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BRIEF REPORT

COVID-19 vaccine inquiries regarding children ages 5–11 years received by NIP-INFO

Elisha Hall PhD, RD, Health Education Specialist[1] | **Sarah Morales MPH, MBA, CHES Health Education Specialist**[2] | **JoEllen Wolicki BS, RN, Nurse Educator**[1] | **Sarah Schillie MD, MPH, MBA, Medical Officer**[3]

[1]COVID-19 Response, Vaccine Task Force, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

[2]Goldbelt C6, LLC; Communication and Education Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

[3]Communication and Education Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

Correspondence
Elisha Hall, COVID-19 Response, Vaccine Task Force; Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, GA 30329-4027, USA.
Email: nyu2@cdc.gov

Abstract

We describe COVID-19 immunization inquiries regarding children age 5–11 years received by NIP-INFO, the Centers for Disease Control and Prevention's (CDC's) e-mail immunization inquiry service for health care professionals, at the launch of vaccination efforts for this age group, using descriptive qualitative analysis. From November 2 through November 30, 2021, NIP-INFO responded to 154 questions regarding COVID-19 vaccination for 5–11-year-old children. The most common questions related to formulation and dosage (39.6%), vaccination schedule (14.3%), CDC's educational materials for health care professionals (9.1%), and vaccine safety (8.4%); 16.2% of questions across all inquiry categories related to a vaccination error. We discuss CDC guidance related to the most common inquiries to inform further pediatric COVID-19 vaccination efforts, including future vaccination of younger pediatric age groups, which will be important to help to curb this pandemic.

KEYWORDS
pediatric nursing, public health nursing education, nursing education, vaccination

1 | BACKGROUND

On October 29, 2021, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine for children age 5–11 years (FDA, 2021b). The Advisory Committee on Immunization Practices (ACIP) published interim recommendations on November 2, 2021 (CDC, 2021). This vaccine is administered to children via intramuscular (IM) injection as a 2-dose series (10 μg, 0.2 ml each), with 21 days between doses (FDA, 2021). Despite these recommendations, COVID-19 vaccination coverage among children remains lower than that in older age groups. As of March 18, 2022, 34.0% of children age 5–11 years had received at least one COVID-19 vaccine dose, compared to 68.2% of adolescents age 12–17 years and between 77.2% and 95.0% for adults age 18 years or older, with increasing coverage in older age groups[1] (CDC, 2022).

NIP-INFO (nipinfo@cdc.gov) is a CDC e-mail immunization inquiry response service staffed by physicians, nurses, and health educators. Health care professionals, public health professionals, and the general public can submit immunization inquiries, including inquiries related to COVID-19 vaccination, to NIP-INFO. NIP-INFO staff respond to inquiries based on CDC or ACIP guidance, generally within 24 hours of inquiry receipt. To inform further pediatric COVID-19 vaccination efforts, we sought to describe COVID-19 immunization inquiries regarding vaccination of children age 5–11 years which were submitted to NIP-INFO at the launch of vaccination efforts for this age group.

[1] As of March 21, 2022

TABLE 1 Question categories and examples

Question category	Number (percentage) of questions received by providers (health care and public health) ($n = 117$)	Number (percentage) of questions received by the general public ($n = 37$)	Example
Administration	6 (5.1%)	1 (2.7%)	What is an acceptable alternative injection site to the deltoid muscle for a child?
Coadministration	5 (4.3%)	1 (2.7%)	Can children receive COVID-19 vaccine and another vaccine on the same day?
Educational materials	14 (12.0%)	0 (0.0%)	When will CDC be updating the health care professional COVID-19 vaccine clinical educational materials?
Formulation and dosage	44 (37.6%)	17 (45.9%)	What product should a child receive if they turn 12 years old between the first and second dose?
Law and policy	8 (6.8%)	0 (0.00%)	Is consent required to vaccinate a minor?
Preparation	7 (6.0%)	2 (5.4%)	Can the 10 ml diluent vials be entered multiple times?
Record	1 (0.9%)	2 (5.4%)	What are vaccine requirements for children to enter the United States?
Safety	4 (3.4%)	9 (24.3%)	Is the post-vaccination observation period required for children?
Schedule	17 (14.5%)	5 (13.5%)	What is the recommended interval for vaccination after a child has COVID-19 disease?
Storage	11 (9.4%)	0 (0.0%)	What is the beyond-use date of the pediatric formulation?
Total	117 (100%)	37 (100%)	

2 | METHODS

NIP-INFO e-mail inquiries received from November 2 to 30, 2021 were used for this descriptive qualitative analysis. Data were coded for vaccine-type by trained staff who respond to inquiries and further cleaned through a standardized process. E-mail inquiries regarding COVID-19 were exported and reviewed to create the final dataset that included inquiries about COVID-19 vaccination for children age 5–11 years or the formulation for this age group. This final dataset of inquiries was further reviewed to identify and disaggregate inquiries that included multiple questions in a single e-mail message. A codebook was developed deductively using a priori codes for topics commonly received by NIP-INFO and inductively using e-mail text to identify emerging codes. The questions were reduced and clustered, resulting in 10 mutually exclusive and collectively exhaustive categories describing the inquiries received (Table 1). Questions were also reviewed and coded by inquirer type (health care professionals, public health professionals, general public). Health care professionals include physicians, nurses, pharmacists, and medical assistants who work for an entity other than a public health agency, while public health professionals include individuals working for a local or state health department or federal health agency. Other inquirers were coded as general public. For intercoder agreement and reliability, two coders analyzed data independently. No significant discrepancies were found, and any differences were resolved through discussion to create the final set of categories. Summary data analysis was conducted to determine frequency of questions by topical category and inquirer type. This activity was reviewed by The National Center for Immunization and Respiratory Diseases' Human Subjects Contact Reviewer and determined to not meet the definition of research as defined in 46.102(l), and therefore did not require Institutional Review Board (IRB) review.

3 | RESULTS

NIP-INFO responded to a total of 147 unique inquiries regarding 5–11-year-old COVID-19 vaccine, representing 16.3% of all inquiries ($n = 903$) and 24.1% of COVID-19 vaccine inquiries ($n = 609$). Some e-mail messages contained multiple questions, resulting in a total of 154 COVID-19 vaccine questions pertaining to 5–11-year-olds; this total was used for all subsequent analyses. Errors accounted for 16.2% of all questions regarding vaccination of 5–11-year-olds.

Formulation and dosage questions were the most common question type, accounting for 39.6% of questions (Figure 1). Questions in this category typically related to age-appropriate formulation and dosage for children ages 11 and 12 years (and those turning 11–12 years between doses) (50.8% of this category), why vaccine dosage is age-based rather than weight-based (24.6%), and actions to take in the event of administration of the incorrect formulation (23.0%). Other frequent categories included vaccination schedule (14.3%), CDC's educational materials for health care professionals (9.1%), and vaccine safety (8.4%).

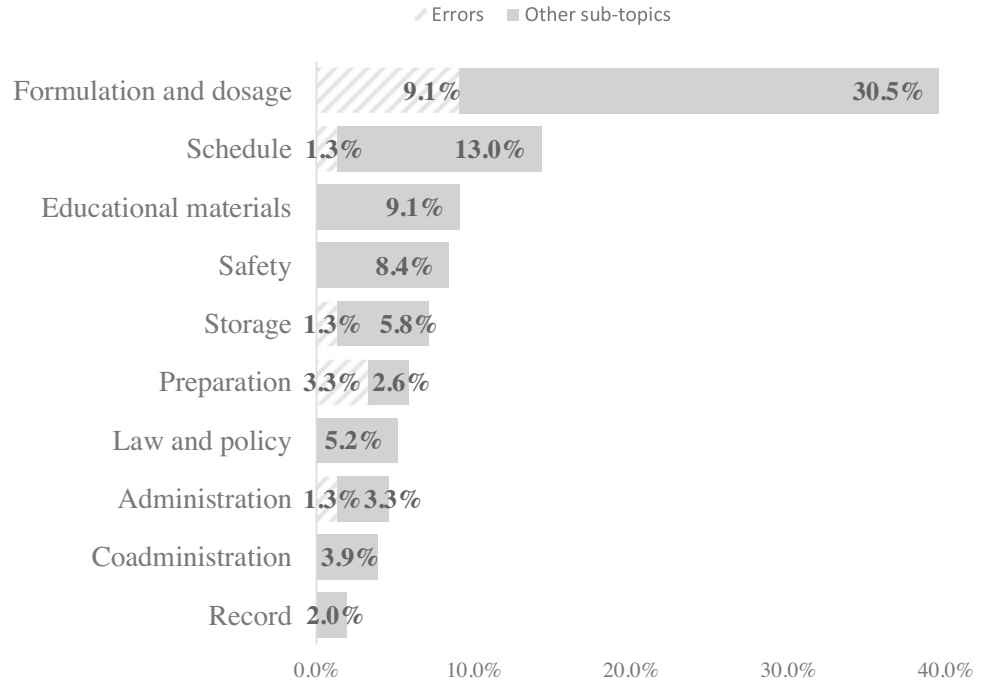

FIGURE 1 Question categories and proportion related to errors

Most questions were from health care professionals (52.6%, $n = 81$), followed by the general public (24.0%, $n = 37$), and public health professionals (23.4%, $n = 36$). Formulation and dosage questions were the most common topic for each of the inquirer types.

4 | DISCUSSION

Findings of this study reveal key themes that characterize questions providers and the public raise as COVID-19 vaccine is expanded to younger age groups. Not surprisingly, questions regarding formulation and dosage accounted for the majority of questions regarding Pfizer-BioNTech COVID-19 vaccine for 5–11-year-olds, and errors accounted for 23.0% of formulation and dosage questions. Important differences exist for COVID-19 vaccine formulation and dosage between the 12 years or older age group and the 5–11 years age group. The formulation for children age 5–11 years is supplied in a vial with an orange cap; each 0.2 ml dose contains 10 μg of modified mRNA. The formulation for persons age 12 years or older is supplied in a vial with a purple cap; each 0.3 mL dose contains 30 μg of modified mRNA (FDA, 2021c). Since the time the pediatric formulation was authorized, another adolescent and adult formulation has become available (gray cap).

Common themes among the formulation and dosage inquiries related to using the 12 years or older formulation or dosage for an 11-year-old whose weight was large for their age, or vice versa. In contrast to many pediatric medications, vaccine dosages (for COVID-19 vaccines and other routinely recommended vaccines) are based on age and not weight (Hall et al., 2021; Kroger et al., 2021). CDC recommends that children should receive the age-appropriate vaccine formulation and dosage based on their age on the day of vaccination (CDC, 2021b). Therefore, a child who turns 12 years of age between dose 1 and dose 2 would typically receive a different formulation and dosage for each of their doses. However, the FDA authorization does allow, for children who turn from 11 years to 12 years of age between their first and second doses, to receive, for either dose, either 10 μg Pfizer-BioNTech COVID-19 Vaccine (orange cap; 0.2 ml) or 30 μg Pfizer-BioNTech COVID-19 Vaccine (purple cap; 0.3 ml) (FDA, 2021).

Schedule questions accounted for 14.3% of questions regarding 5–11-year-olds. Inquirers commonly had questions about the time interval between COVID-19 infection and vaccination. COVID-19 vaccination is recommended, regardless of a history of COVID-19 infection, including for children age 5–11 years old, although current evidence about the optimal timing between COVID-19 infection and vaccination is insufficient to inform guidance (CDC, 2021). A moderate or severe acute illness is a precaution for any vaccination; as such, persons with a current COVID-19 infection should have vaccination deferred until they have recovered from their acute illness and criteria to discontinue isolation have been met (Kroger et al., 2021). Another common question related to the 4-day grace period. As with routine immunizations, a COVID-19 vaccine dose administered within 4 days earlier than the recommend interval does not need to be repeated. However, the 4-day grace period should not be used to prospectively schedule doses (CDC, 2021; Kroger et al., 2021).

Questions regarding coadministration of COVID-19 vaccines with other vaccines are especially relevant for children, particularly younger children, as coadministration of all vaccines for which a person is eligible increases the probability that a person will be up to date with recommended vaccinations (Hall et al., 2021; Kroger et al., 2021; Schilling et al., 2015). COVID-19 vaccines and other vaccines (including live attenuated and nonlive vaccines) may be administered on the same day or separated by any interval (CDC, 2021). If multiple injections are administered at a single visit, each vaccine should be administered in a

different injection site. COVID-19 vaccine should be administered in a different limb, if possible, from vaccines likely to cause a local reaction (e.g., tetanus-toxoid-containing vaccines). While the deltoid muscle is the preferred site for IM vaccine injections in persons age 3 years and older, the vastus lateralis muscle in the anterolateral thigh is an acceptable alternative injection site for all age groups. ACIP recommends, for younger children, if more than two vaccines are injected in a single limb, the thigh is the preferred site because of the greater muscle mass. For older children the deltoid muscle can be used for more than one intramuscular injection (CDC, 2021; Hall et al., 2021; Kroger et al., 2021). In contrast to some routine immunizations, if a COVID-19 vaccine is erroneously administered at an incorrect anatomic site (e.g., gluteal site) or by an incorrect route (e.g., subcutaneously), repeating the dose is NOT recommended (CDC, 2021).

Achieving high COVID-19 vaccination coverage in children is critical to prevent infection in children and transmission within the community (Wanga et al., 2021). The questions received by NIP-INFO reflect vaccine providers' unanswered concerns for children age 5–11 years as they implement vaccine roll-out. The themes covered in this study help to inform potential questions providers may raise as vaccine is expanded to younger pediatric populations and can be used to develop communication and education materials for further pediatric COVID-19 vaccination efforts. Efforts to maximize the proportion of people in the United States who are up to date with their COVID-19 vaccines remain critical to ending the COVID-19 pandemic.

CONFLICTS OF INTEREST

The authors wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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