J Ambulatory Care Manage
Vol. 45, No. 2, pp. 85–94

COVID-19 Patient Vaccine Program Design and Implementation

An Academic Children's Hospital's Model, Approach, and Outcomes

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Abstract: To slow the spread of the 2019 novel coronavirus disease (COVID-19) and reduce the associated morbidity and mortality, the Children's National Hospital developed a multidisciplinary, collaborative vaccine program aimed at equitably and expeditiously vaccinating the pediatric population of the surrounding community. Interdepartmental collaboration, professional expertise, and community partnerships allowed for a dynamic and successful program design that began as large volume–centralized vaccine clinics and expanded to smaller volume ambulatory clinics. This strategy proved successful at meeting local vaccine demand; however, strategies to improve vaccine uptake in communities with high rates of hesitancy are still needed to maximize vaccine equity. **Key words:** *ambulatory care, COVID-19, delivery of health care, health equity, pediatric hospitals, vaccines*

In JANUARY 2020, the SARS-CoV-2 virus was first identified in patients in the United States. Within weeks, the country was inundated with cases of the novel coronavirus (COVID-19) infection and a worldwide pandemic was declared. Governments and communities implemented social distancing and mask guidelines as hospitals and pharmaceutical companies worked tirelessly to deliver novel treatments to those infected.

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The authors acknowledge David Wessel, MD; Eric Balmir, BS, MS, PharmD, CIM; Jessica Herstek, MD; Melanie Anspacher, MD; Margaret Rush, MD; Marc DiFazio, MD; COVID-19 Vaccine Task Force: Jacqueline Forbes, MHA, HACP; John Schultz, MS; Carole Helmandollar, Susan Muma, Sean S. Q. Tan, PharmD; Matthew Berg; Mary Daymont, MSN, RN; and Margie Farrar-Simpson, MSN, RN, PNP-BC, NE-BC, CCM.

The authors have disclosed that they have no significant relationships with, or financial interest in, any commercial companies pertaining to this article.

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DOI: 10.1097/JAC.0000000000000406

Millions were infected and hundreds of thousands were dying, with an excessive burden on communities of color (Goyal et al., 2020). Public health experts agreed that an effective, safe vaccine was needed to end the pandemic and minimize illness and loss.

In December 2020, the US Food and Drug Administration (FDA) granted Emergency Use Authorization for the first COVID-19 vaccine for individuals 16 years of age and older. In response to initial overwhelming demand and varying risk profiles of infection, the Centers for Disease Control and Prevention (CDC) provided recommendations on vaccine prioritization. As a result, vaccines became available in Washington, District of Columbia (DC), on March 1, 2021, for those 16 years and older with serious health problems (Zauzmer Weil, 2021). These guidelines were for all available COVID-19 vaccines (Brice-Sadler & Portnoy, 2021), though the Pfizer-BioNTech COVID-19 vaccine was the only vaccine approved for adolescents 16 and 17 years of age (Centers for Disease Control and Prevention, 2021b). On May 13, 2021, days after the FDA had granted Emergency Use Authorization to Pfizer-BioNTech and the CDC's Advisory Committee on Immunization Practices recommended COVID-19 vaccine for adolescents 12 to 15 years of age, District of Columbia began vaccinating children as young as 12 years of age (Executive Office of the Mayor, 2021a).

Throughout the COVID-19 pandemic, the Children's National Hospital (CNH) leadership has worked closely with local health departments, DC Public Schools, DC Board of Trade, and the DC Hospital Association to orchestrate a regional response, aimed at vaccinating the community at large, not solely patients of the health system. The Children's National Hospital is metropolitan Washington, District of Columbia's only integrated nonprofit pediatric health care system. It includes a 323-bed hospital with nearly 16 000 admissions, 18 000 surgical procedures, 684 000 outpatient visits, and more than 240 000 unique patients each year. The Children's National Hospital provides primary care, emergent care, and specialty care to children and adolescents, serving as the medical safety net for many children of the region.

OBJECTIVE

The purpose of this article is to describe the Children's National Hospital's multidisciplinary, community-focused strategy to efficiently and expeditiously vaccinate the pediatric community with the COVID-19 vaccine.

METHODS

The vaccination model was developed with expertise of numerous disciplines and focused on efficient, equitable distribution of COVID-19 vaccine to children and their family members. Strategy for vaccine administration was developed in the context of government restrictions on eligible individuals and vaccine distribution.

Preparation

In January 2021, following the authorization of COVID-19 vaccination in the United States, the hospital began preparing for vaccination efforts. Models on vaccine ordering, vaccine administration, staffing, and space planning were developed. Procedures were put in place for ordering, documenting, billing, and reporting through our electronic health records (EHRs). An electronic data dashboard was created for tracking vaccine administration for internal use and external reporting.

On January 15, 2021, the first vaccines were provided to a subgroup of patients 18 years of age and older, who are adults, followed by pediatric specialists, given their expertise in the care of these patients (ie, adult congenital heart disease). Lessons from this pilot were used to plan for the surge of volume anticipated with approval of the vaccines for younger populations.

Centralized high-demand model

On March 1, 2021, Washington, District of Columbia, first made COVID-19 vaccines

Table 1. Children's National Hospital's COVID-19 Prioritization Schema

Tier 1+	Combination of 2 or more tiered conditions.
Tier 1	Sickle cell disease, type II diabetes mellitus (DM), neurodevelopmental disorders (ie, severe seizure, neuromuscular disorders), severe metabolic disorders, obesity (BMI >95th percentile for age)
Tier 2	Chronic kidney disease on dialysis, type I DM, cancer/bone marrow failure, solid organ and bone marrow transplant recipients, severe immunodeficiency, congenital or acquired heart disease, tracheostomy and ventilator dependence, trisomy 13, trisomy 18, trisomy 21, chronic liver disease/gastrointestinal disorders, systemic lupus erythematosus
Tier 3	Chronic pulmonary conditions (ie, cystic fibrosis, underlying lung disorders, severe persistent asthma), chronic immunosuppression, chronic kidney disease, additional chronic disorders (genetic, neurologic, rheumatologic, hematologic), schizophrenia, HIV infection
Tier 4	Moderate persistent asthma, obstructive sleep apnea, other neurodevelopmental disorders (including autism, Rett's syndrome), overweight (BMI: 85-94 percentile)

Abbreviation: BMI, body mass index.

available to children, allowing the vaccination of individuals 16 years and older with serious health conditions. To meet the high demand for vaccine in young adult patients, the CNH developed a mass vaccination program to administer the Pfizer-BioNTech vaccines at 4 distinct locations spread throughout our service area. Locations were chosen on the basis of the ability to accommodate large volumes of patients and reach communities most vulnerable to the disease (Executive Office of the Mayor, 2021b). Mass vaccination model was chosen over ambulatory clinic model to meet high demand and to best meet the restrictions of the vaccine supply, which initially required only vaccinating patients who were residents of the supplying jurisdiction. These centralized locations vaccinated patients and eligible family members for both dose 1 and dose 2 of the vaccine series, or solely dose 2 in individuals who were unable to complete their vaccine with the original supplier. Staffing included volunteer clinicians and administrative employees of our health system; individuals who are paid hourly were compensated for their time. These clinics increased time and availability as children aged 12 to 15 years became eligible for the vaccine and demand surged; subsequently, the clinics decreased frequency and availability during times of low demand. Clinics ranged from operating 6 days per week, reaching hundreds of patients daily during peak demand, to operating once or twice weekly with unused availability during low demand times. Appointments were available as scheduled or walk-in. These clinics functioned in addition to the normal hospital operations and continued as patient volumes increased throughout the hospital system.

Patients were prioritized by medical risk (Table 1), priority zip codes (identified by local government), and exposure to disease through work (essential workers, self-declared). There were no national clinical guidelines for high-risk medical conditions; therefore, tiers of risk were made using available evidence from the CDC and published studies (Bellino et al., 2020; Centers for Disease Control and Prevention, 2020; Debiasi et al., 2020; Dooling et al., 2021; Nemani et al., 2021; Nollace et al., 2020), CNH specialty expertise, recommendations related to monoclonal antibody treatment for COVID-19 (US Food and Drug Administration, 2020), and unpublished data on characteristics of patients with COVID-19 illness. The DC Health prioritized vaccinating by zip codes that include areas of the city with residents disproportionately affected by COVID-19 infection and death. These communities also had the lowest percentage of eligible individuals vaccinated against COVID-19 (DC Health, 2021b). Once prioritization occurred,

there was a staged outreach via the EHR appointment reminder system to preregister patients on an external survey marketing tool to best align with available vaccine supply and ensure excellent patient experience with scheduling. Additional outreach to schedule was provided to patients identified by care teams as high risk.

As a major medical center, we are fortunate to have access to ultra-cold freezers and the capacity to run these storage units. As such, Pfizer-BioNTech vaccine was initially the only vaccine supplied by local health departments to the CNH, given the requirement of storage at ultra-cold temperatures (between −80°C and −60°C) for vaccine stability (Centers for Disease Control and Prevention, 2021c). Pfizer-BioNTech vaccine was also the first to be approved for younger adolescents, making this vaccine preferred by the CNH. Johnson and Johnson's Janssen COVID-19 vaccine was initially administered to 15 inpatients older than 18 years, given its efficacy as a 1-dose series. However, when the CDC suspended its use in April 2021 due to the concern for thrombosis with thrombocytopenia syndrome (Centers for Disease Control and Prevention, 2021a), inpatient strategy changed to Pfizer-BioNTech 2-dose vaccine. When the CDC approved the continued use of the Janssen vaccine, it was still available, though rarely preferred by patients.

Sustainable distributive model

Within weeks of announcing a new cohort of eligible individuals, demand for the vaccine decreased, as those without reservation to get the vaccine were able to be vaccinated through our clinics or through other community vaccine providers. To decrease transportation barriers and to increase resources to hesitant individuals, vaccines were made available at patient touch points throughout the health system.

Inpatient and emergency department

Eligible patients were screened daily for vaccine interest and eligibility on admission. When deemed clinically ready by the medical team, vaccines were administered to patients prior to discharge. To guarantee full course of vaccine, second dose of Pfizer-BioNTech vaccine was scheduled prior to discharge.

Primary care clinics

Given the requirement of ultra-cold temperatures for long-term storage of the Pfizer-BioNTech vaccine, it was initially difficult to distribute the vaccine to smaller ambulatory clinics. However, in May 2021, the FDA authorized expanded refrigerator storage times for the Pfizer-BioNTech vaccine (US Food and Drug Administration, 2021). Therefore, beginning June 2021, a "hub and spoke" model of vaccine storage/distribution was created to allow and accelerate broader reach of the COVID-19 vaccination at the CNH's community health centers and primary care practices with vaccine refrigerators. The Mobile Medical Unit, which partnered to deliver care to local schools, and the 2 school-based health centers operated by the CNH also participated in the vaccination efforts. The CNH supplied vaccine, staff trainings, and guidance on vaccine clinic development and reporting. Clinic leadership guaranteed EHR readiness and developed local workflows. Clinics offered vaccine to patients and eligible family members during well care, urgent care, and immunization-specific visits.

Specialty ambulatory clinics

Clinics were chosen on the basis of risk of patient population, interest of staff, and feasibility of vaccine administration. The CNH supplied vaccine, staff trainings, and guidance on vaccine clinic development and reporting. Clinic leadership developed local workflows to identify patients, administer vaccine, and guarantee follow-up. The allergy department created a vaccine challenge clinic to vaccinate those at high risk of allergic reaction to the vaccine, due to either reaction after initial dose or history of reacting to components of the vaccine.

Children with special needs

Children with behavioral, developmental, or medical complexity making routine vaccination difficult were referred to our neuropsychology team to create behavior strategy plans to improve vaccine uptake for these patients. The primary care physician, family, and clinical team would coordinate vaccine administration using the outlined strategies. Patients were not sedated for vaccine administration alone; however, if the patient was undergoing a sedated procedure for other medical needs, it would be incorporated when possible. Johnson and Johnson's Janssen 1-dose COVID-19 vaccine was used in some patients older than 18 years with medical complexity to eliminate need for repeat inoculation.

Community education and outreach

To advertise vaccine access and reach patients and family members who were uncertain about their choice to vaccinate, the CNH needed to partner with various community organizations and stakeholders. By optimizing our internal resources, partnering with local health departments, and collaborating with industry organizations such as DC Board of Trade and the DC Hospital Association, the CNH was able to build a wide network of partners to share information on vaccine eligibility, safety, and access. Our vaccine clinics were advertised on public web pages and various media outlets. Our marketing team developed educational materials to answer frequently asked questions and allay vaccine fear (digital text, videos, broadcast media) to share widely with our community partners (Pediatric Health Network of primary care clinics, school administrators, community organizations, local Federally Qualified Health Centers, and Indian Health Service). The hospital advertised a COVID-19 information hotline to answer questions directly from our community on the disease and the vaccine. An advisory group of clinicians and patient/family representatives was created to advise on our outreach strategy, identifying gaps in education or resources throughout the community. Given the mission of our institution to care for children of our region, an early collaboration with the District of Columbia Public Schools was created to vaccinate their teachers to help safely reopen schools. The CNH also supplied vaccine to the department of youth rehabilitation services to help vaccinate incarcerated youth.

Ensuring completion of vaccine series

To ensure that both doses of the vaccine were administered to each patient, dose 1 and dose 2 were scheduled together. Reminders were given for dose 2 appointments and individuals were contacted if they did not show for the dose 2 appointment. Dose 2 was scheduled for any patient per the CDC guidelines (17-42 days after administration for Pfizer-BioNTech) and, if length of time exceeded 42 days, vaccine was still offered though the patient was made aware that efficacy data could vary, given extra length between doses.

Reducing dose variance

Throughout the program, minimizing dose variance was a priority for the CNH. Initially, the vaccines were drawn up individually for the scheduled patients each clinic day. Efforts were made to find unvaccinated individuals to inoculate with extra doses. As demand decreased and vaccinated individuals increased, dose variance increased. To keep this as low as possible, clinics used only 1 vial at a time, encouraged walk-in appointments, and shared vaccines with inpatient services.

Cost of vaccine

Vaccines were supplied without cost from local jurisdictions to the CNH. Patient's insurance was charged for administration of vaccine during most encounters to help offset cost of staff and supplies needed to vaccinate. Although requested, insurance was not required. No cost was charged to the patient.

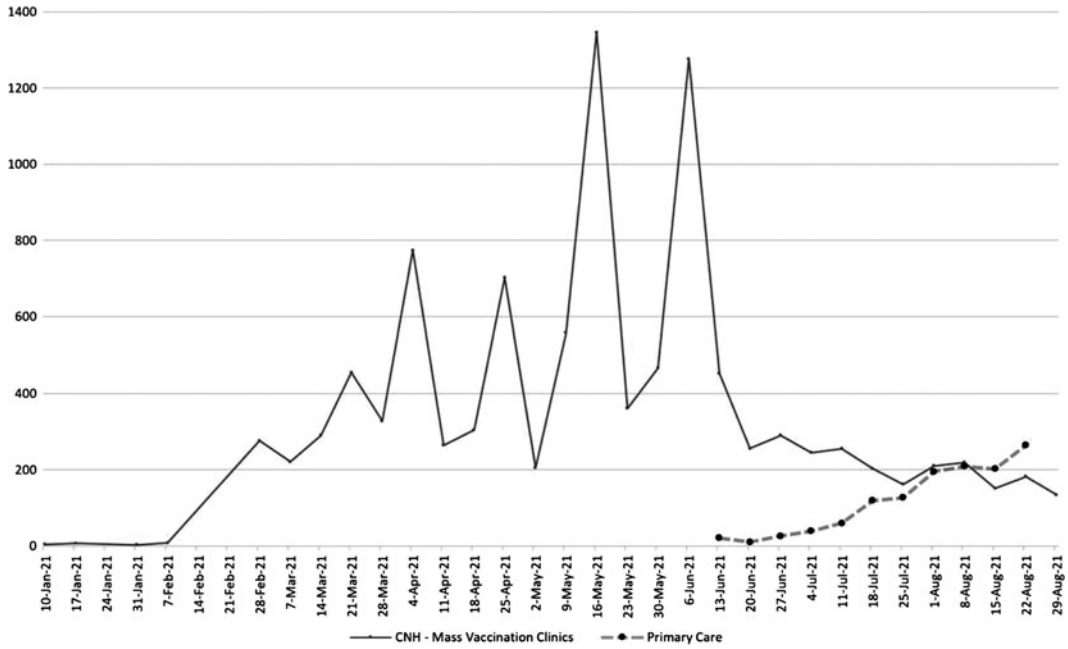

Figure. Children's National Hospital vaccine administration by week. CNH indicates Children's National Hospital.

Reporting

The CNH reported vaccines given to the Department of Health & Human Services and the local departments of health according to their guidelines. The CNH uses 3 separate EHR systems, 2 of which had preestablished connections to the local vaccine registries. Cerner, which did not have a connection to the local immunization registry, developed a reporting system. This required clinical and EHR reconciliation daily to ensure that appropriate information was shared. The CNH reported vaccination data to CRISP (Chesapeake Regional Information System for our Patients), a regional health information exchange. The CNH reported all vaccines supplied to CRISP allowing other provider organizations visibility into vaccinations of patients who are regularly seen at their sites.

Outcomes

Through the centralized delivery model during the time period of January 2021 and August 2021, the patients were encouraged via print and broadcast media to call for an appointment or walk in, while 9472 caregivers of the CNH patients were directly invited to call for an appointment via text message; 10 611 doses were administered to 5585 people. Through the distributive model, an additional 1323 vaccines were administered to 930 people (Figure). Of those vaccinated, 91.3% of those vaccinated were between the ages of 12 and 24 years, 55.6% were Black/African American, and 15.5% were Hispanic (Table 2), which exceed proportions of those communities in the regional population (DC Health Matters, 2021). At our primary care community-based clinics, 75.0% of those vaccinated were Black/African American and 19.6% were Hispanic (Table 3). Approximately 94.5% of individuals who received dose 1 at the CNH returned to our institution for dose 2.

DISCUSSION

Ending the devastation brought about by the COVID-19 pandemic requires a community-wide, collaborative approach to

Table 2. Race and Ethnicity of Patients Vaccinated at Children's National Hospital[a]

	Partially Vaccinated		Fully Vaccinated		Grand Total	
Race and Ethnicity	**Count**	**% of Total**	**Count**	**% of Total**	**Count**	**% of Total**
Race						
African American or Black	488	61.9	3127	54.7	3615	55.6
American Indian or Alaska Native	3	0.4	16	0.3	19	0.3
Asian	15	1.9	114	2.0	129	2.0
White	106	13.4	959	16.8	1065	16.4
Other	19	2.4	55	0.9	200	3.0
Patient declined or unknown	147	18.6	1328	23.2	1475	22.7
Ethnicity						
Hispanic	90	11.4	915	16.0	1005	15.5
Non-Hispanic	541	68.6	4199	73.5	4740	72.9
Patient declined or unknown	158	20.0	656	11.5	814	12.5

[a]Patients have option of choosing more than 1 race/ethnicity.

vaccination. Although children remain at a lower risk of hospitalization and death than their adult counterparts, vaccinating children remains the most effective way to ensure their health and prevent further community spread. Given the CNH's pediatric expertise, connections to the pediatric population of the region, and access to populations at risk for severe outcomes from COVID-19 infections, it was incumbent for the hospital system to develop an effective, efficient, and equitable vaccine program.

The CNH vaccine model was an essential part of the community efforts to deliver vaccines and has successfully vaccinated thousands of patients throughout the first 6 months of the national childhood COVID-19 vaccination efforts. The centralized high-volume model was able to quickly vaccinate eligible individuals during early

Table 3. Race and Ethnicity of Patients Vaccinated at Community-Based Primary Care Practices[a]

	Partially Vaccinated		Fully Vaccinated		Grand Total	
Race and Ethnicity	**Count**	**% of Total**	**Count**	**% of Total**	**Count**	**% of Total**
Race						
African American or Black	242	74.9	198	75.0	440	75.0
American Indian or Alaska Native	0	0	1	0.4	1	0.2
Asian	1	0.3	0	0	1	0.2
White	3	0.9	1	0.4	4	0.7
Other	3	0.9	6	2.3	9	1.5
Patient declined or unknown	74	22.9	58	22.0	132	22.5
Ethnicity						
Hispanic	54	16.7	61	23.1	115	19.6
Non-Hispanic	231	71.5	194	73.5	425	72.4
Patient declined or unknown	38	11.8	94	35.6	132	22.5

[a]Patients have option of choosing more than 1 race/ethnicity.

high demand and then quickly adapted to a broader community-focused distributive model. Making COVID-19 vaccination available at primary care locations throughout the region, in emergency rooms, and at specialty clinics allowed for education about the importance of the vaccine to be paired with ability to administer the vaccine. This led to hundreds of more patients receiving the COVID-19 vaccine.

The CNH's COVID-19 vaccine program was part of a much broader community effort to protect eligible individuals against hospitalization and death related to COVID-19. Having multiple industries and groups throughout the region offer COVID-19 vaccines allowed the region to quickly vaccinate many more individuals than our health system could alone in a short time frame. Partnerships with government officials, health departments, and other hospital systems helped identify needs in the community that were used to develop vaccine strategy. Working with local pediatric networks and community organizations helped tailor the programmatic approach and kept the public informed of the most recent information on vaccine eligibility and access opportunities.

The program required a flexible, creative, multidisciplinary approach to appropriately allocate resources in an unprecedented environment. Government regulations on vaccine eligibility/supply and product storage requirements changed frequently, easing access and distribution to a wider network of providers. Public comfort with the vaccine and delivery location varied as well. To meet the needs of the changing environment, we used expertise from numerous departments, as the efforts impacted staffing trainings and volume, EHR documentation and billing, pharmaceutical ordering and preparation, and community engagement.

Given the disproportionate burden of COVID-19 morbidity and mortality on populations of color, it was essential to create an equitable vaccine program. Our zip code prioritization and medical tiered approach was created to prioritize patients at highest risk for COVID-19 infections and poor outcomes. Despite these efforts, the prioritization quickly became obsolete, as demand for the vaccine dropped sooner than expected. This required the community-focused distributive model to help address barriers to getting the vaccine.

COVID-19 vaccine program development has limitations that need to be considered as efforts continue through this pandemic. Estimating a target population to vaccinate is essential to allocating resources. However, this population is hard to define, given the numerous access points to vaccine in the region, individual preference on location and timing of administration, and individual concerns about the vaccine. Demand seems to follow announcements of more eligible individuals, but when the age for eligibility drops, it is hard to predict the volume of patients who would prefer the centralized mass vaccination model to the primary care distributive model for vaccine delivery. Staffing all locations and swelling to meet demand is difficult with current health care staffing shortages and larger than average volumes (Stead Sellers et al., 2021).

Equitable distribution of the vaccine has also been difficult, given the concerns communities of color have regarding the COVID-19 vaccine. Mistrust in the government/system, speed the vaccine was made, and long-term side effects were primary concerns driving hesitancy in District of Columbia (Kerrigan, 2021). Although our primary care expansion focused on conversations with individuals around the vaccine and has vaccinated primarily children of communities at high risk for COVID-19 infection and mortality, local data still show significant vaccine disparity with most of the unvaccinated or undervaccinated eligible adolescents living in high-risk zip codes (DC Health, 2021a).

CONCLUSION

The CNH's vaccine program made significant impact on the pediatric COVID-19 vaccination rates. There is broad generalizability in the descriptive approach taken

by our health system in an initially centralized model, which morphed to a distributive model. As organizations administer booster vaccines, third shots for immunocompromised individuals, or complete initial or annual COVID-19 vaccine series, the lessons learned and described herein can be implemented in other health care organizations without disruption of care to patients, preserving the core mission of the hospital.

More information is needed on the practices for pandemic vaccine response, including successful approaches to reaching communities with high levels of vaccine hesitancy, as partnering with trusted community leaders to assuage fears and promote safety is part of the work needed to protect each child from infection and community spread. We are confident that this work will evolve and mature.

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