Assessment of COVID-19 Vaccination Practices for 16 Vaccination Providers in Puerto Rico, 2021

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Objective: To assess COVID-19 vaccine providers' adherence to best practices and identify knowledge and practice gaps to guide corrective actions and retraining activities in Puerto Rico.

Methods: A CDC supportive evaluation tool was modified to collect information on vaccine storage, handling, preparation, administration, and post-vaccination care. Assessment visits to COVID-19 vaccine providers in Puerto Rico were conducted a month after the availability of COVID-19 vaccines in the island.

Results: A total 16 vaccine providers were visited, 12 (75%) administering Pfizer-BioNTech vaccine and 4 (25%) administering Moderna vaccine. All providers adhered to correct handling practices after vaccine thawing. Required resources for managing anaphylaxis on site were available in all sites. Few instances of incorrect use of retractable-needle syringes, unapproved temperature monitoring devices, and lack of recorded temperature data were observed. Corrective actions were taken during the evaluation visit.

Conclusion: No major deficiencies that could jeopardize vaccine viability or patient safety were found. The use of a supportive evaluation tool during assessment visits is helpful to determine needs for vaccine providers retraining and to continue the safe administration of COVID-19 vaccines in Puerto Rico. [*P R Health Sci J 2021;40:185-187*]

Key words: COVID-19, Vaccination practices, COVID-19 vaccine, Vaccination site supportive evaluation

As of February 28, 2021, the Puerto Rico Department of Health (PRDH) had reported 92,708 confirmed cases of coronavirus disease 2019 (COVID-19) and 2,037 deaths (1). Two COVID-19 vaccines, manufactured by Pfizer-BioNTech and Moderna, were authorized for emergency use in the United States in December 2020 (2, 3). The PRDH COVID-19 vaccination program started on December 15, 2020, following the phased allocation recommendations of the Advisory Committee on Immunization Practices (ACIP) (4). As of February 28, 2021, Puerto Rico received 799,780 COVID-19 vaccine doses, distributed 745,480 doses, and providers had reported 486,405 doses administered using a hub-and-spoke model (5). We report the results of the assessment visits conducted by PRDH one month after the start of the vaccination program to determine COVID-19 vaccine providers adherence to best practices and identify knowledge and practice gaps to guide corrective actions and retraining activities.

Materials and Methods

PRDH identified at least two vaccine providers in each of the 7 health regions that were offering COVID-19 vaccines and were available for an in-person site visit during the evaluation period of January 12–26, 2021. At the time of the evaluation, there were 350 vaccine providers registered and with a signed agreement with the PRDH. For the visits, the team modified an existing internal supportive supervision evaluation tool, developed by the CDC's Immunization Services Division (National Center for Immunization and Respiratory Diseases) to collect quantitative and qualitative data (Supplement*). This tool captures data based on the evaluator's direct observation of vaccine storage, preparation, administration, and post-vaccination care and interviews with the site's vaccine coordinator, staff, and medical director about anaphylaxis preparedness and data recording into the Puerto Rico Electronic Immunization System (PREIS). If the evaluator observed

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Table 1. Compliance with COVID-19 storage, preparation, administration, and post-vaccination care recommendations, COVID-19 vaccination sites, Puerto Rico, 2021 (n=16).

Competency	Providers (or equipment) observed (n)*	Compliant (n)	%
Storage			
Vials in original packaging in freezer	5	4	80%
Vials stored upright in refrigerator	17	16	94%
Appropriate temperature monitoring device	17	16	94%
Temperature data available for the last 72 hours	17	16	94%
Adequate room temperature post-thawing	16	16	100%
Preparation (Pfizer)			
Use of recommended diluent	12	12	100%
Inverted vial after dilution	12	12	100%
Administration			
Use of prevaccination screening form	16	12	75%
Staff using complete PPE	15	14	93%
Use of new, sterile needle for each patient	15	15	100%
Vial stopper cleaned with new sterile alcohol pad	15	14	93%
Swirled vial before withdrawing new dose	15	13	86%
Correct use of retractable-needle syringes	15	13	86%
Post-vaccination care			
Social distancing in waiting room	16	16	100%
CDC vaccination record card provided to all patients	16	16	100%
Anaphylaxis preparedness			
Three doses of epinephrine available	16	16	100%
Vital signs monitoring equipment available	16	16	100%
Antihistamines available	16	16	100%
Crash cart available	16	14	88%†
Data recording in PREIS‡			
Within 12 hours	16	8	50%
Within 24 hours	16	13	81%

*A total of 17 storage equipment units were observed at 16 vaccination sites. Denominator varies according to what evaluators were able to observe and record during the visits. †The two sites without a crash cart on site had a patient referral protocol in place. ‡PREIS: Puerto Rico Electronic Immunization System.

practices that did not conform to recommendations, the tool provided a script for immediate review of the recommendation and steps for remediation. PRDH vaccination program staff adapted the tool to include questions and corrective actions related to the specific ancillary medical supplies distributed with the vaccines, local jurisdictional requirements for post-vaccination care, and procedures for entering vaccination records into PREIS. All evaluators were familiar with the COVID-19 vaccination campaign in Puerto Rico and completed several hours of training for site visit evaluation and use of this modified supportive supervision evaluation tool. Regular meetings during the evaluation period to reach a consensus among evaluators standardized the implementation of the tool across evaluation teams. We evaluated all equipment (e.g., refrigerators, freezers) and physical spaces (e.g., storage rooms, vaccine administration offices) used for COVID-19 vaccination at each site.

CDC's Human Subjects Office reviewed these activities protocol and provided a non-research determination as it was considered part of the public health response and regular duties of the Puerto Rico Department of Health.

Results

Three evaluation teams visited 16 providers: 6 hospitals, 7 ambulatory facilities, and 3 mass vaccination centers. Twelve (75%) providers used Pfizer-BioNTech vaccine and 4 (25%) providers used Moderna vaccine. Four (33%) of the providers using Pfizer-BioNTech vaccine had an ultra-cold freezer (temperature range: -80^{0}C and -60^{0}C) and one (25%) provider using Moderna had a standard freezer (temperature range: -25°C and -15°C) for vaccine long-term storage. Providers without recommended freezer capabilities stored vaccines in refrigerators (temperature range: 2°C and 8°C) and used them within recommended times (5 days for Pfizer BioNTech, 30 days for Moderna). All providers adhered to correct handling practices after thawing vaccine, including proper storage temperatures and post-dilution and post-puncture time of use. All Pfizer-BioNTech vaccine providers were observed using only the diluent included in the ancillary kits and inverted the vial 10 times after dilution, as recommended by the manufacturer (Table 1).

Vaccinators wore complete, recommended PPE at 14 of 15 sites (93%). During vaccine withdrawal, 14 providers (93%) used a new sterile alcohol pad to clean the vial stopper before each dose, and 13 (86%) swirled the vial before withdrawing a new vaccine dose. Incorrect use of retractable-needle syringes was observed at two sites (12.5%), one provider had an unapproved temperature monitoring device, and one did not have temperature data recorded in the last 72 hours. One facility (6%) reported insufficient needles to administer vaccines; the facility planned to use its own stockpile of needles (Table 1).

All sites provided CDC vaccination record cards and used the PRDH consent form, and 12 (75%) were using a prevaccination screening tool. Completion of prevaccination documents was identified by several providers as a step that could be done at home prior to the appointment that would increase efficiency during the vaccination process. All providers had an area for post-vaccination care that allowed social distancing and the required resources for managing anaphylaxis on site. A crash cart, a mobile unit containing supplies and medications required for resuscitation, was available at 14 of 16 sites (88%), or a patient referral protocol was in place (n=2, 12%). Three of 15 sites (20%) reported receiving a notification of vaccine delivery from PRDH less than 24 hours in advance, at least

once. Thirteen (81%) providers reported entering vaccine administration data into PREIS within 24 hours. We did not evaluate adverse events recognition or reporting (Table 1).

For all observed deficiencies in adherence to the recommended storage or administration practices, the actions prescribed by the supportive supervision tool were taken and immediate changes were made by the vaccine provider staff and managers. The site with an unapproved temperature monitoring device had already ordered an approved device that was implemented the next week. Providers' responses to recommendations were well-received in all instances.

We observed a range of creative solutions developed by vaccine providers to ensure the safety and effectiveness of the COVID-19 vaccination program: the use of color-coded prevaccination questionnaires to guarantee longer post-vaccination observation time for patients requiring it, PRDH vaccine delivery forms repurposed for closely monitoring of vaccine inventories, marking surfaces where vials are thawed with painting tape to identify vials ready to use, and engineering handmade wooden structures to ensure vaccine vials remained upright during transport within a facility.

Discussion

Providers evaluated in this assessment of vaccine providers in Puerto Rico successfully implemented COVID-19 vaccination and adhered to recommended best practices according to the modified supportive evaluation tool. No major deficiencies were found that could jeopardize vaccine viability or patient safety. Observed deficiencies were directly addressed and resolved with vaccine provider staff during the site visit. Furthermore, PRDH staff aggregated all practices that were non-adherent to recommendations, de-identified the site, and reviewed the solutions in weekly virtual office hours attended by all vaccine providers to prevent such deficiencies from occurring in the sites that were not included in this evaluation. Larger programmatic areas for improvement were identified and included the modifications to the communication plan for vaccine delivery dates, technical assistance visits to improve timely reporting in PREIS, regular updates of a central training platform, and suggestions to make prevaccination documents widely available on the PRDH website. As additional vaccines are authorized for use in Puerto Rico, PRDH will continue conducting assessment visits. PRDH's goals are to improve the quality and timeliness of retraining and guarantee the safe administration of COVID-19 vaccines in Puerto Rico.

Resumen

Objetivos: Evaluar la adherencia a buenas prácticas de los proveedores de la vacuna contra el COVID-19 e identificar brechas de conocimiento y práctica para orientar acciones correctivas y actividades de reentrenamiento en Puerto Rico. Métodos: Se modificó una herramienta de evaluación de apoyo de los CDC para recopilar información sobre el almacenamiento, la manipulación, la preparación, la administración y la atención posvacunación de las vacunas. Las visitas de evaluación a los proveedores de la vacuna contra el COVID-19 en Puerto Rico se realizaron un mes después de la disponibilidad de las vacunas en la isla. Resultados: Se visitaron un total de 16 proveedores de vacunas, 12 (75%) administraron la vacuna Pfizer-BioNTech y 4 (25%) administraron la vacuna Moderna. Todos los proveedores se adhirieron a las prácticas correctas de manipulación después de la descongelación de la vacuna. Los suministros necesarios para manejo de anafilaxia estaban disponibles en todos los sitios. Se encontraron pocos casos de uso incorrecto de jeringuillas de aguja retráctil, dispositivos de control de temperatura no aprobados y falta de datos de temperatura registrados. Se tomaron acciones correctivas durante la visita de evaluación. Conclusión: No se encontraron deficiencias importantes que pudieran poner en peligro la viabilidad de la vacuna o la seguridad del paciente. El uso de una herramienta de evaluación de apoyo durante las visitas de evaluación es útil para determinar las necesidades de los proveedores de vacunas.

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*Supplement material is available exclusively in the online version of this publication.