coronavirus 2 were then list ranked by number of risk factors to determine the order in which patients were offered treatment with mAbs.

This list was managed by the system’s population health team, and, through outreach by telephone, patients were proactively offered treatment. This method was applied to any patient who had a positive test for Covid-19 within Geisinger’s Laboratory system, because they were the only tests for which we had a timely result. No referral was necessary, which helped get timely access to the antibody treatment without burdening the primary care provider with additional referral hurdles. For patients whose test for Covid-19 was performed outside the Geisinger system, a direct referral line was established with a dedicated Nurse Triage line. This resource received referrals, screened for compliance with EUA requirements, and scheduled on the basis of location and availability.

**Clinic Scheduling**

Because of the urgency and timing requirements from symptom onset to drug administration (10 days maximum per EUA requirement), staff contacted patients by phone. The daily list of outpatients was generated by the Geisinger analytic team and forwarded to the population health team, whereby one of three nurses performed outbound calls to gain patient agreement for treatment. If the patient was not competent to consent to treatment, the discussion was held with their medical power of attorney if they had the ability to consent. Translation services were available if the patient preferred to have the conversation in a language other than English. The nurses used standardized scripting when offering the treatment to the patient, including language required in the EUA. If patients had any questions, a physician was available for them to speak to. Common concerns included the possibility of mAbs interacting with medications the patients were taking and whether mAbs were safe for medical conditions the patients may have had. Common reasons outpatients gave for not pursuing mAb treatment were that they were not feeling sick or they did not want to travel to a clinic for infusion.
Two local prison health officials reached out to Geisinger, and, collaboratively, we were able to arrange infusions for at-risk individuals within the scheduled and established outpatient clinics located near those two prisons, with appropriate security interventions established.

If a patient consented to the treatment, a brief explanation of the treatment, the risks, and the logistics for the day of administration were reviewed. If patients did not wish to pursue treatment with mAbs, they were given guidance and standard care for Covid-19 and encouraged to follow up with their primary care provider for questions or if they required more care. If the patient agreed to be treated with mAb, the population health team had access to the electronic clinic schedule and was able to communicate the appointment time to the patient at the time of inquiry.

Primary care providers or other providers delivering care to Covid-19–positive patients had the ability to directly refer and support patients who may have had special needs or considerations with phone or Internet access. As volumes surged or declined, the clinic staff adjusted available slots at infusion clinics. Once all slots were filled, the team stopped proactively reaching out to patients. Typically, each site was staffed with a receptionist to check in and register patients and two registered nurses to establish intravenous (IV) access, administer the medication, and provide monitoring for 1 hour after infusion. This work is very fluid and continues today.

**Alternative Settings**

We recognized that patients residing in long-term or personal care facilities had additional barriers to receiving treatment with mAbs at our ambulatory infusion sites. We therefore developed a process to provide the treatment at the facilities. One obstacle we encountered was that staff at these facilities do not maintain competency in IV insertions or the infusing medications. To assist, we used paramedics, whose scope of practice licensure includes administering IV infusions. (State licensure requirements do not allow emergency medical technicians to manage IV infusions.) The paramedics assisted the facilities by establishing IV access and being available in the event of an anaphylaxis reaction. Nurses at the facilities were responsible for hanging the infusion and monitoring the patients.

Geisinger has embedded advanced practice providers who are based within 21 long-term care facilities. These on-site providers were available for monitoring patients for any reaction and for follow-up in the days after the infusion for disease progression. The advanced practice providers were alerted to all positive Covid-19 tests in the nursing home and promptly contacted the operational team to prepare and deliver the therapy for eligible patients. This was most often accomplished in a 24-hour period. The drug was delivered by mobile paramedics who then began the process of IV line insertion. Of the 2,007 patients reviewed in this article, 203 (10.11%) were treated in this manner directly at their residential skilled nursing facility.
There was agreement among the team that patients in need—from a community setting, congregate living, skilled facility, or even prison—should have unprejudiced access to the treatment. Therefore, at the peak of the pandemic, when Geisinger was approached by the alternative settings to support administration of mAb treatments, we were able to respond. Local prison systems and a residential facility serving intellectually and developmentally disabled individuals were seeing growing volumes of patients with Covid-19. Two local prison health officials reached out to Geisinger, and, collaboratively, we were able to arrange infusions for at-risk individuals within the scheduled and established outpatient clinics located near those two prisons, with appropriate security interventions established.

Both of these alternative community settings, the residential facility and the prisons, presented additional challenges for the outpatient, leanly staffed antibody clinic locations.

“Collateral materials were created and distributed, advising providers outside the Geisinger system on how to identify mAb candidates and how to get them connected for treatment.”

The residential facility was committed to treating their residents in place and wanted to avoid the time spent transferring residents to the hospital for acute care. For that scenario, Geisinger would not manage the infusion but rather would serve as the dispensing pharmacy. When the mAb treatment was first authorized in November 2020, alternative settings had no access to the treatments. Using another system resource, Geisinger worked with Vitaline, its own infusion pharmacy, to mix and deliver the medications to the residential facility sites. Patients residing in these facilities did not come into the established clinic locations for infusion.

Two of the prison facilities did not agree to Geisinger staff coming to their facility because it would have required additional security logistics, which would have consumed precious time that would have placed those patients beyond the 10-day window from symptom onset to treatment. In light of that, the Geisinger team scheduled a specific day and time window to treat a group of prisoners at a nearby ambulatory clinic without other community patients present. The hospital site organized additional security measures, coupled with attendants and guards from the prison setting. The treatments and security measures went off without any complications.

**Marketing and Provider Education**

From the onset of the pandemic, Geisinger formed inpatient and outpatient clinical protocol teams to devise and maintain updated care and treatment recommendations for patients with Covid-19. Because the mAb treatment was authorized only for nonhospitalized patients, the outpatient team was tasked with the responsibility for logistics as described throughout this article. One important task was to inform and educate all health care providers caring for patients with Covid-19. Established forums for communications were used, including, for example, daily electronic updates, routine provider meetings, and town halls. Collateral materials were created and
distributed, advising providers outside the Geisinger system on how to identify mAb candidates and how to get them connected for treatment.

## Data and Outcome Tracking

We developed an analytic dashboard to track infusion administration and postinfusion outcomes and created an automated pipeline to keep the data refreshed daily. For those infusions administered in ambulatory clinics, data were readily accessible in the EHR, which facilitated a direct connection to the dashboard. For the alternative settings, however, other than the pharmacy order for the drugs, the Geisinger team had no established way to track infusions for patients. To address this, our clinical informaticians built a structured note template, allowing the residential facility–embedded Geisinger nursing staff to record when infusions were completed and whether patients experienced any adverse reactions. For settings without an embedded provider, such as the prisons or the facility for developmentally disabled residents, our outpatient pharmacy team manually collected and provided these data to the analytic team.

## Methods and Results

The primary postinfusion outcomes of interest to the Geisinger team were inpatient admission, intensive care utilization, use of mechanical ventilation, and inpatient death, all of which were tracked within the 30-day window after the patient’s positive Covid-19 test result. To compare outcomes with those of patients who did not receive mAb therapy by reducing the bias due to confounding factors, we built a propensity score-matching model to match controls on the basis of age, sex, race, smoking status, date of positive Covid-19 testing (defined as 30-day window from the date of the infusion), and comorbidity burden, as measured by the Elixhauser list of conditions. Standardized mean differences (SMDs) of less than 0.10 were used to check the covariate balance distribution between the treated and untreated groups. Risk ratios (RRs) and 95% confidence intervals (CIs) were estimated for the matched cohort. \( P \) values of less than .05 are considered statistically significant. Statistical analyses were performed using RStudio (Version 1.3.1093).

> For the alternative settings, however, other than the pharmacy order for the drugs, the Geisinger team had no established way to track infusions for patients. To address this, our clinical informaticians built a structured note template.”

Between November 23, 2020, and February 15, 2022, 2,007 patients received mAb treatments at Geisinger. The covariates were balanced (SMD < 0.10) between cases and controls in the matched cohort. When this group is compared with the matched set of controls, patients who received mAb therapy were significantly less likely to be admitted (51 vs. 148; RR 0.34 [95% CI 0.25, 0.47]; \( P < .001 \)), to require intensive care (9 vs. 36; RR 0.25 [95% CI 0.12, 0.52]; \( P < .001 \)), to require mechanical ventilation (4 vs. 17; RR 0.24 [95% CI 0.08, 0.70]; \( P = .009 \)), or to expire in the hospital (4 vs. 25; RR 0.16 [95% CI 0.06, 0.46]; \( P < .001 \)).
When stratified by age, these benefits were amplified for patients in the highest age groups. Descriptive statistics are shown in Tables 2 and 3.

Looking Ahead

The logistics of administering mAb treatment necessitated novel approaches to health care delivery so that we could maximize the access of the treatment to those in Geisinger’s patient community, including those who reside in institutional settings such as prisons and nursing homes. To overcome these challenges, the team at Geisinger quickly set up a process to identify the patients at highest risk and to proactively reach out to them for treatment scheduling. Once confirmed, patients were scheduled for treatment at ambulatory clinics for infusions. For patients living in residential or skilled nursing facilities, mobile teams were deployed to treat the patients at the facilities.

Using this agile approach, nearly 3,000 patients have been treated at Geisinger since these treatments were first granted EUA by the FDA in November 2020. Throughout the pandemic, we have adjusted our approach to match national recommendations, including from the FDA. Additionally, we have evolved our processes to improve efficiency and serve as many patients as our resources allowed. This has included a more efficient referral process for patients who tested positive outside of Geisinger. This became critical as home testing became more prevalent, so fewer patients were being tested by Geisinger.

Initially, within Geisinger, the clinical effectiveness of these treatments was unclear. Preliminary data suggested that the medications decreased viral load and the subsequent need for hospitalizations.

| Patient Outcomes                            | Case (N = 2,007) | Control (N = 2,007) | P Values   | All Covid-19–Positive Patients (N = 91,417) |
|----------------------------------------------|------------------|--------------------|------------|-------------------------------------------|
| Admission Within 30 Days of Positive Test    |                  |                    |            |                                           |
| Yes                                          | 51 (2.5)         | 148 (7.4)          | <.001      | 2,313 (2.5)                               |
| No                                           | 1,956 (97.5)     | 1,859 (92.6)       |            | 89,104 (97.5)                             |
| ICU Utilization                              |                  |                    |            |                                           |
| Yes                                          | 9 (0.4)          | 36 (1.8)           | <.001      | 541 (0.6)                                 |
| No                                           | 1,998 (99.6)     | 1,971 (98.2)       |            | 90,876 (99.4)                             |
| Mechanical Ventilation                       |                  |                    |            |                                           |
| Yes                                          | 4 (0.2)          | 17 (0.8)           | .009       | 299 (0.3)                                 |
| No                                           | 2,003 (99.8)     | 1,990 (99.2)       |            | 91,118 (99.7)                             |
| Inpatient Death                              |                  |                    |            |                                           |
| Yes                                          | 4 (0.2)          | 25 (1.2)           | <.001      | 351 (0.4)                                 |
| No                                           | 2,003 (99.8)     | 1,982 (98.8)       |            | 91,066 (99.6)                             |

* Data are presented as No. (%). Source: The authors
**Table 3. Patient Outcomes for Monoclonal Antibody Cases Versus Controls, Stratified by Age Group**

| Patient Outcomes                      | Age (years)        | 18–34 (N = 178) | 35–49 (N = 416) | 50–64 (N = 644) | 65–79 (N = 588) | ≥80 (N = 574) |
|---------------------------------------|--------------------|------------------|-----------------|-----------------|----------------|---------------|
| Admission Within 30 Days of Positive Test | Yes                | 1 (0.6)          | 7 (1.7)         | 18 (2.8)        | 37 (5.7)       | 62 (10.8)     | 5 (2.8)       | 29 (15.3)     |
|                                       | No                 | 177 (99.4)       | 409 (98.3)      | 626 (97.2)      | 568 (96.6)     | 512 (89.2)    | 176 (97.2)    | 161 (84.7)    |
| ICU Utilization                       | Yes                | 0 (0)            | 0 (0)           | 1 (0.2)         | 7 (1.1)        | 4 (0.7)       | 8 (1.4)       | 0 (0)         | 1 (0.5)       |
|                                       | No                 | 178 (100)        | 416 (100)       | 643 (99.8)      | 584 (99.3)     | 566 (98.6)    | 181 (100)     | 186 (97.9)    |
| Mechanical Ventilation               | Yes                | 0 (0)            | 0 (0)           | 0 (0)           | 1 (0.2)        | 4 (0.7)       | 8 (1.4)       | 0 (0)         | 1 (0.5)       |
|                                       | No                 | 178 (100)        | 416 (100)       | 644 (100)       | 584 (99.3)     | 566 (98.6)    | 181 (100)     | 189 (99.5)    |
| Inpatient Death                       | Yes                | 0 (0)            | 0 (0)           | 0 (0)           | 1 (0.2)        | 4 (0.7)       | 17 (3.0)      | 0 (0)         | 5 (2.6)       |
|                                       | No                 | 178 (100)        | 416 (100)       | 644 (100)       | 584 (99.3)     | 557 (97.0)    | 181 (100)     | 185 (97.4)    |

* Data are presented as No. (%). Source: The authors
Subsequent data have further supported this, including improvement in other outcomes.\textsuperscript{1,2} Our data support these findings, including, compared with a control cohort, lower rates of admissions, ER visits, ICU utilization, mechanical ventilation use, and death for those treated with mAb treatment.

The clinical value reinforces our commitment to continue to seek novel approaches to deliver care to at-risk patients in our community, including those who require an alternative setting.

**Amy Minnich, MHSA, BSN**
Associate Vice President and Former Senior Director of Quality, Safety, and Patient Experience, Geisinger, Danville, Pennsylvania, USA

**Daniel Rocha, MM**
Phenomic Data Analyst, Phenomic Analytics and Clinical Data Core, Geisinger, Danville, Pennsylvania, USA

**Yirui Hu, PhD**
Assistant Professor, Department of Population Health Sciences, Geisinger, Danville, Pennsylvania, USA

**Keith Boell, DO, MSHQSM**
Chief Quality Officer, Population Initiatives, and Vice Chairman, Medicine Institute, Geisinger, Danville, Pennsylvania, USA

**Greg F. Burke, MD**
Chief Patient Experience Officer, Geisinger, Danville, Pennsylvania, USA

Medical Director, Emmanuel Skilled Nursing Center, Danville, Pennsylvania, USA

*Disclosures: Amy Minnich, Daniel Rocha, Yirui Hu, Keith Boell, and Greg F. Burke have nothing to disclose.*

**References**

1. Gupta A, Gonzalez-Rojas Y, Juarez E, et al.; COMET-ICE Investigators. Early treatment for Covid-19 with SARS-CoV-2 neutralizing antibody sotrovimab. N Engl J Med 2021;385:1941-50 https://www.nejm.org/doi/full/10.1056/NEJMoa2107934 https://doi.org/10.1056/NEJMoa2107934.

2. Weinreich DM, Sivapalasingam S, Norton T, et al.; Trial Investigators. REGEN-COV antibody combination and outcomes in outpatients with Covid-19. N Engl J Med 2021;385:e81 https://www.nejm.org/doi/10.1056/NEJMoa2108163 https://doi.org/10.1056/NEJMoa2108163.