Rapid implementation of pharmacy infusion services for emergency use authorization COVID-19 treatments at a field hospital

The Baltimore Convention Center Field Hospital (BCCFH) was developed through a partnership between the state of Maryland, the Johns Hopkins Hospital (JHH), and the University of Maryland Medical System (UMMS) in an effort to increase hospital bed capacity statewide during the coronavirus disease 2019 (COVID-19) pandemic. The BCCFH began as a 250-bed field hospital admitting COVID-19–positive patients who were recovering from the coronavirus and required care before being discharged home.[1] In just 3 weeks of planning and setup, what originally was a food court during concerts and events was transformed into an inpatient pharmacy. We ensured that the pharmacy met state regulations and worked with the Maryland Pharmacy Board and Office of Controlled Substances Administration to obtain a pharmacy permit and registration to dispense controlled substances. The onsite pharmacy, located inside the "hot zone," or patient care area, is accessible to all clinicians and provides services 24 hours a day, 7 days a week. A limited drug formulary was created to support general patient needs and medical emergencies. The medication distribution model has changed since the BCCFH opened. At the inception of the field hospital, patients were transferred from local hospitals and brought their own medications to be administered by BCCFH's nursing staff. This workflow was effective during the first 6 months of the pandemic, as most of the patients admitted were stable, requiring only short lengths of stay, and the patient census remained low. As the number of cases across the state increased significantly to unprecedented numbers during the fall of 2020, the BCCFH saw a commensurate rise in patient volume. To better serve the increased patient census and complexity of conditions for the admitted patients, the medication model was adjusted and automated dispensing cabinets were incorporated to better support a decentralized model, as the BCCFH began to operate similarly to a regular acute care hospital.

In addition to serving patients recovering from COVID-19, the BCCFH expanded its clinical services to include outpatient COVID-19 testing, ensuring availability for Marylanders.[2,3] Within hours of notification that the Food and Drug Administration (FDA) had issued emergency use authorization (EUA) for the product bamlanivimab and the combination of casirivimab and imdevimab for the treatment of mild to moderate COVID-19, the BCCFH again expanded its mission to administer infusion therapies for COVID-19–positive patients.[2,4]

EUA of monoclonal antibody therapies for treatment of COVID-19. Monoclonal antibody therapies have been granted EUA for the treatment of mild or moderate COVID-19 in nonhospitalized patients who are 12 years of age and older, weigh at least 40 kg, and are at high risk of progressing to severe disease or hospitalization. On November 9, 2020, FDA issued an EUA for bamlanivimab, a neutralizing immune globulin G1 (IgG1) monoclonal antibody that reduces viral replication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by binding to its spike protein. Bamlanivimab is given as a single 700-mg intravenous infusion, via intravenous infusion pump or gravity.[5] On November 21, 2020, FDA issued an EUA for casirivimab (REGN10933) and imdevimab (REGN10987), recombinant human IgG1 monoclonal antibodies that also target the receptor-binding domain of the spike protein of SARS-CoV-2, reducing viral replication. Casirivimab and imdevimab are each supplied in individual single-use vials and must be administered together after dilution as an intravenous infusion. The recommended dose is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single intravenous infusion.[6] Most recently, FDA issued an EUA for bamlanivimab and etesevimab, both of which are neutralizing IgG1 monoclonal antibodies that bind to different but overlapping epitopes in the receptor-binding domain of the spike protein. Using both antibodies together is expected to reduce the risk of viral resistance.

Bamlanivimab and etesevimab are each supplied in individual single-use vials and must be administered together after dilution as an intravenous infusion. The recommended dose is 700 mg of bamlanivimab and 1,400 mg of etesevimab administered together as a single intravenous infusion.[6] The authorized dosage for all these monoclonal antibody therapies should be administered as soon as possible after a positive viral test for SARS-CoV-2 and within 10 days of symptom onset.[5] There is no recommended dose adjustment for renal or hepatic impairment nor contraindications at this time. Table 1 summarizes the different monoclonal antibody therapies for COVID-19. The EUAs for monoclonal antibody therapies have been, and continue to be, revised regularly. These revisions may include updated dosing, packaging, and infusion times, among other recommendations. This article may include references to outdated EUA components. Because of the limited supply, these

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Table 1. Comparison of Monoclonal Antibody Therapies for COVID-19

Characteristic	Bamlanivimab[5]	Casirivimab and Imdevimab[7]	Bamlanivimab and Etesevimab[6]
Manufacturer	Eli Lilly	Regeneron Pharmaceuticals	Eli Lilly
Date of EUA	November 9, 2020	November 21, 2020	February 9, 2021
Dose	700 mg of bamlanivimab in 50, 100, 150, 200, or 250 mL	1,200 mg of casirivimab and 1,200 mg of imdevimab in 250 mL	700 mg of bamlanivimab and 1,400 mg of etesevimab in 50, 100, 150, 200, or 250 mL
Minimum infusion time	50 mL over 16 minutes, 100 mL over 27 minutes, 150 mL over 38 minutes, or 250 mL over 60 minutes	250 mL over 60 minutes	Patients ≥50 kg: 50 mL over 21 minutes, 100 mL over 31 minutes, 150 mL over 41 minutes, or 250 mL over 60 minutes Patients <50 kg: 50 mL over 21 minutes, 100 mL over 31 minutes, 150 mL over 41 minutes, or 250 mL over 70 minutes
Stability	Refrigerator: 24 hours Room temperature: 7 hours If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes before administration.	Refrigerator: 36 hours Room temperature: 4 hours If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 30 minutes before administration.	Refrigerator: 24 hours Room temperature: 7 hours If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes before administration.

Abbreviations: COVID-19, coronavirus disease 2019; EUA, emergency use authorization.

products are allocated by the federal government to states, territories, and federal entities on a weekly basis. Access to the products and accountability are of upmost importance. The pharmacy department is responsible for reporting weekly usage to the Maryland Department of Health.

The BCCFH was among the first infusion centers in Maryland to administer monoclonal antibody therapies.[8] The creation of an infusion center at the BCCFH was again a partnership and multidisciplinary effort. In the current workflow, outpatient providers complete an online referral form to refer a patient for treatment at the BCCFH infusion center. The BCCFH infusion center suite team reviews the referral form upon receipt and contacts patients who meet required criteria to schedule an appointment at our infusion center. The allocation methodology is based on time since symptom onset.

Several considerations were evaluated to safely implement additional pharmacy services to support the infusion center within the field hospital. For the purpose of this article, we will focus on relevant pharmacy operations related to monoclonal antibody therapies for the management of COVID-19 disease. The preparation and dispensing of monoclonal antibody therapies was a collaborative effort between the University of Maryland Medical Center (UMMC) and the BCCFH. Because of the lack of sterile compounding space in the BCCFH pharmacy, the decision was made to compound the monoclonal antibody therapies at UMMC, and a workflow was designed to facilitate ordering, compounding, and delivery of these infusions to the BCCFH.

The main goals during workflow design for storage and dispensing were to ensure that the vials of each product were received, stored securely, and accounted for at all stages from receipt to dispensing. The vials are received by designated personnel at UMMC and stored securely. The infusions are compounded using aseptic technique in the UMMC critical care pharmacy cleanroom. The inventory in the critical care pharmacy is managed closely by documenting vials received and doses dispensed.

Product dispensing, compounding, and delivery to the field hospital. On the day before administration of monoclonal antibody therapy, the BCCFH pharmacist runs a report in the electronic medical record system to determine the number of patients scheduled to receive infusions the following day and communicates the number of scheduled patients to the BCCFH pharmacist-in-charge, the UMMC director of inpatient pharmacy operations, and the UMMC critical care pharmacy manager via a secure web-based application. The critical care pharmacy manager then communicates the number of doses to be compounded to the critical care pharmacy team. The critical care pharmacist removes the number of vials needed from the refrigerator and documents this in the logbook, including information on lot number and expiration date. The infusions are compounded by the designated sterile compounding pharmacy technician. Upon pharmacist verification of the final product, the pharmacist places doses prepared in a tamper-evident bag

inside an insulated delivery box with ice packs. The infusions are immediately sent to the BCCFH by courier service. Patient appointment compliance is monitored daily by BCCFH pharmacists, and additional infusions are requested from the UMMC pharmacy as appropriate. Dispensing of ad hoc infusions follows the same process. The process for ordering and compounding monoclonal antibody therapies the day before infusion is summarized in Figure 1.

Necessary considerations in the compounding and dispensing process include timely delivery of infusions to the field hospital, administration of the compounded product before its expiration, and minimal impact on day-to-day pharmacy operations. To have the infusions readily available and stable at the BCCFH infusion center, the infusions are preemptively batched on the day before the scheduled administration.

Pharmacy workflow at the BCCFH infusion center. The BCCFH infusion center operates Monday through Saturday from 8:00 AM to 6:00 PM. Patients who are referred by a provider and meet the criteria to receive monoclonal antibody therapy are contacted for scheduling. The orders for monoclonal antibody therapy are signed and held in the electronic medical record by the infusion center medical director. On the day of infusion, the BCCFH nurse releases the order in the electronic medical record upon patient arrival. The BCCFH pharmacist performs order verification in the electronic medical record. The BCCFH pharmacist attaches a patient-specific label to the compounded product, maintains the infusion at room temperature for 20 minutes for bamlanivimab and etesevimab or 30 minutes for casirivimab and imdevimab, and then delivers the dose directly to the patient's nurse at the infusion center. To maintain chain of custody of the product, the infusion center nurse signs a delivery log to confirm receipt of the dose. The BCCFH pharmacist assists the infusion center clinical team in determining the need for additional doses for newly scheduled patients. The BCCFH pharmacist evaluates the patient schedule throughout the day and requests additional doses from the UMMC critical care pharmacy if needed. The process for dispensing and administration of monoclonal antibody therapies the day of infusion is summarized in Figure 2.

Safe administration of monoclonal antibody therapies. The BCCFH infusion center has administered over 1,700 doses of monoclonal antibody therapy in a 4-month period. An infusion pump is used to provide the safest and most consistent infusion rate, for which it is necessary to use tubing with a 0.20- to 0.22-μm inline filter during administration. If the patient experiences an infusion reaction, the infusion can be easily stopped and restarted at a different rate if appropriate. If infusion pumps are not available, infusion by gravity can be used.

Patients are educated about the risks and potential adverse drug events before they consent to receive an infusion. Patients are monitored during the infusion and for 1 hour after and are told to report any symptoms promptly to the nurse. Vital signs are taken at 15 and 45 minutes after the start of the infusion. Although the incidence of anaphylactic reactions was low in clinical trials, it is imperative to have rescue medications readily available if needed.

The BCCFH pharmacy created a hypersensitivity kit, which is kept in the infusion area for rapid administration of medications in the event of a hypersensitivity reaction. Each hypersensitivity kit contains an autoinjector with 0.3 mg of epinephrine, prefilled syringes of diphenhydramine injection (50 mg/mL), an injection with 40 mg of methylprednisolone, and an albuterol inhaler (90 μg/actuation). Kits are inspected daily by pharmacy personnel, and medications are restocked if used or expired. Once the hypersensitivity kit is replenished, the BBCFH pharmacist signs a dedicated form to verify that all medications were reviewed and are within their expiration dates and replaces the tamper-evident seal. To assist nursing staff, hypersensitivity kits are labeled with their contents and the earliest expiration date on the outside of the kit.

If an adverse drug event occurs during an infusion, the medical provider determines the type of treatment needed

Figure 1. Process for ordering and compounding monoclonal antibody therapies the day before infusion. BCCFH indicates Baltimore Convention Center Field Hospital; EMR, electronic medical record; UMMC, University of Maryland Medical Center.

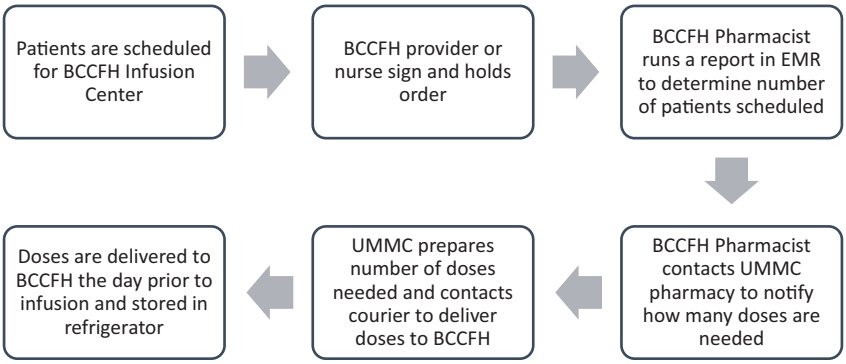

Figure 2. Process for dispensing and administration of monoclonal antibody therapies the day of infusion. BCCFH indicates Baltimore Convention Center Field Hospital; EMR, electronic medical record.

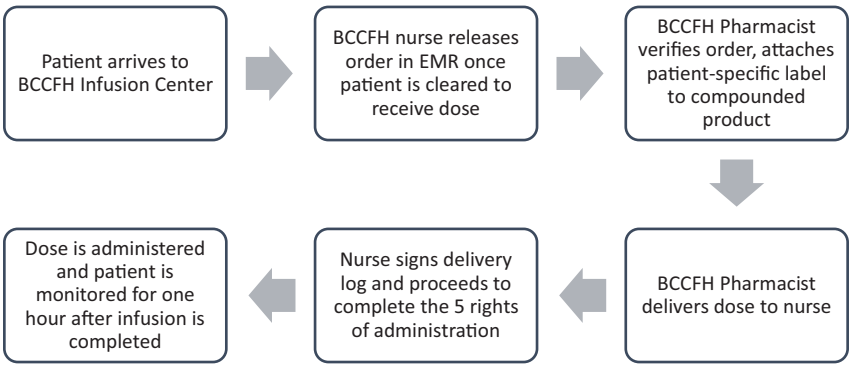

Table 2. Requirements for Implementation of Pharmacy Services at a Field Hospital Infusion Center

Category	Description
Supporting pharmacy with sterile compounding space	For compounding of medications using aseptic technique
Refrigerator and temperature monitoring devices	For storage of the compounded product
Supplies needed for administration	For safe administration of medications; supplies may include IV tubing and filters
Medical devices	IV pump, vital sign monitor, and pulse oximeter
Courier services	For delivery of compounded product to field hospital
Electronic medical record system	For safe order entry and reporting
Staff training, communication, and workflow design	For efficient and safe dispensing of medications
Delivery logs	For accountability for all doses dispensed
Hypersensitivity kits	For quick access to medications needed for hypersensitivity reactions; a process needs to be established to ensure the contents are monitored daily, are up to date, and are replenished as needed

Abbreviation: IV, intravenous.

and if the infusion may be continued. Any remaining monoclonal antibody therapy is returned to the pharmacy for disposal. Per the EUAs, all medication errors and all serious adverse drug events must be reported to FDA within 7 calendar days. All adverse drug events must also be reported to the manufacturer.

Much is unknown about these therapies, as extensive evaluation has not been performed. Considerations related to added compounding complexity, different rates of administration, and scheduling were at the forefront of planning for the safe addition of this therapy at the BCCFH. Because of the nature of the facility and the limited and basic resources available at a field hospital, there is strong reliance on having safe systems in place. A summary of the requirements for implementation of pharmacy services at a field hospital infusion center is provided in Table 2. During these uncertain times, the pharmacy profession continues to contribute through the development of creative workflow solutions to improve medication access. Multidisciplinary coordination and flexibility have been integral to the implementation of the infusion center. As new agents are approved in the fight against COVID-19, we stand ready.

1. Smith P. State taps Johns Hopkins, University of Maryland to open COVID-19 recovery unit at Baltimore Convention Center. *Johns Hopkins Medicine*. Published April 23, 2020. Accessed December 16, 2020. https://www.hopkinsmedicine.org/coronavirus/articles/covid-19-recovery-unit.html
2. University of Maryland Medical System. Baltimore Convention Center: COVID testing and treatment. Accessed December 16, 2020. https://www.umms.org/coronavirus/fighting-covid/expanded-clinical-locations/baltimore-convention-center
3. McCabe D, Gischlar C. Baltimore Convention Center Field Hospital COVID-19 testing site serves as a model in the transition to safe, comfortable winterized sites. *Maryland Department of Health*. Published November 6, 2020. Accessed December 16, 2020. https://health.maryland.gov/newsroom/Pages/Baltimore-Convention-Center-Field-Hospital-COVID-19-testing-site-serves-as-a-model-in-the-transition-to-safe,-comfortable-w.aspx
4. Miller H. Baltimore City Convention Center opens antibody 'infusion center' to treat most at-risk coronavirus patients. *Baltimore Sun*. Published November 25, 2020. Accessed Decem-

ber 16, 2020. https://www.baltimoresun.com/coronavirus/bs-md-baltimore-convention-center-infusion-antibody-20201125-klq4rkrl7je27hrackuahk5gya-story.html
5. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization (EUA) of bamlanivimab. Accessed November 13, 2020. https://www.fda.gov/media/143603/download
6. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization (EUA) of bamlanivimab and etesevimab. Accessed May 14, 2021. http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf
7. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization (EUA) of casirivimab and imdevimab. Accessed November 21, 2020. https://www.fda.gov/media/143892/download
8. Maryland Department of Health. Monoclonal antibody treatments. Published December 1, 2020. Accessed December 16, 2020. https://health.maryland.gov/mdpcp/Documents/Clinician%20Letter_Monoclonal%20Antibody%20Treatments%2012012020%20final%20signed.pdf

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