DESCRIPTIVE REPORT

Strategies used to meet the challenges of mass COVID-19 vaccination by the pharmacy department in a large academic medical center

**Purpose.** Highly effective coronavirus disease 2019 (COVID-19) vaccines have brought hope for ending the pandemic. Unprecedented mass vaccination started first among healthcare workers. The aim of this report is to describe key strategies undertaken by a large hospital pharmacy department to meet the challenges of preparing a large quantity of COVID-19 vaccine doses in a short period of time.

**Summary.** MedStar Washington Hospital Center (MWHC) was in the first group of hospitals in Washington, DC, to receive Pfizer-BioNTech vaccine in December 2020. The pharmacy department faced challenges including stringent vaccine storage requirements, a need for specific equipment and workflow, limited funding, and staffing constraints. The pharmacy department’s senior leaders defined pharmacy responsibilities, budgeted for equipment, participated in vaccination center design, and instructed pharmacy informatics personnel. The vaccine coordinators were appointed to oversee all vaccination-related operations. An ultra–low temperature freezer was installed 2 weeks before arrival of the first shipment of vaccine. All pharmacy order entry tools and operating procedures were standardized, and staff training and schedules were finalized by December 15. The first dose of the vaccine was administered on December 16 at the vaccination center. Pharmacy staff members dispensed the vaccine doses and monitored patients. By January 6, 2021, MWHC had vaccinated 3,812 employees with their first vaccine dose, with an average of 228 doses administered daily.

**Conclusion.** Key strategies such as systemic coordination, early preparation, detailed planning, operating procedure development, and staff education and engagement proved successful in facilitating preparation of thousands of COVID-19 vaccine doses for hospital employees within a short period of time.

**Keywords:** COVID-19, emergent response, pharmacy service, pharmacy operations, vaccine

Since the World Health Organization (WHO) declared a global pandemic in March 2020, coronavirus disease 2019 (COVID-19) has been contracted by millions of people and caused thousands of deaths in the United States and the rest of the world. With few emergently approved drugs available for treatment of severe acute respiratory syndrome virus 2 (SARS-CoV-2) infection, use of safe and effective vaccines is the most effective approach to contain and end the pandemic. One of the first vaccines granted emergency use authorization (EUA) by the US Food and Drug Administration (FDA) is made by Pfizer and BioNTech and was shown to provide 95% protection against COVID-19 in people 16 years old or older in an ongoing multinational, placebo-controlled, observer-blinded trial. Based on Centers for Disease Control
and Prevention (CDC) recommendations, the top priority after granting of the EUA was to vaccinate the highest-risk populations, including healthcare personnel and residents of long-term care facilities.4

MedStar Washington Hospital Center (MWHC) is the largest tertiary academic medical center in Washington, DC. It has over 900 inpatient hospital beds, an emergency room, various ambulatory clinics, and over 7,000 employees. During the first 9 months of the COVID-19 pandemic, MWHC treated up to 200 patients with COVID-19 daily. It was identified by the Washington, DC, department of health (DC-DOH) to not only receive and administer the Pfizer-BioNTech COVID-19 vaccine inside MWHC but also transfer COVID-19 vaccines to 2 nearby hospitals. The aim of this report is to describe how the pharmacy department responded to unprecedented challenges to provide Pfizer-BioNTech vaccine to hospital associates through systemic leadership coordination, protocol development, staff engagement and training, and collaboration with other healthcare professionals.

**Vaccination center development and implementation**

MWHC was among the first groups of hospitals to receive the Pfizer-BioNTech vaccine. Unlike other FDA-approved vaccines, Pfizer-BioNTech vaccine required especially stringent handling conditions. The vaccine stock needed to be kept frozen at no higher than –60°C to maintain its efficacy. Prior to reconstitution the vaccine had to be thawed. Once reconstituted, it was stable for only 6 hours at room temperature. Each vial contained 5 or 6 doses, and individual doses needed to be drawn immediately before administration. Furthermore, the vaccine series required a second dose 21 days after the first administration. As a result, the pharmacy department faced several major challenges:

**Pharmacy leadership and systemic coordination.** MWHC was the largest hospital designated to treat patients with COVID-19 in Washington, DC. Since the start of the COVID-19 pandemic, the pharmacy department had worked closely with both the hospital leadership and the MedStar Health system leadership to dispense several COVID-19 therapeutic treatments, such as remdesivir, bamlanivimab, and casirivimab/imdevimab, and had participated in the development of hospital COVID-19 treatment guidelines. At the same time, the pharmacy department leadership realized the potential for future vaccination efforts since the summer of 2020 and followed the progression of vaccine development and clinical trials closely. When the COVID-19 vaccination task was assigned, the pharmacy leadership team first developed departmental strategies (Figure 1) to be aligned with the federal and state regulations, including those of CDC, FDA, and DC-DOH. The pharmacy department contacted DC-DOH to confirm the type of vaccine and quantities of vaccine the hospital would receive and clarified associated regulatory requirements. Next, the pharmacy department worked with the hospital leadership team, including hospital administrators, providers, and nursing staff, to define responsibilities of the pharmacy department in vaccine preparation and dispensing as well as roles in the planned vaccination center. Based on the defined vaccination needs, the pharmacy department leadership developed plans to rearrange the current workforce, optimize workflow, purchase and install the required equipment, and seek support from internal and pro re nata (PRN) staff. Most importantly, the pharmacy leadership team appointed a primary vaccine coordinator from among the pharmacy managers, along with an alternate, to be in charge of the vaccination-related initiatives. The primary vaccine coordinator and the alternate had the following responsibilities:

- Developing the standard operating procedures (SOPs) related to the vaccines, including emergency preparedness plans and alternative sites for...
The primary vaccine coordinator oversaw timely implementation of all policies and workflow before the vaccine’s arrival. After the vaccination center opened on December 16, 2020, the pharmacy department leadership team had a daily huddle with vaccine coordinators to address issues identified and make immediate adjustments to meet vaccination needs (Figure 2).

**Pharmacy informatics support and order entry tools.** The pharmacy informatics team of MWHC and MedStar Health Corporate provided critical support in executing the mass vaccination plan. Within days after the Pfizer-BioNTech COVID-19 vaccine was approved on December 11, the pharmacy informatics specialists of MWHC worked with other informatics team members across the MedStar Health system to build 3 new tools in the Cerner EMR (MedConnectHealth, Montgomery, AL) computerized provider order entry (CPOE) system used at MWHC: (1) a MedConnect PowerForm with screening questions aligned with CDC guidelines and the manufacturer’s instructions; (2) a Multiphase PowerPlan for Pfizer-BioNTech COVID-19 vaccine, which included all associated medications for treating hypersensitivity reactions; (3) an immunization tracking system to track the vaccine lot number, doses administered, and remaining balance of the vaccine inventory, which was linked to the electronic medication administration record (eMAR). While corporate IT personnel drafted the tools, the MWHC pharmacy informatics team modified them to comply with the policies and best practice of our own hospital. The pharmacy informatics team then validated and tested these new tools in the CPOE system before the vaccination start date of December 16. Once the vaccinations started, the pharmacy informatics team monitored the use of the vaccine and identified and
reconciled any discrepancies among registration and eMAR records and the physical pharmacy inventory. In addition, they distributed updated analytical reports of vaccine usage to hospital and department leaderships and provided required documentation to CDC according to specified guidelines.

**Vaccine storage unit and temperature monitoring.** As previously mentioned, storage of the Pfizer-BioNTech vaccine requires an ultra-low freezer. However, the MWHC main pharmacy did not have an ultra-low freezer prior to the pandemic. In November 2020, once MWHC was informed about the possibility of receiving the Pfizer-BioNTech vaccine, the department leadership obtained approval from the hospital and MedStar Health Corporate to buy a large new pharmaceutical-grade ultra-low freezer. Before the arrival of the large freezer, serial steps of preparation were completed, including generating SOPs for freezer access, temperature monitoring and documentation; reserving designated space to ensure proper ventilation; and installation of a new power outlet connected to an uninterrupted power supply by the engineering department. The new freezer arrived in late November and was immediately installed and calibrated. A digital data logger, a device for continuous temperature monitoring, was also installed onsite. To ensure safety, the freezer was locked, with key access available only to designated pharmacists. In addition, a smaller ultra-low freezer in the MWHC cancer institute was calibrated as the backup unit. This collaborative approach put MWHC in the position of receiving and storing the Pfizer-BioNTech vaccine and contributed to the successful opening of the vaccination center on December 16, 2020.

**Staff training.** Since COVID-19 vaccine preparation and dispensing was a new and elaborate process, it was necessary to train the pharmacy staff. The MWHC pharmacy department required all staff to review vaccine storage and handling training materials from FDA, CDC, and the Pfizer-BioNTech resource website, as well as MWHC site-specific COVID-19 vaccination SOPs, before the first shipment of Pfizer-BioNTech COVID-19 vaccine arrived.45 Site-specific instructions developed by the primary pharmacy coordinator included vaccine shipment receipt and temperature monitoring. The education included a mixed variety of online modules and videos, written procedures/protocols, and hands-on training at the vaccine center. After the vaccination center was open, at least one pharmacist experienced with the vaccination process was scheduled for each shift to ensure appropriate continuity and training of the other associates.

**Vaccine receiving, storage and preparation.** The vaccine was delivered to the MWHC central pharmacy, where the ultra-low freezer was located, on December 15, 2020. Upon delivery, the vaccine was promptly transferred into the ultra-low freezer according to the manufacturer guidelines. A freezer logbook was kept to document current inventory, access times, temperatures, and employee access. Only trained, designated pharmacists handled freezer operations. A storage container was placed next...
to the freezer and equipped with safe-handling tools such as gloves, a box cutter, and directions for use. The department purchased proper gloves to ensure safety. An important strategy to maximize efficiency and minimize the frequency of accessing the freezer was to estimate the number of vaccine vials needed daily and retrieve all those vials at one time. Based on beyond-use date (BUD) recommendations for the Pfizer-BioNTech vaccine (ie, 120 hours with refrigeration), MWHC pharmacy personnel analyzed the vaccination center schedule and pulled a 1-day supply of vials from the freezer and placed them into the locked and monitored 4°C refrigerator. These vaccine vials were clearly labeled in a bag with an updated BUD. A refrigerator logbook was used to track the perpetual inventory, which was later compared against doses administered in the vaccination center to ensure its accuracy.

One and a half hours before the vaccination center opened, pharmacy staff started vaccine preparation. Pharmacists reviewed the vaccination center patient schedule and estimated how many vials would be needed for the first round of vaccinations in the morning. The pharmacist took out the appropriate number of vials from the 4°C refrigerator and allowed the vials to thaw at room temperature. Then the pharmacist or pharmacy technician reconstituted the vials per Pfizer-BioNTech instructions and in accordance with United States Pharmacopeia chapter 797 (USP <797>) requirements. After reconstitution, a pharmacist labeled the vials and finished appropriate documentation in the logbook. The pharmacy staff, which included 1 or 2 pharmacists, delivered the reconstituted vaccine vials in a designated concealed transport bag to the vaccination center 15 minutes before the center opened. Throughout the day, a pharmacist closely monitored the vaccine supply against the vaccine schedule and then notified the pharmacy to begin preparation of the next batch approximately 1 hour before the supply would run out (Figure 3).

**Vaccine administration and monitoring.** The vaccination center was converted from a conference room to accommodate 5 patients simultaneously, with the capacity to provide 250 to 300 daily vaccine administrations. Three pharmacy staff, including at least 2 pharmacists, teamed up with 1 hospital administrator, 2 registration staff, and 5 vaccinators (registered nurse and physician volunteers) to ensure safe and efficient administration of the vaccine. Associates scheduled appointments in advance. Upon their arrival, associates were registered and waited in a socially distanced line until being called to one of 5 vaccination bays. Vaccinators, who were credentialed healthcare workers, determined if an associate—now considered a patient of the vaccination center—met the vaccination criteria based on their answers to preprogrammed screening questions, such as questions about body temperature and COVID-19-associated symptoms. Vaccinators also reviewed patients' vaccination process, as well as possible adverse effects, and answered any questions. After vaccination, patients were monitored for any immediate adverse events for 15 minutes (30 minutes for patients with a history of any allergy) and given the vaccination information sheet and CDC vaccination card. Finally, patients checked out at any available vaccination bay, and the registration staff scheduled them for their next appointment. Associates were reminded to self-monitor for common and serious adverse effects and instructed to report to occupational health personnel or the emergency room according to the severity of signs and symptoms.

Pharmacy staff were the only team members that prepared the vaccine doses. One pharmacy staff member was responsible for drawing up a dose into a syringe with aseptic technique at the designated pharmacy station; a second pharmacy staff member was responsible for double-checking the volume, labeling each syringe, and delivering

![Figure 3. COVID-19 vaccine preparation and delivery workflow at MedStar Washington Hospital Center. IV indicates intravenous; RPh, pharmacist.](https://academic.oup.com/ajhp/article/78/18/1724/6250087)
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Each dose to each vaccination bay; and a third pharmacy staff member was responsible for verifying the orders, tracking each dose, reconciling records with registration information, and anticipating when the next batch of doses would need to be thawed. An antimicrobial stewardship/infectious diseases pharmacist served as the primary vaccination center point person and facilitated training of the other pharmacy associates. Other pharmacy staff served rotations in the vaccination center on a voluntary basis.

Pharmacists in the vaccination center worked with vaccinators to manage adverse effects. Pharmacy staff kept a hypersensitivity kit with all required emergent medications and monitored patients after the vaccine was administered. If an associate developed any adverse events, a pharmacist was ready to respond and prepare urgent medications until the rapid response team arrived.

The pharmacy team conducted daily huddles. During the huddles, discussions included pharmacy operational times, pharmacy staffing and training, vaccination center workflow for scheduled associate appointments versus associate walk-ins, syringe and needle supplies, vial par level for the refrigerator, reconstituted vial par level for the vaccination center, and vaccine dose tracking. Adjustments were continually made on the basis of feedback including number and timing of doses needed throughout the day and ways to optimize pharmacy efficiency and workflow.

**Early vaccination results**

The MWHC vaccination center opened at 7 AM on December 16, 2020, and was operational 14 hours a day, 7 days a week. By January 6, 2021, MWHC had vaccinated 3,812 associates with their first dose of COVID-19 vaccine. The MWHC pharmacy department prepared 98 batches comprising the total of 3,812 doses of vaccine, with an average of 228 doses administered daily. Only 1 dose of prepared vaccine was wasted. The pharmacy department scheduled 36 volunteers for a total of 2,016 hours to fulfill the vaccination center’s staffing needs. By the end of February 2021, 4,600 employees who voluntarily registered for vaccination had received at least 1 dose and approximately 4,000 employees had received both prescribed doses. There were no serious immediate adverse events in the clinic, with just 1 moderate adverse reaction event reported to occupational health personnel post vaccination.

**Discussion**

Highly effective COVID-19 vaccines have brought hope for ending the pandemic that is rampaging in the United States and around the world. However, mass immunization with COVID-19 vaccine has brought unprecedented challenges to hospital pharmacies, including stringent vaccine storage requirements, a need for specific equipment and workflow, insufficient funding, and staffing challenges. Lessons had to be continually learned in order to overcome these hurdles and successfully roll out an early-phase vaccination plan in a short period of time.

A strong pharmacy management team was critical for the success of this mission. The team fully understood the task, evaluated available resources and potential barriers, developed clear timelines of important milestones, and then divided responsibilities among team members. Senior leadership members were responsible for communicating with hospital and department leaders to obtain financial support, arrange equipment installation, and clarify pharmacy staff responsibilities within the institution. Managers in each division motivated pharmacy staff and adjusted clinical and operational workflow to provide staff support. Most importantly, the primary vaccine coordinator was appointed to take charge of implementing policies, SOPs, workflow, operations, staff education, and other activities directly associated with the vaccination effort.

Early preparation was key to ensure the success of the vaccination plan. MWHC was able to start vaccination of the associates only 2 business days after FDA approval of the EUA. The department leaders followed vaccine development closely and anticipated the needs as early as the start of phase 3 clinical trials in July 2020. Shortly after receiving notice in November from DC-DOH about the possibility of receiving the Pfizer-BioNTech vaccine, the primary vaccine coordinator was appointed and SOP development and purchasing of a ultra-low freezer were initiated. The ultra-low freezer was installed 2 weeks before the vaccine’s arrival. After FDA approved the EUA for the Pfizer-BioNTech vaccine on December 11, 2020, all CPOE system changes and vaccination SOPs were finalized by December 14, 2020. On December 15, 2020, the staff schedule and initial training were completed. All of these proactive approaches well positioned MWHC to start vaccination on December 16, two business days after FDA’s EUA approval.

Detailed planning was needed to maximize the use of each vaccine vial when COVID-19 vaccine supply was limited. The Pfizer-BioNTech vaccine was available as multidose vials, with each containing enough vaccine for an initially recommended 5 doses per vial. The reconstituted vaccine was stable for only 6 hours. Preparing more doses than what would be needed in 6 hours could lead to waste, but preparation of an insufficient number of doses would require frequent access to the ultra-low freezer and cause a delay in vaccine administration. MWHC initially prepared vaccine batches based on the 5-dose-per-vial recommendation and the projected number of patients scheduled for vaccination before the assigned vaccine expiration time. Later, after updated guidance from FDA and Pfizer and BioNTech, MWHC was able to consistently draw 6 doses per vial, which allowed for additional vaccinations. During the day, the lead clinical pharmacist in the vaccination center monitored vaccine usage and the patient schedule. The lead clinical pharmacist notified
the central pharmacy approximately 1 hour before running out of doses so that the next batch of vaccines could be made on time. Before the last vaccine batch was made at the end of the day, the lead pharmacist worked with the registration and administration staff to get a final count of doses needed. The registration staff contacted the scheduled associates to confirm their appointments. If there were more doses than scheduled associates, the registration staff contacted associates on the waiting list. Additionally, the administration staff called various units throughout the hospital and identified available associates still in need of the vaccine. With this approach, the pharmacy department was able to prepare over 3,800 vaccine doses, with only 1 wasted dose in the first 3 weeks.

The pharmacy department played an important role in the mass COVID-19 vaccination plan. Instead of simply storing and dispensing vaccine vials, the MWHC pharmacy department extended the service to include drawing up each vaccine dose at a designated station. This strategy allowed tight control of dose inventory, which resulted in minimal waste, while also allowing the vaccinators to efficiently administer the vaccine. Based on this model, MWHC scheduled 1 clinical pharmacist as a leader, with 2 additional pharmacy staff scheduled to work in the vaccination center. There were several advantages to use of pharmacy personnel to prepare the vaccine doses. First, the vaccine could be reconstituted centrally in a USP <797>–compliant sterile environment via aseptic technique to minimize the risk of contamination. Second, pharmacy staff were able to track total doses of vaccine made and document required information according to CDC regulations. Third, a pharmacist could counsel patients, be available to respond to the possible hypersensitivity reactions, or answer questions from other staff. Finally, coordination between pharmacy staff at the vaccination center and the central pharmacy maximized the use of each Pfizer-BioNTech vaccine vial with minimal waste. (For institutions where vaccinators are needed, immunization-certified pharmacy staff could also administer the vaccine, a practice endorsed by recently issued ASHP guidelines.) There was a sufficient number of vaccinators, who were enlisted from other healthcare disciplines, but MWHC immunization-certified pharmacists were ready to extend services to help more associates if needed.

As there was high demand with limited initial vaccine allocation, it was necessary to prioritize vaccination based on an associate’s level of risk for contracting COVID-19. High-risk associates included those working in areas such as the emergency department, air transportation, designated COVID-19 units, critical care units, labor and delivery, anesthesiology, and rapid response teams, and they were offered vaccine appointments first. The next highest-risk group of people were those with any direct patient contact. Once those associates were offered vaccination, it was offered to any associate, including hospital administrators and department leaders. In addition, the hospital and the pharmacy department sent out vaccine information and answers to common questions to all employees, strongly encouraging but not mandating that associates register for vaccination. From December 16, 2020, to January 6, 2021, MWHC vaccinated approximately 50% of associates with their first dose. While administration of second doses began after that, staff continued to register for the first dose of the vaccine. MWHC’s associate vaccination rate was over 60% at the end of February 2021, lower than the goal of 70% to 85% but similar to reported rates at other institutions nationwide. At the time of writing, future directions included utilizing PRN staff, pharmacy residents, and pharmacy students.

At the time of writing, future directions included planned efforts to improve vaccination rates in associates. It is important to continue to share facts about COVID-19 vaccines through various ways and promote the benefits of vaccination to individuals, families, communities, and society at large. It is equally important to encourage associates to voice their concerns or questions about the vaccine and then provide individualized support. Future directions also included expanding vaccination services to members of the local community. MWHC began vaccinating individuals in the community starting at the end of January 2021.

**Conclusion**

The urgent need for mass administration of Pfizer-BioNTech COVID-19 vaccine brought many unprecedented challenges to hospital pharmacies due to the vaccine’s storage and preparation characteristics and limited time and resources for vaccination efforts. However, pharmacy departments could use the key strategies described here—formation of a strong leadership team, systemic coordination, SOP development, staff training and engagement, and multidisciplinary teamwork—to facilitate completion of vaccination tasks. Continuous monitoring for changes during mass immunization efforts and seeking innovative solutions are essential to maintain successful vaccination initiatives.

**Disclosures**

The authors have declared no potential conflicts of interest.
References
1. US Centers for Disease Control and Prevention. COVID-19. Accessed January 14, 2021. https://www.cdc.gov/coronavirus/2019-ncov/index.html
2. World Health Organization. Coronavirus disease (COVID-19) pandemic. Accessed January 14, 2021. https://www.who.int/emergencies/diseases/novel-coronavirus-2019
3. Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020;383:2603-2615.
4. Dooling K, Marin M, Wallace M, et al. The Advisory Committee on Immunization Practices’ updated interim recommendation for allocation of COVID-19 vaccine — United States, December 2020. MMWR Morb Mortal Wkly Rep. 2021;69:1657-1660.
5. Pfizer Inc. Pfizer-BioNTech COVID-19 vaccine. Accessed January 14, 2021. https://www.cvdvaccine-us.com/product-storage-and-dry-ice
6. American Society of Health-System Pharmacists. ASHP principles for COVID-19 vaccine distribution, allocation, and mass immunization. Am J Health-Syst Pharm. 2020;77(24):2112-2113.