

Implementation of a pharmacist-led COVID-19 vaccination clinic at a community teaching hospital

Prior to the emergency use authorization (EUA) for the first vaccines for the prevention of coronavirus disease 2019 (COVID-19) and in accordance with recommendations from the Advisory Committee on Immunization Practices (ACIP), local and state departments of health (DOHs) prepared a phased approach to vaccine distribution, with initial allocation in phase 1a to the highest-risk personnel, such as emergency room workers, critical care staff, and employees who provide direct, in-person patient care in healthcare settings on a daily basis.¹ A few days after the Pfizer/BioNTech COVID-19 vaccine was authorized under an EUA by the Food and Drug Administration (FDA) on December 11, 2020, the first doses of the vaccine were administered to New York City (NYC) healthcare personnel on December 14, 2020.²

Distribution of the Pfizer/BioNTech COVID-19 vaccine in phase 1a posed several operational challenges, including required storage at ultralow temperatures, the vaccine's short shelf life upon dilution, and its administration as a 2-dose series.³ To facilitate the local and state DOH COVID-19 vaccination program and address these particular challenges, The Brooklyn Hospital Center (TBHC) implemented a pharmacist-led COVID-19 vaccine immunization clinic based on an established point-of-distribution model for emergency preparedness at the institution.⁴

Practice setting. TBHC is a community teaching hospital with several off-site clinic and urgent care locations throughout Brooklyn, NY. Included among the approximately 2,700 employees are trainees from the hospital's robust graduate medical and pharmacy residency programs. The department of pharmacy is closely affiliated with Long Island University's Arnold & Marie Schwartz College of Pharmacy and Health Sciences. Within the hospital, pharmacotherapy specialists are credentialed as part of the professional staff, working under hospital-wide collaborative drug therapy management agreements. The department of pharmacy is comprised of approximately 60 employees, including a senior director of pharmacotherapy, a director of pharmacy operations, 3 pharmacy managers, 16 staff pharmacists, 5 ambulatory care pharmacotherapy specialists, 7 acute care pharmacotherapy specialists, 1 infectious diseases fellow, 5 postgraduate year 1 residents, and 6 postgraduate

year 2 residents among ambulatory care, emergency medicine, and infectious diseases specialties.

Preplanning. Previous to the COVID-19 pandemic, the pharmacy department had an established role in promotion of seasonal influenza vaccines and shared responsibility for vaccine administration to hospital employees with the office of employee health. Seasonal influenza vaccines were administered to hospital employees by pharmacists in several locations, including an on-site outpatient pharmacy and a satellite pharmacy within the emergency department.

The pharmacy department was identified as best equipped to lead the institution's vaccination campaign (with full support from all departments of TBHC) given its integral role in all aspects of the immunization process—from vaccine receipt and storage to preparation, administration, and monitoring—and ongoing involvement with seasonal influenza vaccine administration. For the COVID-19 vaccine campaign, pharmacy leaders were briefed by local and state DOH representatives via Web conferencing in the weeks prior to initial vaccine distribution. Presentation materials provided by the Centers for Disease Control and Prevention (CDC) were disseminated to pharmacy staff and included important information on the Pfizer/BioNTech COVID-19 vaccine, such as contraindications and precautions, considerations for special populations, counseling points, dosing guidance, and administration instructions.⁵ Resources also included links to helpful communication resources and FDA briefing documents for EUA.³ Additionally, pharmacy staff were educated on vaccine reconstitution and dose preparation through in-person instruction from an assigned team leader prior to each shift.

Pharmacy staff prepared a monograph for the Pfizer/BioNTech COVID-19 vaccine evaluating available safety and efficacy data and recommending its addition to the TBHC formulary with no restrictions, in alignment with ACIP recommendations.⁶ The monograph proceeded through full approval by the pharmacy and therapeutics committee and executive medical board through electronic means and was completed within 4 days rather than a typical 4-week time frame. While expedited, the process maintained the rigor of a typical review and led to the addition of the Pfizer/BioNTech COVID-19 vaccine to the TBHC formulary on December 14, 2020.

Significant planning was done to mitigate potential safety concerns with distribution of a new vaccine. Acetaminophen was repackaged to offer to clinic patrons at no cost to alleviate mild adverse reactions. Additional supplies, equipment, and medications (eg, epinephrine) for managing serious, life-threatening reactions were obtained for staging in the

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clinic area in accordance with CDC recommendations.⁷ To augment reporting resources provided through the CDC-sponsored v-safe program, an adverse events telephone hotline was created to facilitate reporting of potential adverse reactions. This hotline was managed by pharmacy students on their advanced pharmacy practice experience (APPE) rotations under preceptor supervision. Any serious adverse effects reported through the hotline were then reported to the federal Vaccine Adverse Event Report System. A survey was also designed to capture additional safety data at the point of the second dose administration.

As TBHC does not have a freezer capable of cooling to -80°C , a location for long-term storage of the vaccine was quickly identified in the preplanning phase. The pharmacotherapy department at TBHC secured a storage space with remote temperature monitoring at a neighboring academic institution. Frozen vials of the Pfizer/BioNTech COVID-19 vaccine were transported to TBHC via an insulated container on ice as needed for thawing prior to clinic sessions, with no subsequent issues.

Clinic promotion and communication. Identification of and communication to eligible hospital employees began prior to delivery of the vaccine. Reviewing data provided by the human resources department, employees were stratified based on potential for exposure in accordance with ACIP recommendations. Employees at highest risk were given priority to receive initial doses of vaccine in phase 1a.⁶ Employees considered at highest risk included those working directly with patients with probable or confirmed COVID-19, including medical residents and physicians, nursing staff, pharmacotherapy specialists, and pharmacy residents and fellows, as well as nonclinical staffers who were considered at high risk (security and environmental services personnel, transporters, etc). On-site health professions students, including pharmacy students on their APPE rotations, were also considered to have priority and vaccinated based on guidance from the DOH.

In coordination with the marketing department, a campaign was launched to inform and educate hospital staff on the vaccine and encourage vaccination. This campaign addressed the barrier of employee apprehension towards the vaccine and included daily email messages, preparation of a document with answers to frequently asked questions about the Pfizer/BioNTech COVID-19 vaccine, and instructions for signing up to be vaccinated. A free online scheduling tool, SignUpGenius (SignUpGenius, Inc, Charlotte, NC), was utilized to estimate the volume of interested employees; an access link was emailed to hospital staff several days prior to delivery of vaccines. Using the tool, staff were able to select the date and time to receive the first dose of vaccine, with a maximum of 10 employees scheduled for each 15-minute time slot. While the clinic was initially expected to open on December 16, 2020, the first shipment of Pfizer/BioNTech COVID-19

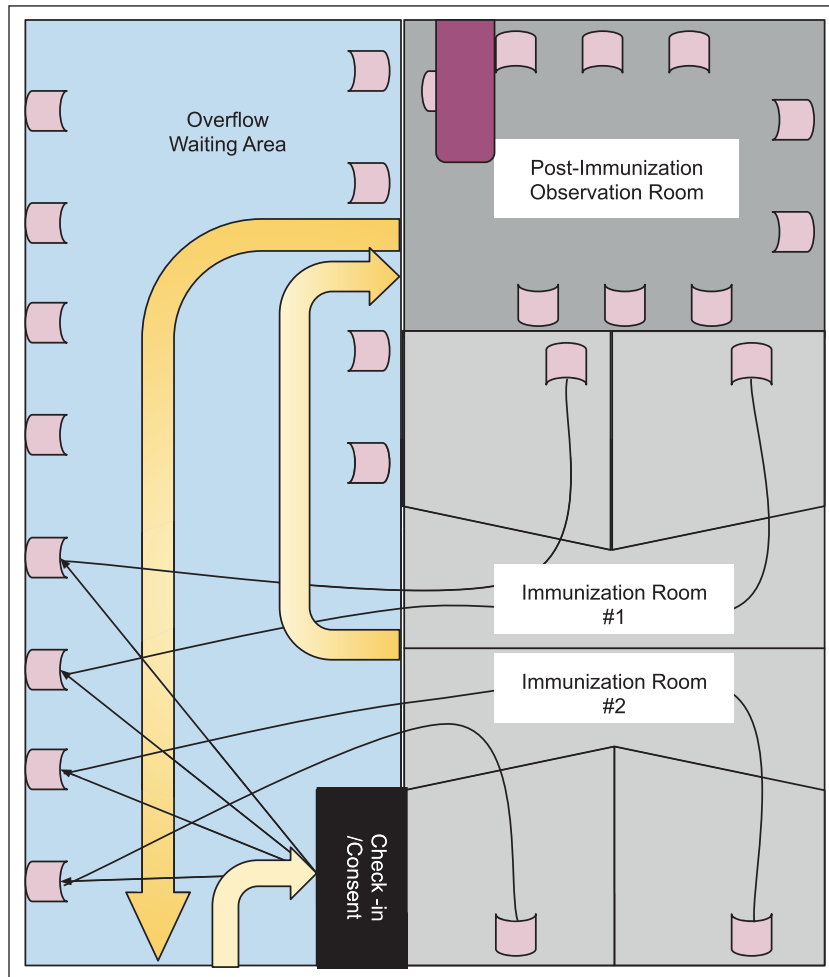
vaccine arrived a day early, allowing pharmacy staff to begin immunization on December 15, 2020. A cross-platform encrypted messaging service and email were used to inform the emergency department, critical care, and internal medicine staffs that the vaccine was available. This method allowed for rapid notification of employees in the highest-risk group and led to administration of over 100 doses within hours of receipt of the vaccine. Promotional efforts continued after the initial vaccine delivery and included signage placed throughout clinical areas, announcements issued on the hospital intranet, and daily emails to address concerns and encourage participation.

The online scheduling tool was set up to enable registration for a second dose of vaccine and made available to each employee upon receipt of the first dose. Employees were able to select a date and time for a second appointment 17 to 21 days later, in accordance with CDC recommendations.⁵ The tool was designed to send an appointment confirmation and reminder via email to optimize adherence.

Clinic location and layout. The specified location for the clinic included 3 separate rooms on an upper floor of the hospital that was formerly used as a patient care unit and converted into administrative offices. Rooms contained sinks for handwashing and patient privacy curtains. Additionally, the unit supplied chairs, work surfaces, computers, a refrigerator for storage of thawed vaccine vials, sharps containers, a cardiac resuscitation cart, a vital signs monitor, and personal protective equipment for clinic staff. The clinic served employees at this location by appointment daily, Monday through Friday from 6:15 to 9:00 AM and from 5:00 to 9:00 PM. These hours were selected to coincide with change of shift to prevent clinical staff from having to leave work areas while on duty. This approach also allowed employees to return home after vaccination, since adverse effects would have impeded their ability to work. Due to projected demand, a second immunization location was identified and implemented at the outpatient pharmacy located within the hospital for appointments daily, Monday through Saturday from 10 AM to 3 PM.

A check-in station was set up in an adjacent hallway for employees to sign in upon arrival for their scheduled appointment. Chairs were set up 6 feet apart to form a waiting area, where employees were instructed to complete an immunization screening and consent form provided by the DOH. Separate rooms for 4 vaccine administration stations, as well as an observation area for the required monitoring period after vaccine administration, were designated. In the observation area, employees were provided with a COVID-19 vaccination record card. They were also instructed to schedule their second appointment using the online scheduling tool installed on mobile tablets provided by the information and technology department or to access the tool by using their personal mobile devices to scan quick response (QR) codes posted around the room (Figure 1).

Figure 1. Vaccination clinic layout, with patient flow indicated by yellow arrows.



Clinic staffing and workflow. An initial staffing plan was developed to ensure that adequate staff (eg, at least 2 certified immunizers and 1–3 additional staff members) were present during all time slots for both clinical and administrative roles. Clinical roles included patient screening, dose preparation, vaccine administration and documentation, and patient monitoring. Administrative roles included data entry and facilitation of patient flow through various clinic stations. During the clinic implementation period, pharmacotherapy specialists and pharmacy residents staffed the clinic before and/or after work hours to ensure they maintained regular duty hours for pharmacotherapy services. Pharmacy students on APPE rotations were incorporated into both clinical and administrative roles to support pharmacotherapy services staff. All pharmacists and APPE students who were already certified immunizers or had completed the American Pharmacists Association’s immunization course and the training provided by CDC administered the vaccine. No additional pharmacists became certified for the purposes of staffing the clinic. However, extensive local

advocacy efforts had led to the release of an executive order (on December 14, 2020) that permitted pharmacists and interns, including those not certified to immunize in the state of New York, to administer vaccinations authorized for prevention of COVID-19.⁸ Medical students also volunteered in the clinic and were incorporated for administrative roles when available. At the end of each day, demographic data and vaccine administration information for all individuals who received a vaccine dose were compiled in an encrypted electronic spreadsheet to ensure health information privacy and submitted to the DOH. This data directly impacted the quantity of additional doses allocated to TBHC each week and supported the planned distribution of an adequate supply for all immunized individuals to receive a second dose as scheduled.

As the demand for the vaccine increased throughout the first 2 weeks of administration, workflow and role delineation were adjusted to improve efficiency. To reduce clinic wait times and support higher volumes, an additional immunizer was scheduled for each session, and staff reported

an hour earlier during weekday shifts. To prevent waste, a designated individual was assigned to each session to draw up doses in syringes according to observed need. After 1 week of active operations at the clinic, the following roles were designated for each session: 3 immunizers; 1 individual with a flexible role in both vaccine preparation and immunization, as needed; 1 individual responsible for data entry and safety monitoring; and 1 individual responsible for traffic flow. Given the novelty of this clinic, implementation and evaluation was a dynamic process, and frequent improvements were made to workflow and staffing components.

Discussion. The pharmacist-led COVID-19 vaccine immunization clinic optimized an initial allotment of 975 doses of Pfizer/BioNTech COVID-19 vaccine and, in less than 10 days, administered all available doses in the original vaccine shipment to the highest-risk employees (eg, emergency room workers, critical care staff, and employees who provide direct in-person patient care in healthcare settings on a daily basis) in phase 1a of the COVID-19 vaccination program.

Key components of planning and implementation that ensured success were a proactive employee communication campaign, a user-friendly online scheduling tool, immunization clinic hours built around clinical staffing shifts, and incorporation of APPE students into the staffing model. Both clinical and administrative roles were noteworthy experiences for APPE students, who were recruited on a volunteer basis from the pool of on-site rotational students and volunteered for multiple shifts with enthusiasm. The executive order issued by the New York State governor was critical to enabling a pharmacy-led clinic at this practice site, highlighting the importance of continued advocacy efforts to raise awareness of pharmacist scope of practice.

The timely coordination of dose preparation and administration was an anticipated challenge given the 6-hour shelf life of diluted vaccine at room temperature. In the first week of implementation, clinic staff encountered multiple instances in which reconstitution of a new vial of vaccine was required for vaccination of the last individual with a scheduled appointment during a session. To prevent this, hospital-wide announcements were made over the intercom in the last hour of each clinic session to promote additional employee visits to the clinic on a first-come, first-served basis. Additionally, clinic sessions remained open for longer than intended during the first week of implementation to ensure that no doses were wasted at the close of any clinic session.

While used successfully for employee vaccination efforts, the clinic location is not optimal for public vaccination, as its use for that purpose would require individuals to navigate through patient care areas within the hospital. As such, additional clinic models were developed for vaccine distribution to the outpatient population, with consideration given to patient access as well as integration of a registration process within the electronic health record.

Closing notes. In the first 2 weeks of a pharmacist-led COVID-19 vaccine immunization clinic, 100% of the 975 doses allotted to TBHC for distribution in phase 1a of the national vaccination initiative were administered to the highest-risk employees. This vaccination rate far outpaced initially reported administration rates of 42% for vaccine doses provided in New York City and 19% of vaccine doses administered nationally.⁹ The success at TBHC supports a pharmacist-led model for vaccine distribution to optimize efforts and mitigate the spread of COVID-19 across the United States by the implementation of the national COVID-19 vaccination program.

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Disclosures: The authors have declared no potential conflicts of interest.

Acknowledgments: We are grateful to the senior leadership of TBHC for their support of the pharmacist-led COVID-19 vaccine immunization clinic. We also thank the TBHC pharmacy department and pharmacy students of Arnold & Marie Schwartz College of Pharmacy and Health Sciences for their hard work and participation in the COVID-19 vaccine immunization clinic.

Keywords: COVID-19, immunization, public health, vaccines

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DOI 10.1093/ajhp/zxab135