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BRIEF REPORT

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Analysis on the characteristics of delayed EV71 vaccination among children in the birth cohort from 2017 to 2022

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ABSTRACT

To analyze the changes in the proportion of Human enterovirus 71 (EV71) vaccination among children born in the 2017–2022 cohort, understand the delay of the first dose of EV71 vaccination in Suzhou, and explore the seasonal distribution and influencing factors of EV71 vaccination among children born in the 2017–2022 cohort. Personal information and EV71 vaccination information of registered children born between January 1, 2017 and December 31, 2022 in Suzhou were collected through the children module of Jiangsu Province Immunization Service Management Information System. The quantitative characteristics and influencing factors were analyzed by ecological research and descriptive epidemiology. The proportion of children born during 2017–2022 who received at least one-dose EV71 vaccination ranged from 21.9% to 32.5%, and full course of EV71 vaccination proportion ranged from 20.6% to 32.1%. In addition, with the exception of the 2017 birth cohort, the number of EV71 vaccination in the 2018–2022 birth cohort reached its peak at 11 months of age. There were 10,497 children (5.0%) who received the first dose at 6 months of age (recommended starting month), and 98,918 children (47.1%) who received the first dose at 7 to 12 months of age. The extended duration M (P_{25}, P_{75}) was 70 (27, 102) days. Regarding the recommended vaccination season, the distribution of inoculation season was not consistent with the actual season, and most of them were delayed by one season. Summer and autumn seasons were associated with timely vaccination, while the winter was the main delay season. The overall EV71 vaccination proportion among children born in Suzhou from 2017 to 2022 was low, but among those who initiated vaccination, completion of the two-dose schedule was high. The timeliness of the first EV71 vaccination was poor and associated by the seasons. Emphasize the dissemination of knowledge about seasonal associations of EV71 to enhance confidence in EV71 vaccination.

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Introduction

Hand foot and mouth disease (HFMD) is a contagious disease caused by enteroviruses. Various pathogens can cause infection, such as human enterovirus 71 (EV71), coxsackievirus A16 (CVA16), and coxsackievirus A6 (CVA6).[1,2] The incubation period averages 3 to 5 d and the primary susceptible group is children under 5 y old. Furthermore, the typical symptoms usually manifest as characteristic herpes on the hands, feet, and mouth. HFMD has a strong contagiousness and multiple transmission routes, which can be infected through close contact with the secretions of infected persons and contaminated articles. HFMD is one of the diseases with high incidence rate among the category C infectious diseases.[3]

Following the inclusion of HFMD into Chinese Category C notifiable infectious disease management system in 2008, the average annual reported incidence rate for the period 2008–2017 was 134.75 per 100,000 population, with an average annual reported mortality rate of 0.027 per 100,000 population.[4] EV71 vaccination is a non-National Immunization Program (non-NIP) vaccination and has been licensed in China since 2016. Studies have demonstrated a protective efficacy exceeding 90% against EV71 associated HFMD, and EV71 vaccination confers significant protection against EV71

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infection.[5,6] Three types of EV71 vaccination are currently in use in Suzhou, including Sinovac Biotech Ltd., Wuhan Institute of Biological Products Co., and Institute of Medical Biology, Chinese Academy of Medical Sciences.[5,7,8] Three types of EV71 vaccination are administered in two doses, with an interval of 1 month. The starting age for vaccination is 6 months old. The protective efficacy of the three vaccines against HFMD caused by EV71 was more than 90%, showing good and protective effect. The number of HFDM deaths have shown a downward trend with the improvement of vaccine coverage.[9,10] According to the national notifiable disease statistics, the HFMD mortality rate decreased to 0.0006 per 100,000 population in 2021, and further declined to 0.0001 per 100,000 population in 2023.[11]

HFMD exhibits distinct periodicity and seasonality within China, characterized by a bimodal peak pattern. The primary epidemic peak occurs during spring and summer (April–July), while a secondary surge is observed in the autumn (October–November).[12] Previous studies have demonstrated that meteorological factors can influence HFMD incidence,[13] however, studies investigating potential seasonal trends in EV71 vaccination uptake remain limited. Therefore, this study analyzed the EV71 vaccination status among children born in Suzhou from 2017 to 2022. And this study explored the factors influencing parental decisions regarding EV71 vaccination and provided reference for optimizing the prevention and control measures of HFMD.

Method

Children registered in Suzhou City with birth dates ranging from January 1, 2017, to December 31, 2022, were selected as the study cohort from the Jiangsu Province Immunization Service Management Information System. Date of personal information and EV71 vaccination information were collected. The EV71 vaccination of children across different birth cohorts was stratified and analyzed according to different attributes. The deadline for vaccination data was July 31, 2024. Seasonal classifications were operationally defined as follows based on the solar calendar months: March, April and May of the whole year are defined as spring; June, July and August are summer months; September, October and November are autumn; December, January and February are designated as winter. The seasonal vaccination status was calculated according to the monthly distribution of vaccination time. The recommended vaccination time was defined as 6 months of age, and the season for administering the vaccines was inferred. Data management and statistical analyses were conducted using WPS Office and SPSS 21.0. The delay time of first-dose EV71 vaccination was presented as median (M) with interquartile range (IQR). Vaccination proportions were analyzed using the χ^2 test, with statistical significance defined at $P < .05$.

Vaccination Proportion Calculation:

Annual EV71 vaccination proportion (%) = Number of EV71 vaccination doses in the annual birth cohort/Total children in the annual birth cohort × 100%

Proportion for a specific vaccine dose within a birth cohort (%) = Number of children receiving the specified EV71 vaccination dose within the annual cohort/Total children in the annual birth cohort × 100%

Total children in the annual birth cohort were derived from children registered in Jiangsu Province Immunization Service Management Information System. Timely vaccination was defined as completion of the first-dose EV71 vaccination at 6 months of age. Currently, vaccination rate was used to calculate the vaccine of the National Immunization Program (NIP) in China. To facilitate comparison and description, this study adopts the term "vaccination proportion." Its definition is derived by analogy to the formula used for calculating the NIP vaccination rate.

Results

Study population and characteristics

The proportion of children born during 2017–2022 who received at least one dose EV71 vaccination ranged from 21.9% to 32.5%, and the proportion varied greatly among different cohorts ($\chi^2 = 5404.304$, $P < .001$). Full course of EV71 (two doses) vaccination proportion ranged from 20.6% to 32.0%, and vaccination

Table 1. Information of EV71 vaccination of children born in Suzhou from 2017 to 2022.

		Receive at least one dose				Full course of EV71 vaccination			
Birth year	Number of total children	Number of children vaccinated	Proportion (%) (95%CI)	χ^2	*P*	Number of children vaccinated	Proportion (%) (95%CI)	χ^2	*P*
2017	157,730	34,535	21.9 (21.7–22.1)	5404.304	<.001	32534	20.6 (20.4–20.8)	6083.904	<.001
2018	134,988	34,310	25.4 (25.2–25.6)			32719	24.2 (24.0–24.5)		
2019	136,623	34,160	25.0 (24.8–25.2)			33671	24.6 (24.4–24.9)		
2020	112,374	36,541	32.5 (32.2–32.8)			36010	32.0 (31.8–32.3)		
2021	101,172	31,251	30.9 (30.6–31.2)			30790	30.4 (30.1–30.7)		
2022	91,492	27,233	29.8 (29.5–30.1)			25726	28.1 (27.8–28.4)		

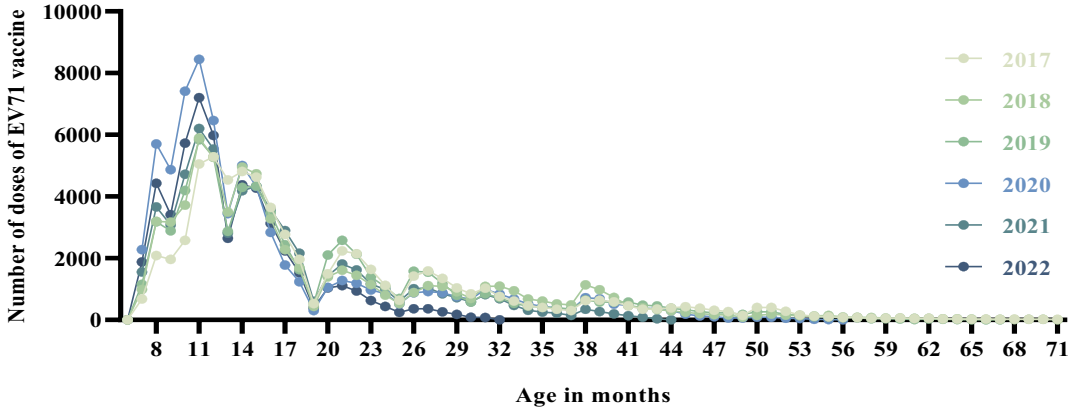

Figure 1. Distribution of EV71 vaccination age among children born in Suzhou from 2017 to 2022.

proportion increased from 2017, peaked in 2020, followed by a subsequent decline ($\chi^2 = 6083.904$, $P < .001$), as shown in Table 1.

Distribution of age at EV71 vaccination

Across birth cohorts from 2018 to 2022, the number of EV71 vaccination reached the peak at the age of 11 months, and the EV71 vaccination proportion at the age of 11 months was 8.8%, 8.6%, 11.6%, 10.1% and 13.6%, respectively. The 2017 birth cohort peaked at 12 months of age, as shown in Figure 1.

Distribution of delay in the first-dose EV71 vaccination

Among children born in Suzhou from 2017 to 2022, 10,497 (5.0%) children had their first-dose EV71 vaccination in a timely manner according to recommendations at 6 months of age. In total, 98,918 children received the vaccination at 7–12 months of age, accounting for 47.1%, the median (interquartile range) extended duration was 70 d (range 27, 102), as shown in Table 2.

Table 2. Distribution of delay in the first-dose EV71 vaccination among children born in Suzhou from 2017 to 2022.

	First-dose EV71 vaccination		
Vaccination age (month)	Number of children vaccinated	Proportion (%)	Extended duration, day [*M* (P_{25}, P_{75})]
6	10,497	5.0	–
7–12	98,918	47.1	70 (27, 102)
13–24	66,496	31.7	242 (194, 364)
≥25	34,169	16.3	733 (604, 938)

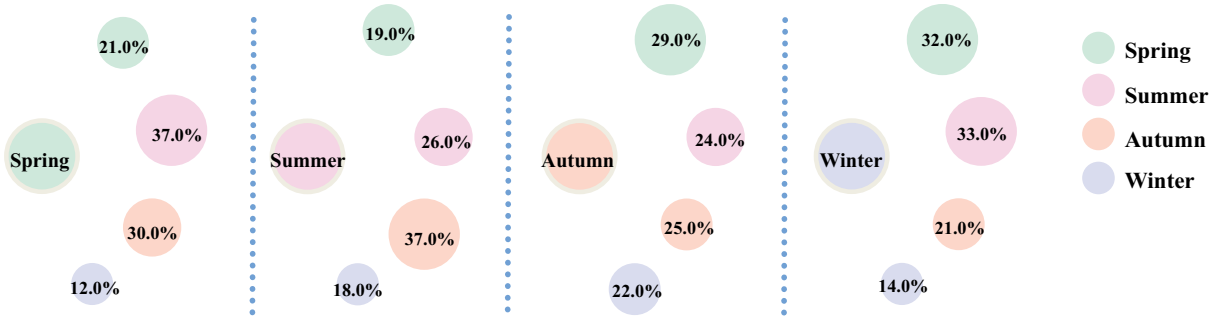

Figure 2. Seasonal distribution of recommended and actual EV71 vaccination among children born in Suzhou from 2017 to 2022.

Seasonal distribution of EV71 vaccination

The distribution of actual EV71 vaccination seasons consistently lagged behind the recommended seasonal windows by one season. For vaccinations recommended in spring: 21.0% children received doses on schedule (spring), 37.0% children completed vaccination with mild delay (summer), 30.0% children completed with moderate delay (autumn); 12.0% children completed with severe delay (winter). For vaccinations recommended in summer: 26.0% children received doses on schedule (summer), 37.0% children completed with mild delay (autumn), 18.0% children completed with moderate delay (winter), 19.0% children completed with severe delay (spring of the following year). The proportion of EV71 vaccination according to children recommended seasonal was as follows: summer (26.0%) > autumn (25.0%) > spring (21.0%) > winter (14.0%), as shown in Figure 2.

Discussion

The incidence rate of HFMD in Suzhou during 2017–2019 consistently exceeded 150.00/100,000,[14] significantly higher than the national incidence rate of HFMD (137.34/100,000) from 2015 to 2020.[3] The incidence rate showed a fluctuating decline in the following y. The HFMD incidence rate in Suzhou dropped to 122.58/100,000 in 2021, which was lower than the average reported incidence rate of 138.85/100,000 in Hangzhou from 2010 to 2023,[15] but higher than 84.42/100,000 in Shenzhen in 2020.[16] EV71 vaccination is an effective strategy for preventing HFMD caused by EV71. Since 2016, three types of EV71 vaccination have been launched in China, with the basic immunization program consisting of two doses, and the vaccination age range is from 6 months to 5 y.

The EV71 vaccination proportion of children born in Suzhou from 2017 to 2022 was lower than that of Shenzhen from 2017 to 2020 (45.6%–78.8%).[16] This discrepancy may reflect regional differences in vaccine accessibility and public awareness. In this study, the proportion of children born during 2017–2022 who received at least one-dose EV71 vaccination and full course of EV71 vaccination proportion were comparable to those of the Lianyungang birth cohort (24.34%–35.1%/20.9%–31.8%),[17] but lower than those in Shanghai (39.3%/35.1%).[18] Despite the vaccination proportion is on the rise, the coverage proportion of this non-NIP vaccination is still lower than that in economically developed regions. The coverage proportion of non-NIP vaccines was affected by many factors such as parents' education level, vaccine price, service quality and vaccination schedule.[19,20] In terms of vaccination schedule, studies have shown that EV71 vaccination can be administered at the same time as several vaccine, with good immunogenicity and safety.[21] Furthermore, the decline in the proportion of EV71 vaccination after 2020 may be attributed to the following reasons: (1) Association with the COVID-19 pandemic. Restrictions such as lockdowns prevent willingness for non-emergency vaccination.[22] (2) Shift in vaccine market dynamics. Due to the decreasing population base and the development of vaccine technology, the vaccine market has gradually shifted to adults.[23] (3) Pronounced vaccine hesitancy. The proliferation of misinformation and disinformation around vaccine safety and efficacy has led to a decline in vaccine uptake.[24] (4) Increased economic burden. After COVID-19, the number of unemployed

people has increased, and the family economic burden has increased6. High cost of non-NIP vaccines was a primary factor influencing vaccination.[25] (5) Change in viral dominance. The predominant pathogen causing HFMD has shifted from EV-A71 to CVA6 in recent y.[26] Additionally, studies have shown that the protection rate after completing two doses of EV71 vaccination is higher than that of a single dose.[27] Thus, improving the full-course vaccination proportion has a positive effect on reducing HFMD incidence and severe outcomes. This study found that the full vaccination proportion of EV71 vaccination was almost the same as the first dose vaccination proportion, indicating that parents in Suzhou have a high awareness of completing the full vaccination of EV71 vaccination and good compliance. This high adherence may be attributed to the simple immunization program of EV71 vaccination, the short interval between the two doses, and the appropriate price.

The EV71 vaccination of children in Suzhou was concentrated in the 8–17 month old age group, and the 11-month-old age was the peak vaccination time. The vaccination trend was consistent with the research results of Zhangjiagang city.[28] Although this study extracted data prior to July 2024, the children born in 2023 were not included in it. This was related to the fact that most children chose to receive EV71 vaccination at the age of 11 months, which would result in data loss for the 2023 birth cohort. The three types of EV71 vaccinations currently available in China all recommend vaccination after 6 months. However, this study showed that the timely rate of vaccination at 6 months was relatively low. This may be related to the high number of vaccines scheduled within the NIP at the 6-month mark, creating potential scheduling conflicts. While children under 5 y old are universally susceptible to HFMD, the peak incidence occurs predominantly in the 1–2 y age group.[4] Delaying the first dose consequently postpones the completion of the full vaccination course. This delay means the vaccine cannot exert its maximal protective effect during the period of highest disease risk. Therefore, it is recommended to strategically coordinate the timing of NIP and non-NIP vaccinations to facilitate the early completion of the EV71 vaccination series.

Jiangsu province exhibits a bimodal pattern for HFMD, with the summer peak being higher than the autumn peak.[29] Some studies have also shown that meteorological factors such as temperature, humidity, and wind speed are closely related to the incidence of HFMD. Specifically, for every 1°C increase in monthly average temperature, the number of cases is projected to increase by 6%,[30] and relative humidity shows a positive correlation with HFMD incidence.[31] This study revealed a seasonal distribution of EV71 vaccinations as follows: summer > autumn > spring > winter, suggesting that winter is an obstacle factor affecting the timely vaccination. Summer and autumn serve as facilitating factors for timely vaccination. This may be related to the following reasons: (1) Stronger Vaccination Willingness. HFMD is a viral disease of the digestive tract, and parents are more willing to have their children vaccinated in the summer and autumn. Conversely, winter, characterized by colder weather, sees lower activity of enteroviruses and a reduced incidence of enteric-related diseases. (2) Better Physical Fitness for Vaccination. The climate in summer and autumn is generally more favorable, and children tend to be in better health with a lower likelihood of suffering from respiratory illnesses, making them more suitable candidates for vaccination. (3) Favorable Weather Conditions Facilitating Travel. The EV71 vaccination is a non-NIP vaccine and is voluntarily and self-funded for vaccination. Parents may be willing to choose to vaccinate when the temperature, humidity, and wind speed are suitable. In addition, parents have a strong awareness of supplementary vaccination, and most of them delay the supplementary vaccination by one season. Hence, increasing the publicity of knowledge about diseases caused by enteroviruses can enhance parents' acceptance of vaccines.

This study has several limitations. When calculating vaccination proportions, the denominator was defined as the total number of children registered in Jiangsu Province Immunization Service Management Information System, rather than using census-based population data. This approach may introduce selection bias. In analyzing the seasonal distribution of vaccinations, a uniform 90-d duration was applied to each three-month season, which may lead to measurement errors in seasonal classification. Additionally, children born in 2022 had a shorter follow-up time, which may lead to an underestimation of their ultimate vaccination proportion. This study was primarily based on vaccination proportion data and demographic statistics and did not collect individual-level data on the drivers of vaccination decisions. This lack of data limits an in-depth exploration of the complex decision-making mechanisms underlying vaccination behaviors.

In conclusion, the EV71 vaccination proportion in Suzhou was low and associated with seasonal variation. Therefore, it is recommended to intensify publicity efforts regarding the seasonal transmission patterns of HFMD, strengthen parental recognition of EV71 risks, so as to strengthen the confidence of EV71 vaccination and ensure the effective prevention of HFMD.

Author contributions

CRediT: **Jinling Gao:** Project administration, Writing – original draft, Writing – review & editing; **Na Liu:** Conceptualization, Project administration, Writing – original draft, Writing – review & editing; **Kunpeng Zhu:** Project administration, Supervision; **Lin Luan:** Formal analysis, Methodology, Project administration; **Juan Xu:** Formal analysis, Methodology, Project administration; **Yiheng Zhu:** Project administration, Resources, Supervision; **Xianquan Fan:** Project administration, Resources, Supervision; **Haitao Wang:** Conceptualization, Writing – review & editing.

Disclosure statement

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Suzhou Municipal Health Commission [No. GSWS2023065].

Notes on contributor

Haitao Wang, associate chief physician of Suzhou Center for Disease Control and Prevention, China, mainly engaged in the prevention and control of infectious diseases.

Ethics approval statement

The study was approved by the Medical Science Research Ethics Committee of Suzhou Center for Disease Control and Prevention (NO. SZJKMG2024–007). An informed consent waiver has been applied for this study.

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