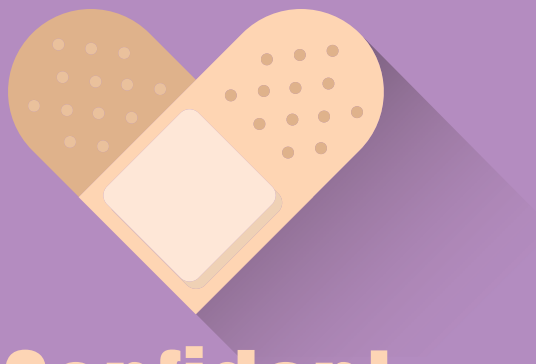
FINAL REPORT

Optimizing Pharmacy Engagement in Vaccinating Children Under 3 Years of Age for COVID-19



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Introduction

The coronavirus disease first reported in 2019 (COVID-19) is one of the worst global public health crises in modern times, and the precariousness has not fully abated. Public health organizations and agencies in the United States and around the globe continue to develop strategies to bring the COVID-19 pandemic under control while preparing for new subvariants of the virus and further anticipated waves of people becoming infected. Additionally, other communicable respiratory diseases and other illnesses have increased the strain on public health resources and the health of communities. Strategies being implemented to address the COVID-19 pandemic include expanding the population of those eligible for COVID-19 vaccines, increasing vaccination rates, improving the acceptance of current recommendations for COVID-19 and annual influenza vaccinations, and implementing infection control measures.

On March 10, 2020, the U.S. Secretary of Health and Human Services (HHS) issued a declaration under the 2005 Public Readiness and Emergency Preparedness Act (PREP Act) "covering COVID-19 tests, drugs, and vaccines, and providing liability protections to manufacturers, distributors, states, localities, licensed health care professionals, and others identified by the Secretary (qualified persons) who administer COVID-19 countermeasures."[1] Ten amendments have been added to the PREP Act since the issuance of the declaration.

How can pharmacists reach children aged 3 years and younger?

To help states increase their COVID-19 vaccination workforces in fighting the pandemic and to get more people vaccinated against COVID-19, the Seventh Amendment added to the PREP Act (effective March 11, 2021) expanded the category of individuals authorized to administer COVID-19 vaccines. Pharmacists, pharmacy interns, and pharmacy technicians are listed as health care providers (qualified persons) in the expanded COVID-19 vaccine workforce under the PREP Act.[2] This amendment preempts "any state or local law that prohibits or effectively prohibits the individuals authorized in the Seventh Amendment from administering COVID-19 vaccines."[3]

Subsequently, the U.S. Food and Drug Administration (FDA) amended its emergency use authorization (EUA) for COVID-19 vaccines, making children from ages 6 months to 17 years eligible to receive the vaccines from pharmacists.[4]

Many pharmacists are prepared to vaccinate children 3 years of age and younger; however, despite the changes made to the PREP Act and the FDA's changes to its COVID-19 vaccine EUA, pharmacists encounter obstacles in reaching children in this age group. This raises key questions such as: How can pharmacists reach the population aged 3 years and younger? What obstacles prevent pharmacists from reaching this age group? What obstacles prevent this age group from getting the COVID-19 vaccine?

This report presents findings from articles and published research, COVID-19 vaccination rate statistics, and results of structured interviews conducted with pharmacists to gain insight into the obstacles facing pharmacists in their attempts to reach children aged 3 years and younger, the opportunities that are available to overcome these challenges, and strategies to optimize pharmacy engagement in vaccinating children this age group.

Many pharmacists are prepared and ready to vaccinate children 3 years of age and younger; however, despite the changes made to the PREP Act and the FDA's changes to its COVID-19 vaccine EUA, pharmacists are encountering obstacles in reaching children in this age group. This raises key questions such as: How can pharmacists reach the population aged 3 years and younger? What obstacles are preventing pharmacists from reaching this age group? What obstacles are preventing this age group from getting the COVID-19 vaccine? This report presents findings from articles and published research, COVID-19 vaccination rate statistics, and structured interviews conducted with pharmacists to gain insight into the obstacles challenging pharmacists in their attempts to reach children aged 3 years and younger and to elucidate opportunities that may be available for overcoming challenges to optimize pharmacy engagement in vaccinating these young patients.

What obstacles are preventing pharmacists from reaching this age group?

Overview

COVID-19 vaccination previously had been only for persons aged 5 years and older. To expand the population eligible to receive COVID-19 vaccines, the FDA amended its EUA to include children. The Centers for Disease Control and Prevention (CDC) announced, on June 18, 2022, that it endorsed the Advisory Committee on Immunization Practices (ACIP) recommendation that all children 6 months through 5 years of age should receive a COVID-19 vaccine, which expanded eligibility for vaccination to nearly 20 million additional children.[5]

In announcing the CDC's endorsement of the ACIP recommendation, CDC Director Rochelle P. Walensky, MD, MPH, mentioned pharmacists as one group of health care providers who parents and caregivers should speak with about COVID-19 vaccines for their children. "We know millions of parents and caregivers are eager to get their young children vaccinated, and with today's decision, they can. I encourage parents and caregivers with questions to talk to their doctor, nurse, or *local pharmacist* to learn more about the benefits of vaccinations and the importance of protecting their children by getting them vaccinated."[5]

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As noted by the CDC Director, pharmacists are frontline health care professionals who provide expert advice about the safety and use of vaccines and other needed medications. They play a critical role in our health care system by maintaining and improving the health of patients, which was clearly demonstrated during the COVID-19 pandemic and proved that pharmacists can contribute much more to the U.S. health care system. It is estimated that pharmacists administered more than 270 million COVID-19 vaccinations in community-based pharmacy programs, which accounts for more than 50% of U.S. COVID-19 vaccinations and averted more than 1 million pandemic deaths.[6]

Given pharmacists' training and abilities to reach and communicate with diverse populations (pharmacy teams made significant strides to improve equity in vaccine distribution by vaccinating a greater share of non-Hispanic Asian and Hispanic/Latino persons), it is vitally important that pharmacists continue to be engaged in vaccinating children of all ages against COVID-19.[6] Achieving this goal, however, may require changes to state laws. Some states have set age limits at which pharmacists may vaccinate children, although the PREP Act amendments may temporarily preempt these state limitations. A further amendment to the PREP Act to clarify and align with the recent changes made by the FDA to its EUA and the CDC's recent endorsement regarding vaccinating children of all age groups by pharmacists in their pharmacies may be warranted.

In addition to granting practice authority, the scope of engagement is dependent on the comfort level of the individual pharmacy team members. Even if team members do not administer vaccines to certain age groups, they can contribute to vaccinations through education and facilitation activities.

The Problem: Obstacles and Challenges Defined

Many pharmacists are prepared and ready to vaccinate children 3 years of age and younger. However, despite the recent FDA COVID-19 vaccine EUA, pharmacists encounter obstacles in reaching children in this age group. Recent research and reports show the primary obstacles and challenges are:

1. Several state laws set limitations on ages of children that pharmacists can vaccinate as well as on which vaccines pharmacists can administer.
2. Confusion over authorities and PREP Act amendments. The PREP Act amendments authorize vaccine administration to individuals 3 years of age and older.
3. Many children are missing well-child visits and are not getting vaccinated.
4. Children in certain socioeconomic groups who are experiencing the impact of social determinants of health may not see any health care provider.
5. Vaccine hesitancy and vaccine misinformation cause parents to not want vaccines for their children.
6. Some pharmacists are concerned about the liability of vaccinating children 3 years of age and younger.
7. Pharmacists experience problems with vaccine payment mechanisms and access to the federal Vaccines for Children program.
8. Pharmacists confront a variety of additional barriers and challenges to the provision of COVID-19 vaccines to young children.

1. State Laws Setting Age Limitations on Vaccination of Children by Pharmacists

Although every state allows pharmacists to administer vaccines to some extent, state laws vary regarding which vaccines may be administered and which age groups may receive vaccination from a pharmacist. Under temporary federal PREP Act authority, pharmacists can order/prescribe and administer, and pharmacy interns and pharmacy technicians can administer, all routine childhood immunizations and COVID-19 vaccines to individuals ages 3 years and older as well as influenza vaccines, provided through numerous PREP Act amendments.[7] The PREP Act and its amendments, as confirmed in a January 19, 2021, slip opinion from the U.S. Deputy Assistant Attorney General, Office of Legal Counsel, "expressly preempts state and local requirements to the extent that they would effectively prohibit qualifying pharmacists from ordering and administering COVID-19 tests and vaccines authorized by the Secretary's declaration."[8]

With the recent changes to the PREP Act and the FDA's EUA (allowing children 3 years down to 6 months of age to receive the Pfizer-BioNTech or Moderna COVID-19 vaccine), some state laws may need to be changed to allow pharmacists to administer vaccine to this age group. Even though the PREP Act preempts state laws, it has been reported there is confusion about the recent changes and that some state agencies maintain their restrictions supersede recent PREP Act amendments, thereby not authorizing pharmacists to administer COVID-19 vaccines to this age group in those states. The converse also causes confusion when the state authority permits pharmacist engagement beyond what the PREP Act authorizes. Most commonly, the pharmacist defaults to the state authority.

Currently, 17 states allow pharmacists to order COVID-19 vaccines for any age group, and 26 states allow pharmacists to administer COVID-19 vaccines to any age group, which includes those aged 3 years and younger.[7] State regulatory agencies have the authority to issue emergency rules that could resolve these restrictions.

Many children are missing well-child visits and not receiving routine vaccinations or vaccinations for COVID-19.

2. Confusion Over Authorities

When the FDA amended its EUA for COVID-19 vaccines, making children from ages 6 months to 17 years eligible to receive vaccines from pharmacists, confusion over pharmacists' authorities ensued in some states. Some states allow pharmacists to administer COVID-19 vaccines for any age group, either under their own authority or under a protocol or individual prescription. At times, there was confusion that needed to be resolved over which authority prevailed—state law or the PREP Act. As the U.S. Deputy Assistant Attorney General's slip opinion states, the PREP Act preempts state law to expand authorities, however it does not intend to take away authorities granted under state law.[8]

One pharmacist in Region 3 of the Centers for Medicare & Medicaid Services (CMS) Regional Offices indicated in the structured interviews conducted by the National Alliance of State Pharmacy Associations (NASPA) for this report that the health department originally stated pharmacists could not administer COVID-19 vaccines to children under 3 years of age, even though state law allowed because the PREP Act only went down to age 3 years. Later, after consultation with the state's Board of Pharmacy, the health department amended its statement and maintained the authority that already existed prior to the PREP Act.

3. Children Missing Well-Child Visits and Not Getting Vaccinated

Well-child visits (WCVs) play a crucial role in ensuring children complete their immunizations. However, a 2020 study by Wolf and colleagues showed that children miss 30% to 50% of WCVs despite the benefits. Although the study indicated that little is known about why WCVs are missed, the 17 respondents surveyed identified structural and social barriers for missing visits, including transportation, difficulty taking time off from work, child care, language differences, and immigration status. The study also pointed out that "poor, uninsured, and African American children miss a greater proportion of these visits compared with upper-income, privately insured, and white counterparts" even though many states provide and support safety net practices that promote access to WCVs.[9]

In an earlier study conducted of children 0 to 6 years old between 2011 and 2016 (152,418 children in 2 health networks spanning 20 states) to look at gaps in WCVs, investigators showed the 2-, 4-, and 6-month visits were the most frequently attended, while the 15- and 18-month and 4-year visits were the least attended.[10] The study suggested that one possible reason for low attendance at the 15- and 18-month visits is that fewer vaccinations are required compared with early infancy, while low attendance between ages 3 and 5 years is because parents may be waiting until children are 5 years old to bring them for school entry required vaccinations. Lastly, it was noted that children of low-income homes are at higher risk for missed WCVs.[10]

> 30% of parents say they don't have time to worry about their child's health unless it's a medical emergency.

4. Social Determinants of Health Affecting Children's Access to Health Care and Vaccinations

Social determinants of health (SDOH) affect children's access to health care. This was confirmed in 2019 by the Nemours Foundation, which partnered with The Harris Poll to conduct a national survey of more than 1,000 parents of children under the age of 18 years. The findings show that 32% of parents said they missed at least one of their child's medical appointments in 2018 because they were unable to pay for the visit; 30% said they don't have time to worry about their child's health unless it's a medical emergency; and 23% said they worried about running out of food before getting money to buy more groceries.[11] *Sixty-five percent of American parents of children under 18 years reported at least one economic, environmental, or lifestyle factor that limits their family's ability to live a healthy life.*[12] Interestingly, 55% of the parents reported that a health care provider/insurer never asked them about nonmedical health factors (i.e., SDOH) such as access to healthy food, transportation, exposure to violence, safe housing, etc.[11]

Further validating the effect of SDOH on WCVs is a 2021 study by Roberts et al., which concluded that adverse SDOH, such as financial hardship, housing instability, and childcare difficulty, were associated with missed WCVs and "can negatively impact pediatric well-child care compliance."[12] These studies reinforce HHS action to issue a PREP Act amendment allowing pharmacists to administer vaccines to children ages 3 to 18 years to address a public health crisis.[11,12]

5. Vaccine Hesitancy and Misinformation Preventing Children From Receiving the COVID-19 Vaccine

In 2019, the World Health Organization (WHO) declared vaccine hesitancy among the top 10 threats to global health.[13] The WHO defines vaccine hesitancy as "the reluctance or refusal to vaccinate despite the availability of vaccines," that "threatens to reverse progress made in tackling vaccine-preventable diseases." Vaccine hesitancy has been linked to vaccine-preventable disease outbreaks in the past 2 decades as well as to the continuing spread of COVID-19. The reasons people choose not to get vaccinated are complex, although the WHO identified complacency, lack of confidence in vaccines, and inconvenience in accessing vaccines as key reasons.[13]

A KFF survey sheds light on the issue of vaccine hesitancy. More than 4 in 10 parents of children under 5 years old who are eligible for the COVID-19 vaccine said they will "definitely not" vaccinate their children.[14] Responses were polarized and broke along political party affiliation: 15% of Democratic or Democratic-leaning parents with a child under 5 years of age said their child has already received at least one dose of the COVID-19 vaccine, compared with only 3% of Republican or Republican-leaning parents. Republican/Republican-leaning parents are 3 times as likely as Democratic/Democratic-leaning parents to say they will "definitely not" be vaccinating their young children (64% vs. 21%, respectively).[14]

Results of the KFF survey pointed out that *a perceived lack of research, potential side effects, and safety concerns were the top 3 reasons why parents said they will not vaccinate their young children.* Other reasons included that the child does not need it/not worried about COVID; too young; want to wait and see; and vaccine does not work/not effective. Survey data on perception show:[14]

- 53% of parents of children between ages 6 months and 4 years old said the vaccine poses a bigger risk to their child's health than a COVID-19 infection. This is also higher among Republican/Republican-leaning parents (73%) than Democratic/Democratic-leaning parents (29%).
- 55% of parents of children younger than age 5 years said COVID-19 vaccine information from federal health agencies is confusing.

The KFF survey focused on the role of pediatricians and found that 70% of parents of children ages 6 months to 4 years old have not spoken to their pediatrician or other health care provider about the COVID-19 vaccine for their children. Among parents who are considering getting their child vaccinated, 70% said they will wait until their child's regular check-up to discuss the vaccine, while 27% said they will make an appointment.[14]

According to the CDC, other barriers include misinformation about the COVID-19 vaccines and "inadequate public awareness about adult vaccines" (e.g., vaccine administration, inadequate or varying payment for vaccines).[15]

6. Pharmacists Concerned About Liability

A concern and possible barrier expressed in structured interviews with some pharmacists is perceived liability for administering COVID-19 vaccines to patients 3 years of age and under. One independent pharmacist in CMS Region 8 interviewed by NASPA stated that the vaccine protocol for their Pharmacy Service Administration Organization (PSAO) did not include patients under 3 years of age because "the liability was too much." PSAOs negotiate contracts on behalf of their pharmacy members for pharmacy services. To provide the COVID-19 vaccine to this age group, this pharmacist partnered with a physician who signed a protocol so that the pharmacist could legally administer influenza and COVID-19 vaccines to children down to 6 months of age. This is not an unusual occurrence for pharmacists in states requiring protocols, although it can be challenging to find a physician partner. This same pharmacist works in a community where the public health department has reached out regarding providing access to the vaccine for mpox, but her partnering physician is not comfortable signing a protocol for her to extend services in her community for this infectious disease.

7. Payment and Access Barriers

A specific concern raised by some pharmacists is payment issues. One interviewed pharmacist pointed out that some insurance companies rejected claims for individuals under 2 years of age, requiring vaccinations for these patients only be administered in physician offices. Another pointed out that payment for vaccinating children under 3 years of age would not be made if the pharmacist brought in a registered nurse to administer the COVID-19 vaccines; (pharmacists were not authorized to administer vaccines to patients under 3 years of age in this state). In this instance, the pharmacist paid the nurse and absorbed the cost.

Another pharmacist who provides COVID-19 and influenza vaccines reported that although state Medicaid covers COVID-19 vaccinations for patients under 19 years of age, it does not cover flu shots for the same group, while another pharmacist said Medicaid requires a "roundabout way" to bill. A pharmacy technician indicated the pharmacy had not implemented a COVID-19 vaccine service for the under 3-year-old age group because of the time and expense of setting up the service and the lack of reimbursement for such. Lastly, payment and administrative burdens related to the Vaccines for Children (VFC) program often prevent pharmacist participation as VFC providers.

8. Other Barriers and Challenges for Pharmacists

Pharmacists interviewed by NASPA also mentioned other barriers to the provision of COVID-19 vaccines to this age group:

- A prescription is needed in some states to vaccinate anyone under 3 years of age. In CMS Region 5, which requires a prescription, the pharmacist said that when a parent schedules an appointment, they make the parent aware that a prescription is needed. Additionally, the pharmacy has a local physician partner who will authorize the COVID-19 vaccine for a parent who does not have a physician. A pharmacist in CMS Region 6 also reported the prescription requirement as a barrier.
- In CMS Region 1, an interviewee reported that it does not appear any pharmacists vaccinating children under 3 years of age. "There is a low appetite among our pharmacists to do pediatric vaccinations at all, and not in the lower age range. There are also some practical barriers that have been very hard to crack here, so there really hasn't been any growth in this space."
- When the PREP Act expires, pharmacists in some states will no longer be able to vaccinate children under 3 years age; current state law, in some states, is ages 6 years and up, making this a "huge, missed opportunity."
- To vaccinate those under 3 years of age, a CMS Region 3 pharmacy not vaccinating this age group reported that a nurse would need to be hired to administer the vaccine.
- Need for county/state to include nurses (if pharmacists do not have authority) to protocols that can work collaboratively with pharmacists (and subsequent payment; see preceding *Payment and Access Barriers* section).
- Extreme stretch of public health resources because of other crises (mpox, polio, Ebola) that drain limited resources leaving scheduling of clinics completely up to the pharmacy team to continue.

Pharmacists' Role: Opportunities for Engaging Pharmacists in COVID-19 Vaccinations

Pharmacists remain one of the most trusted and accessible health care professionals for communities across the country and are critical to health care management teams. They can be trusted to provide guidance, credible information, and access to vaccines. Pharmacists are ideally positioned to act as patient educators, build vaccine confidence, and encourage parents to get their children vaccinated.[15] Pharmacists exceeded all expectations and helped their communities throughout the COVID-19 pandemic by embracing "the tenets embodied in the 'immunization neighborhood'—collaboration, coordination, and communication."[6] These tenets "proved to be essential in protecting health and preventing disease" during the pandemic.[6]

Recent amendments to the PREP Act provided pharmacists with an opportunity to further collaborate and partner with others, particularly with local public health services and agencies. The focus of the PREP Act is to vaccinate children ages 3 years and up; however, in some communities, public health officials, pediatrician offices, family practice physicians, and parents were asking pharmacists to vaccinate the population under 3 years of age. This has been successful where a strong partnership with public health exists. For example, in states where pharmacists do not have the authority to administer vaccines to children under 3 years old, clinics coordinated with public health where the pharmacy team vaccinated populations over 3 years of age while the public health providers vaccinated children under 3 years of age. These efforts were successful in advancing COVID-19 vaccinations and boosting vaccine confidence. In counties where there were no public health agencies, pharmacies stepped up and served as the immunization destination for all.

Pharmacists have provided more than 270 million COVID-19 vaccinations in their community pharmacies and in long-term facilities, which accounts for more than 50% of U.S. COVID-19 vaccinations.[6] "Pharmacists…contributed to America's health and recovery during the COVID-19 pandemic by providing [more than] 350 million clinical interventions to [more than] 150 million people in the form of testing, parenteral antibodies, vaccinations, antiviral therapies, and inpatient care."[6] Pharmacists are able to have an impact during the pandemic because they expanded their clinical services to help their communities in every practice setting and because their pharmacies are located close to the communities they serve and have convenient hours.[6] "Often, pharmacists reached where few others could, crossing vast distances and crossing cultural or linguistic divides to reach disadvantaged communities."[6]

A recent study provided a nationwide analysis of distance to community pharmacies. The findings indicate that 88.9% of the U.S. population live within 5 miles of a community pharmacy, while 48.1% live within 1 mile, and 96.5% live within 10 miles.[16] The results also show that 8.3% of counties in the United States had a least 50% of residents living more than 10 miles from a community pharmacy (mainly Alaska, Montana, North Dakota, and South Dakota). The study identified 61,715 pharmacies nationwide that include 37,954 (61.5%) chain pharmacies, 23,521 (38.1%) regional franchises or independently owned pharmacies, and 240 (0.4%) government pharmacies.[16]

Although chain pharmacies make up the largest percentage of community pharmacies, the study noted that rural areas heavily rely on regional franchises and independent pharmacies. In many instances, especially in rural and underserved areas, pharmacists are the first point of contact for health care by patients and their caregivers. The number of lives that community pharmacists touch, care for, and influence continues to rise.[6]

Pharmacists are prepared to administer COVID-19 vaccines to children 3 years of age and younger. Immunizations are part of the curriculum in pharmacy schools, and many schools utilize a course that was developed by the American Pharmacists Association (APhA). According to a survey released by APhA in June 2022, 66% of pharmacists responding said they would be prepared to administer COVID-19 vaccines to children under 5 years old if authorized to do so.[17] Additionally, 44% said they are currently planning to vaccinate based on community needs and abilities of pharmacy teams following FDA and CDC authorization and guidance.[17]

“Pharmacists play a fundamental role in dispelling common concerns about vaccine-related adverse effects and in improving vaccinations rates.”[15] As health care advocates, pharmacists have opportunities to engage with parents by discussing COVID-19 vaccines, encouraging parents to talk openly about their vaccine concerns or fears, and listening to them. These actions set parents at ease and motivate them to obtain recommended vaccines.[15] “Hearing from multiple trusted sources and having repeated conversations with patients are needed to influence the ‘movable middle,’”[18] particularly those parents “who can change their mind” or have yet to decide about having their children 3 years of age and under vaccinated for COVID-19. Pharmacists can readily address any concern parents have by sharing key facts and credible information and sources, especially to counter misinformation.[18]

Conclusion

We have experienced one of the worst global public health crises in modern times and the predicament has not fully abated. Public health organizations and agencies in the United States and around the globe continue developing strategies to bring the COVID-19 pandemic under control while preparing for new subvariants of the virus and further waves of people becoming infected. One strategy being implemented is expanding the population of those eligible for COVID-19 vaccines to get more people vaccinated.

Recent changes to the PREP Act allowing pharmacists to administer COVID-19 vaccines and the FDA EUA, which recently authorized children 6 months through 5 years of age to receive a COVID-19 vaccine, made nearly 20 million children eligible. While overall demand is still low, motivated parents are tremendously grateful and will travel great distances to find an access point to obtain COVID-19 immunization for their child. Pharmacists are a vital access point, and all barriers should be removed to optimize pharmacy and public health working as a team to improve access to immunizations across the lifespan.

As noted in this report, numerous barriers and challenges have been encountered, especially by pharmacists who play a critical role in administering COVID-19 vaccines. As frontline health care providers and one of the most trusted health care professionals in their communities, pharmacists are a linchpin to helping ensure the goal of getting more people vaccinated. The success of this goal requires that barriers and challenges be overcome.

As leaders and health care advocates located centrally in most communities, pharmacists are well positioned to help remove these barriers and challenges. Pharmacists can determine who needs to be vaccinated. They can ease parents' concerns and fears by providing credible information to increase vaccine confidence and address vaccine hesitancy and misinformation among parents reluctant to have their children vaccinated. By talking with parents, pharmacists also can help address SDOH and the impact these have on children's access to health care and vaccines.

Pharmacists play a critical role in disease prevention for all age groups, and as established throughout this discussion, they should be engaged in vaccinating children under 3 years of age against COVID-19. A strategy focused on the public health of communities—through the optimization of trusted, willing, ready, and able pharmacy team vaccination providers—will result in enhanced protection for the people in our communities.

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Notes

Notes

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