



Published in final edited form as:

Vaccine. 2025 April 30; 54: 126891. doi:10.1016/j.vaccine.2025.126891.

Concordance between parent-reported and documented COVID-19 vaccination status among hospitalized children and adolescents: Implications for vaccine effectiveness estimates, May 2021–October 2023

Sarah Hamid^{a,b,*}, Regina M. Simeone^b, Margaret M. Newhams^c, Natasha Halasa^d, Katherine E. Fleming-Dutra^b, Amber O. Orzel-Lockwood^c, Michael J. Wu^b, Adrienne G. Randolph^{c,e}, Angela P. Campbell^b, Laura D. Zambrano^b, Overcoming COVID-19 Investigators¹

^aEpidemic Intelligence Service, Centers for Disease Control and Prevention, Atlanta, GA, United States

^bCoronavirus and Other Respiratory Viruses Division, National Center for Immunization and Respiratory Diseases, CDC, Atlanta, GA, United States

^cDepartment of Anesthesiology, Critical Care, and Pain Medicine, Boston Children's Hospital, Boston, MA, United States

^dDivision of Pediatric Infectious Diseases, Department of Pediatrics, Vanderbilt University Medical Center, Nashville, TN, United States

^eDepartments of Anaesthesia and Pediatrics, Harvard Medical School, Boston, MA, United States

Abstract

Background: During the U.S. COVID-19 Public Health Emergency (PHE), healthcare providers were required to report all administered COVID-19 vaccines in Immunization Information Systems (IIS), a key data source for vaccine effectiveness (VE) evaluations. Expiration of the PHE and commercialization of COVID-19 vaccines raised concerns about IIS data completeness. Parental report is an alternative source of vaccination data but might be inaccurate.

This is an open access article under the CC BY-NC license (<http://creativecommons.org/licenses/by-nc/4.0/>).

*Corresponding author at: 1600 Clifton Rd NE, Atlanta, GA 30333, United States. shamid@cdc.gov (S. Hamid).

¹Overcoming COVID-19 Investigators: Michele Kong, Katherine Irby, Ronald C. Sanders, Melissa A. Cameron, Matt S. Zinter, Natalie Z. Cvijanovich, Pia S. Pannaraj, Kanokporn Mongkolrattanothai, Aline B. Maddux, Ivan Gonzalez, Satoshi Kamidani, Kelly N. Michelson, Bria M. Coates, Samina S. Bhumbra, Tamara T. Bradford, Sabrina M. Heidemann, Janet R. Hume, Emily R. Levy, Charlotte V. Hobbs, Jennifer E. Schuster, Melissa L. Cullimore, Shira J. Gertz, Melissa S. Stockwell, Thomas J. Connors, Stephanie P. Schwartz, Tracie C. Walker, Ryan A. Nofziger, Mary Allen Staat, Katherine Blin, Elizabeth H. Mack, Austin Biggs, Julie A. Boom, Leila C. Sahni, Hillary Crandall

CRedit authorship contribution statement

Sarah Hamid: Writing – review & editing, Writing – original draft, Visualization, Methodology, Formal analysis, Conceptualization.

Regina M. Simeone: Writing – review & editing, Project administration, Methodology. **Margaret M. Newhams:** Project

administration, Data curation. **Natasha Halasa:** Writing – review & editing, Investigation. **Katherine E. Fleming-Dutra:**

Writing – review & editing. **Amber O. Orzel-Lockwood:** Project administration. **Michael J. Wu:** Data curation. **Adrienne G.**

Randolph: Writing – review & editing, Funding acquisition. **Angela P. Campbell:** Writing – review & editing, Supervision,

Project administration, Conceptualization. **Laura D. Zambrano:** Writing – review & editing, Supervision, Project administration, Methodology, Data curation, Conceptualization.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.vaccine.2025.126891>.

Methods: Using VE surveillance network data during May 2021–October 2023, we compared parent-reported and documented COVID-19 vaccine doses for patients aged 5–18 years admitted to 35 hospitals in 25 states, overall and by case/control status. We calculated percent agreement, kappa, sensitivity, specificity, and positive and negative predictive value (NPV) of parental report. We compared proportions of patients with discordant vaccination history by demographics and incident SARS-CoV-2 infection status. We estimated VE separately using parental report and independently documented sources.

Results: Among 3262 patients, agreement between parent-reported and documented COVID-19 vaccination doses was 88 % (kappa = 0.77). Most discordant pairs (346/390) were because of parental over-reporting of doses. Among patients documented as unvaccinated, most (specificity = 90 %) were reported as such by parents; nearly all reported as unvaccinated by parents had no documented vaccination (NPV = 99 %). Discordance decreased with shorter admission-to-interview intervals and varied regionally from 8 % in the Midwest to 16 % in the West. Proportions of discordant reports were similar between patients with and without SARS-CoV-2 infection (11 % vs 13 %). Median days from last vaccine dose to hospital admission was 167 (IQR: 86–288). VE of two doses (99 % original formula) against COVID-19–related hospitalization was 58 % using documented sources and 60 % using parental report.

Conclusions: Parental report of COVID-19 vaccination agreed strongly with documented sources, especially among unvaccinated patients. Despite discrepancies from parental overreporting, VE estimates from both sources were similar. As reliance on parental report increases, reducing admission-to-interview time is important for accurate vaccination history.

Keywords

Concordance; COVID-19 vaccination; Registry; Parental report; Vaccine effectiveness; Bias

1. Introduction

Accurate documentation of COVID-19 vaccination is essential for monitoring vaccine uptake and assessing vaccine effectiveness (VE) in real-world conditions [1]. In the United States, VE evaluations have used self-reported vaccination history and documented sources, such as state immunization information systems (IIS), electronic medical records, pharmacy records, and vaccination cards [2–6]. During the COVID-19 Public Health Emergency (declared on January 31, 2020), providers were required to report vaccine administration into jurisdictional IISs [7–9], making it a key data source for VE analyses. However, this federal reporting requirement was lifted following the conclusion of the COVID-19 Public Health Emergency in May 2023 [10] and subsequent commercialization of COVID-19 vaccines, raising concerns about completeness and validity of IIS vaccination records.

To address these concerns, alternative sources of vaccination data have been considered. Self-report, wherein the patient or a proxy verbally provides a history of prior vaccination, is one such alternative. However, relying on self-report may introduce misclassification of vaccination status due to factors such as recall and social desirability bias. If misclassification of vaccine exposure is non-differential and independent of other errors it would bias VE estimates towards the null [11,12]. If incident SARS-CoV-2 infection

influences parental reporting of vaccination status (i.e., differential misclassification between case-patients and control-patients), estimates could be biased in either direction [11–13]. Thus, the World Health Organization recommended against the use of self-reported COVID-19 vaccination as the sole source indicating that a person is vaccinated in COVID-19 VE evaluations [1]. Nevertheless, previous evaluations among adults have found high agreement between self-reported and documented COVID-19 vaccination status [14–16]. These analyses were conducted early in the pandemic when the shorter time between vaccination and hospitalization, along with fewer doses received, likely made recall more accurate. Additionally, they did not include children and adolescents whose parents or guardians report their vaccination status.

Studies of influenza vaccination have found that parental report of vaccination is highly sensitive; a high percentage of children with documented vaccine receipt also had parental report of vaccination [17,18]. However, parental report is less specific; it tends towards false positives in which parents of unvaccinated children incorrectly report that their child received an influenza vaccine [17,18]. Notably, simulation studies of influenza VE have shown that the use of self-reported vaccination history can meaningfully bias VE in test-negative studies, especially when the specificity of self-report is low [19]. Therefore, reviewing immunization records is considered the preferable method for determining vaccination status in children. Validating self-reported data is important when documented sources are not available.

To assess the validity of parent-reported COVID-19 vaccination during and after the U.S. COVID-19 Public Health Emergency, we compared parent-reported COVID-19 vaccination status to documented sources among hospitalized children. Additionally, we compared VE estimates using parent-reported vaccination data only with estimates based on documented vaccination data only. Understanding the implications of relying on parental report is important for accurate COVID-19 vaccination coverage and effectiveness assessment, especially if documentation declines in the post-emergency period.

2. Methods

2.1. Study population and setting

We used data from the Overcoming COVID-19 Network, a multistate surveillance network that conducts analyses of VE against COVID-19-related hospitalizations [20]. This analysis included hospitalized children and adolescents aged 5–18 years admitted to 35 participating hospitals and medical centers in 25 states from May 16, 2021 through October 29, 2023. Site personnel screened medical charts and SARS-CoV-2 specimen test results daily at participating sites to identify hospitalized patients eligible for enrollment. Patients admitted to the hospital for an acute illness and who tested positive for SARS-CoV-2 by nucleic acid amplification test (NAAT) or antigen test at the time of admission were included as COVID-19 case-patients. Control patients hospitalized for COVID-19–like illness were matched to case-patients (1:1) by site, age group (5–11 years, 12–15 years, 16–18 years inclusive) and date of hospital admission ($\pm$ 3 weeks), but received a negative SARS-CoV-2 test result by NAAT during or $\leq$ 7 days before hospital admission, with no positive NAAT/antigen test result <3 days after hospitalization. Patients with multisystem

inflammatory syndrome in children (MIS-C) were excluded. During hospitalization or after discharge, baseline demographic characteristics, clinical information, SARS-CoV-2 testing history, and COVID-19 vaccination history were obtained through parent or guardian interviews, and review of the patient's electronic medical record.

2.2. COVID-19 Vaccination History

Proof of vaccination was collected from several sources. Parent-reported vaccination data, including the number of doses received and vaccine manufacturer, were collected through structured in-person or telephone interviews. Study personnel also reviewed state vaccination registries, electronic medical records, or sources including documentation from primary care providers, schools, and pharmacy records. Documented vaccination was defined as vaccination status recorded on one or more of the following sources: COVID-19 vaccine card, hospital electronic medical record, state IIS (viewed at the time of parent interview), and documentation from primary care providers. If parents provided COVID-19 vaccination record cards, information from the card was recorded separately from parent-reported vaccination data during the interview.

2.3. Concordance between parent-reported and documented COVID-19 vaccination

Patients were included in the analysis of concordance between parent-reported and documented COVID-19 vaccination status if their parent or guardian completed an interview reporting the number of vaccine doses received, including unvaccinated status (i.e., zero doses) and vaccine documentation sources were checked. If no doses were identified in the documented sources, the participant was classified as unvaccinated (zero doses). We described characteristics of vaccinated and unvaccinated patients stratified by parent-report vs. documented vaccination status using counts and percentages for categorical variables, and medians and interquartile ranges for continuous variables. Characteristics of SARS-CoV-2 test-positive case-patients and test-negative control-patients were described similarly.

Parental report of child vaccination status was compared to documented vaccination records (considered the gold standard for this analysis) using several metrics. Percentage agreement was defined as the proportion of patients whose parents reported the same number of vaccine doses as was recorded in documented sources. Kappa (κ) statistics were estimated to measure the degree of nonrandom agreement between the number doses reported by parents and those recorded in documented sources, with $\kappa = 1$ representing perfect agreement and $\kappa = 0$ indicating no more agreement than would be expected by chance. Sensitivity of parent-reported child COVID-19 vaccination history was estimated as the proportion of patients with ≥ 1 COVID-19 vaccine documented (denominator) whose parent also reported child receipt of ≥ 1 COVID-19 vaccine (numerator). Specificity was estimated as the proportion of patients with no documented vaccine (denominator) whose parent also reported him/her as unvaccinated (numerator). Positive predictive value (PPV) was calculated as the proportion of patients reported by parents as having ≥ 1 COVID-19 vaccine dose (denominator) who also had documented receipt of ≥ 1 COVID-19 vaccine dose (numerator). Negative predictive value (NPV) was calculated as the proportion of patients reported by parents as being unvaccinated (denominator) who also had no documentation of vaccination (numerator).

These concordance measures were stratified by case and control status to assess potential differences in accuracy by SARS-CoV-2 infection status.

We assessed factors associated with discordance between parental report and documented vaccination information by comparing the proportions of patients with discordant vaccine history by demographic characteristics (age, sex, race/ethnicity, region), clinical characteristics (presence of ≥ 1 underlying medical condition, SARS-CoV-2 test result), and time between hospital admission and parent interview using discordance prevalence ratios (PR). Adjusted PRs were estimated using multivariable log binomial regression including age group (5–11 years, 12–18 years), sex, race and ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic or Latino, multiple or other races, or unknown), social vulnerability index (SVI, a continuous measure ranging from 0 to 1 calculated based on ZIP code of residence and categorized as low, medium, high) [21], Census region, presence of ≥ 1 underlying medical condition, days from admission to parent interview (≤ 7 days, 8–50 days, > 50 days), and SARS-CoV-2 infection status at admission. We used the Wilcoxon rank sum test to compare distributions of days between hospital admission and parent interview for patients with discordant versus concordant vaccine status.

2.4. COVID-19 VE comparison

To assess whether VE estimates were similar across data sources, we compared VE estimates generated using (1) parent-reported data only and (2) documented sources only. The subset of patients included in the VE analysis differed from that of the concordance analysis (Fig. 1). For inclusion in the VE analysis using parent-reported data, we required participants' parents to provide the approximate date of the last dose to confirm that it was administered at least 14 days before hospital admission. For both VE analyses, vaccination status was classified as (1) unvaccinated (no vaccine doses received before hospital admission), (2) vaccinated with 2 doses (second dose of a two-dose mRNA vaccine series received ≥ 14 days before hospital admission, 99 % original formula), or (3) vaccinated with ≥ 2 doses of an mRNA vaccine with the second dose received ≥ 14 days before hospital admission or the third dose received ≥ 7 days before hospital admission. Numbers were insufficient to estimate VE for ≥ 3 doses or for the bivalent COVID-19 vaccine; no patients had received an updated (2023-2024 formulation) monovalent dose.

VE was estimated by comparing the odds of COVID-19 vaccination among SARS-CoV-2 test-positive case-patients to the odds of vaccination among test-negative control-patients ($VE = [1 - \text{adjusted odds ratio}] \times 100 \%$). Multivariable logistic regression models included hospital site as a repeated effect using generalized estimating equations to account for clustering within hospital site, and adjusted for the presence of ≥ 1 underlying medical condition, age (in years), bimonthly interval of hospitalization, U.S. Census Bureau region of hospital, SVI, and race and ethnicity. We estimated VE for the entire study period and by period of SARS-CoV-2 variant predominance defined as follows: Delta (May 16, 2021–December 18, 2021); Omicron BA.1 (December 19, 2021–March 19, 2022); and Omicron BA.2 and subsequent subvariants (March 20, 2022–October 29, 2023).

SAS software (version 9.4; SAS Institute) was used to conduct VE analyses. R (version 4.4.0) was used for all other analyses. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.²

3. Results

3.1. Characteristics of patients included in concordance analysis

From 16 May 2021 through 29 October 2023, 5496 inpatients aged 5–18 years without MIS-C were enrolled in the Overcoming COVID-19 surveillance network; children aged 5–11 years enrolled prior to November 2021, before FDA approved and CDC recommended COVID-19 vaccines for this age group, were excluded ($n = 12$) (Fig. 1). Test-positive case-patients and test-negative controls were evenly distributed over time (Fig. 2). The concordance analysis was restricted to 3262 (59 %) patients for whom both parent-reported and documented COVID-19 vaccination information was available (Fig. 1). Hospitalized patients included in the concordance analysis had a median age of 13 years (IQR: 9–16) and 49 % were female (Table 1). Most patients (76 %) had ≥ 1 underlying medical condition.

Of the 3262 children included in the concordance analysis, 1274 (39 %) were reported by parents to have received at least one dose of the COVID-19 vaccine. This proportion was higher compared to those confirmed through verified documentation ($n = 1068$, 33 %). However, demographic and clinical characteristics of patients classified as vaccinated (or unvaccinated) according to parent report were similar to those classified as vaccinated (or unvaccinated) according to documented sources. Similarly, demographic characteristics were similar between case-patients and test-negative control-patients (Table 2). However, case-patients were more likely to have an underlying medical condition (80 % vs 72 %, $\chi^2 p < 0.01$) and to be unvaccinated according to documented sources (75 % vs 60 %, $\chi^2 p < 0.01$) and parental report (68 % vs 54 %, $\chi^2 p < 0.01$).

3.2. Concordance between parent-reported and documented vaccination

Among 3262 patients with both parent-reported and documented COVID-19 vaccination information, percent agreement between the number of parent-reported and documented vaccine doses was 88.0 % (95 % CI: 86.9–89.1 %), with a kappa of 0.77 (95 % CI: 0.75–0.79) (Table 3). Most discordant pairs (346/390) were because of parents reporting more doses than were found in documented sources (Table 4, Supplementary Table), which was reflected in the high sensitivity (98.2 %) and lower specificity (89.7 %) of parent report (Table 3). Parents reported an average of 0.8 doses (SD: 1.1) compared to a documented mean of 0.7 doses (SD: 1.0). Percent agreement was highest in the earlier periods at 89.6 % (95 % CI: 87.8–91.3) and 91.1 (95 % CI: (89.3–93.0) in the Delta (16 May 2021–18 Dec 2021) and Omicron BA.1 (19 Dec 2021–19 Mar 2022) predominant periods, respectively, but declined with time to 84.1 % (95 % CI: 82.0–86.1) when the Omicron BA.2 SARS-CoV-2 variant became predominant (20 Mar 2022–29 Oct 2023). A similar trend was observed with a kappa statistic of 0.77 (95 % CI: 0.74–0.81) and 0.84 (95 % CI: 0.80–0.87)

²See e.g., 45C.F.R. part 46.102(l)(2), 21C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

in the Delta and Omicron BA.1 predominant periods, respectively that declined to 0.72 (95 % CI: 0.69–0.76) when Omicron BA.2 became predominant.

We explored whether the time between parent interview and hospital admission influenced the observed decline in agreement over time. The number of days between admission and parent interview increased from 18 days (IQR: 4–60) in the Delta period to 36 days (IQR: 5–137) by the Omicron BA.2 period. The median time between hospital admission and parent interview was greater for children with discordant vaccine status (58 days [IQR: 18–131]) than for those with concordant status (18 days [IQR: 3–63]) ($p < 0.01$). When stratified by time between hospital admission and parent interview, the trend of lower percent agreement between the Delta and Omicron BA.2+ periods was evident among participants interviewed within 7 days of hospital admission, with percent agreement declining from 97.9 % (95 % CI: 96.4–99.5) during the Delta period to 84.9 % (95 % CI: 81.0–88.8) during the Omicron BA.2+ period. A similar, though less pronounced, decline was observed among participants interviewed 8–50 days after admission, with percent agreement decreasing from 93.0 % (95 % CI: 90.3–95.8) in the Delta period to 86.7 % (95 % CI: 82.9–90.6) in the Omicron BA.2+ period. However, among participants interviewed more than 50 days after admission, no clear trend was observed; percent agreement fluctuated across periods: 78.0 % (95 % CI: 73.3–82.8) during the Delta period, 83.4 % (95 % CI: 78.3–88.6) during the Omicron BA.1 period, and 80.5 % (95 % CI: 76.9–84.0) during the Omicron BA.2+ period.

The proportion of children reported by their parents to have received ≥ 1 vaccine dose who also had documentation of receiving ≥ 1 vaccine, was lower for case-patients (PPV: 76.9 % [95 % CI: 73.0–80.3]) compared to control patients (PPV: 85.8 % [95 % CI: 83.1–88.1]), indicating more overreporting by parents of case-patients than by parents of control patients (Table 3). However, this difference between case-patients and control patients declined following the Delta period. The proportion of children reported by their parents as having received no vaccines who also had no documented vaccines, was high (>98 %) for both case-patients and control patients across all time periods, indicating a high level of accuracy in parental reporting when children were unvaccinated.

In addition to the time between hospital admission and parent interview, region was associated with discordance between parent report and documented vaccination (Table 5). Compared to patients in the South, the proportion of patients with discordant vaccination status was 1.9 (95 % CI: 1.4–2.4) times as high in the West and 1.9 (95 % CI: 1.4–2.5) times as high in the Northeast. Discordance did not differ by age, sex, race or ethnicity, SARS-CoV-2 infection status, or with the presence/absence of ≥ 1 select underlying medical conditions.

3.3. VE comparison

Of 5496 children and adolescents hospitalized from 16 May 2021 through 29 October 2023, 5215 (94.9 %) were included in the VE analyses. Among these 5215 patients, 3049 (58.5 %) were included in VE estimates using parent-reported vaccination status and 5143 (98.6 %) were included in the VE analysis using documented vaccination status (Fig. 1). Demographic and clinical characteristics of patients included in the two VE analyses were similar (Table 6).

VE of two vaccine doses against COVID-19-related hospitalization was 57.8 % (95 % CI 49.5–64.7) for the entire study period when using vaccination status from documented sources and 59.5 % (95 % CI 50.3–67.0) when using vaccination status reported by parents (Table 7). During this period, the median time from the most recent vaccine dose to hospital admission was 167 days (IQR: 86–288) among patients with documented vaccination status (for whom date of vaccination was available). Over each successive variant predominant period, the time from most recent vaccine dose to hospital admission increased coinciding with a decline in VE. Among patients with documented receipt of ≥ 2 doses, the median time from most recent COVID-19 vaccine dose to hospitalization was 98 days (IQR: 59–139) in the Delta predominant period (16 May 2021–18 Dec 2021), 124 days (IQR: 46–193) in the Omicron BA.1 period (19 Dec 2021–19 Mar 2022), and 280 days (IQR: 158–408) when the SARS-CoV-2 Omicron BA.2 variant became predominant (20 Mar 2022–29 Oct 2023). Despite this decline in VE, estimates based on documented sources and parent report remained similar, with overlapping confidence intervals. Specifically, for vaccination status from documented sources, effectiveness of 2 doses dropped from 89.9 % (95 % CI: 85.6–92.9 %) during the Delta predominant period to 56.5 % (95 % CI: 39.3–68.9) during the Omicron BA.1 predominant period and further to 12.2 % (95 % CI: –6.3–27.4 %) by the Omicron BA.2 predominant period. Similarly, for vaccination status reported by parents, effectiveness dropped from 86.2 % (95 % CI: 80.6–90.2 %) to 60.1 % (95 % CI: 44.1–71.5 %) by the Omicron BA.1 period and to –7.6 % (95 % CI: –39.0–16.8 %) by the Omicron BA.2 predominant period.

4. Discussion

Parent-reported COVID-19 vaccination status agreed substantially with documented status among pediatric patients but agreement declined slightly in the period starting in March 2022. Despite this decline, VE estimates based on documented sources and parental report were similar, with overlapping confidence intervals throughout the study period. Nearly all patients whose parents reported them as unvaccinated had no documented COVID-19 vaccination. Discrepancies in the number of vaccine doses reported by parents and those recorded in documented sources were more often because of parents reporting more doses than were documented. Discordance was positively associated with longer times from hospital admission to parent interview and residing in the Northeast and West compared to the South and Midwest Census regions.

These findings suggest that researchers can generally rely on parental reports of no history of COVID-19 vaccination and no additional verification is needed, as these reports of zero doses were almost always confirmed by documented sources. The higher accuracy of parental reports indicating no COVID-19 vaccination compared to those reporting ≥ 1 vaccine may account for the observed regional variations in agreement. Specifically, greater agreement in the Midwest and South compared to the Northeast and West could reflect lower vaccination coverage in the former regions since agreement tends to be higher when children are unvaccinated [22].

These findings have important implications for COVID-19 VE evaluations, which often rely on documented sources that might be less complete following the May 2023

commercialization of COVID-19 vaccines and the lifting of reporting mandates to IIS [2,3,23]. During our study period, parent-reported COVID-19 vaccination status was a reliable alternative, but results could vary when evaluating recall of multiple updated vaccines in future analyses. The tendency of parents to report more doses than were documented could indicate that parental report captures doses missed by documentation or it could indicate social desirability bias. Previous studies show that overreporting of vaccinations can bias VE estimates towards the null, and this bias is particularly pronounced when vaccine coverage is low (<40 %) [19]. In our study population > 40 % of controls had received ≥ 1 COVID-19 vaccine dose and VE estimates based on parental report were similar to those using documented sources. However, coverage with updated COVID-19 vaccine formulations might be lower in future VE evaluations limiting the generalizability of our findings to future VE analyses.

Our findings of strong concordance between parent-reported and documented COVID-19 vaccination in a pediatric population are consistent with findings in other populations [14–16] and for other vaccine-preventable diseases [17,18]. Studies in adults and pregnant women found high concordance ($\kappa > 0.91$) between self-reported and documented COVID-19 vaccinations [14,16]. These studies also noted that documented sources often recorded lower vaccination rates than self-report. Among adults, a primary reason for discordance was vaccinations received outside the state or country and thus not recorded in jurisdictional IIS [16]. A previous study also found that shorter time between self-report and vaccination was associated with higher agreement between self-report and vaccination documented in electronic health records [15].

This analysis is subject to several limitations. First, our concordance analysis assumes that documented sources are the gold standard for vaccination information, but parents might provide more timely and complete information, especially following the removal of national reporting requirements. For instance, vaccines reported by parents but not recorded in a jurisdictional IIS might have been administered in a different state, country, or in federal facilities, which were not subject to jurisdictional reporting requirements. We lacked parent-reported data on the state or country where children received the vaccine, which prevented us from differentiating between a missing IIS record and not being vaccinated.

Second, the time since vaccination is important for assessing the durability of immunity in VE analyses, and previous analyses have documented waning immunity following vaccination [2]. However, we did not collect the exact date of vaccination from parents, preventing us from assessing the accuracy of parent-reported COVID-19 vaccination dates. Instead, parents were asked if their child had received a vaccine within the 14 days before hospital admission to ensure that only vaccines administered with sufficient time for the immune system to develop a response were counted.

Finally, a substantial proportion (44 %) of parents did not participate in interviews to report their child's vaccination information. Although strong concordance between parental report and documented vaccination sources may reduce concerns about exposure misclassification in VE studies, selection bias remains an important consideration that could impact VE estimates relying on parental report [24]. However, we found that VE estimates and

demographic and clinical characteristics of children with parent-reported vaccination status ($n = 3049$) and those with documented vaccination status ($n = 5143$) were similar, suggesting that selection bias introduced by non-participation in parent interviews may be limited.

Despite these limitations, our analysis demonstrates that parent-reported and documented child vaccination histories were highly concordant, particularly when parents reported that their child was unvaccinated. Although parental report was a reliable alternative to documented sources for classifying COVID-19 vaccination status in children and adolescents, even with high concordance, the tendency of parents to report more doses than are documented (i.e., lower specificity of parental report) could lead to differences in future VE estimates based on documented versus parent-reported vaccination. These potential differences should be considered when interpreting VE estimates based on parental report. As future evaluations of COVID-19 VE may increasingly rely on parental report because of reduced COVID-19 vaccination reporting requirements, it is important to minimize the time between the parent interview and the child's hospital admission to enhance accuracy of parent-reported child vaccination history.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

This work was funded by the Centers for Disease Control and Prevention (CDC) under a contract (75D30122C13330) with Boston Children's Hospital. 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.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Regina Simeone reports a relationship with Pfizer Inc. that includes: equity or stocks. Natasha Halasa reports a relationship with Merck & Co Inc. that includes: funding grants. Natasha Halasa reports a relationship with Seqirus Inc. that includes: advisory board membership. Adrienne Randolph reports a relationship with Thermo Fisher Scientific Inc. that includes: consulting or advisory. Adrienne Randolph reports a relationship with Inotrem SA that includes: consulting or advisory. Adrienne Randolph reports a relationship with UptoDate Inc. that includes: royalties. Other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Deidentified participant data in a limited dataset may be made available upon formal request for a specified purpose for researchers whose proposed use of the data has been approved.

References

- [1]. WHO. Evaluation of COVID-19 vaccine effectiveness. Geneva, Switzerland: World Health Organization; 2021.
- [2]. Zambrano LD, Newhams MM, Simeone RM, Payne AB, Wu M, Orzel-Lockwood AO, et al. Durability of original monovalent mRNA vaccine effectiveness against COVID-19 omicron-associated hospitalization in children and adolescents - United States, 2021-2023. *MMWR Morb Mortal Wkly Rep* 2024;73:330–8. [PubMed: 38635481]

- [3]. Link-Gelles R, Ciesla AA, Rowley EAK, Klein NP, Naleway AL, Payne AB, et al. Effectiveness of monovalent and bivalent mRNA vaccines in preventing COVID-19-associated emergency department and urgent care encounters among children aged 6 Months-5 years - VISION network, United States, July 2022-June 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:886–92. [PubMed: 37590187]
- [4]. Tannis A, Englund JA, Perez A, Harker EJ, Staat MA, Schlaudecker EP, et al. SARS-CoV-2 epidemiology and COVID-19 mRNA vaccine effectiveness among infants and children aged 6 Months-4 years - new vaccine surveillance network, United States, July 2022-September 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:1300–6. [PubMed: 38032834]
- [5]. Link-Gelles R, Ciesla AA, Mak J, Miller JD, Silk BJ, Lambrou AS, et al. Early Estimates of Updated 2023–2024 (Monovalent XBB.1.5) COVID-19 Vaccine Effectiveness Against Symptomatic SARS-CoV-2 Infection Attributable to Co-Circulating Omicron Variants Among Immunocompetent Adults - Increasing Community Access to Testing Program, United States, September 2023–January 2024. *MMWR Morbidity and mortality weekly report* 2024;73:77–83. [PubMed: 38300853]
- [6]. DeCuir J, Surie D, Zhu Y, Gaglani M, Ginde AA, Douin DJ, et al. Effectiveness of Monovalent mRNA COVID-19 Vaccination in Preventing COVID-19-Associated Invasive Mechanical Ventilation and Death Among Immunocompetent Adults During the Omicron Variant Period - IVY Network, 19 U.S. States, February 1, 2022-January 31, 2023. In: *MMWR Morbidity and mortality weekly report*. 72;2023. p. 463–8. [PubMed: 37104244]
- [7]. CDC. CDC COVID-19 Vaccination Program Provider Requirements and Support. 2022.
- [8]. U.S. Department of Health and Human Services. COVID-19 public health emergency. U.S. Department of Health and Human Services; 2023.
- [9]. U.S. Department of Health and Human Services. Determination that a public health emergency exists. U.S. Department of Health and Human Services; 2020.
- [10]. U.S. Department of Health and Human Services. HHS Secretary Xavier Becerra Statement on End of the COVID-19 Public Health Emergency. 2025.
- [11]. Jurek AM, Greenland S, Maldonado G. How far from non-differential does exposure or disease misclassification have to be to bias measures of association away from the null? *Int J Epidemiol* 2008;37:382–5. [PubMed: 18184671]
- [12]. Copeland KT, Checkoway H, McMichael AJ, Holbrook RH. Bias due to misclassification in the estimation of relative risk. *Am J Epidemiol* 1977;105:488–95. [PubMed: 871121]
- [13]. De Smedt T, Merrall E, Macina D, Perez-Vilar S, Andrews N, Bollaerts K. Bias due to differential and non-differential disease- and exposure misclassification in studies of vaccine effectiveness. *PLoS One* 2018;13:e0199180. [PubMed: 29906276]
- [14]. Wielgosz K, Dawood FS, Stockwell MS, Varner M, Newes-Adeyi G, Ellington S, et al. Agreement between pregnant Individuals' Self-report of coronavirus disease 2019 (COVID-19) vaccination and medical record documentation. *Obstet Gynecol* 2022;140:989–92. [PubMed: 36357976]
- [15]. Tjaden AH, Fette LM, Edelstein SL, Gibbs M, Hinkelman AN, Runyon M, et al. Self-reported SARS-CoV-2 vaccination is consistent with electronic health record data among the COVID-19 community research partnership. *Vaccines (Basel)* 2022;10. [PubMed: 36679855]
- [16]. Stephenson M, Olson SM, Self WH, Ginde AA, Mohr NM, Gaglani M, et al. Ascertainment of vaccination status by self-report versus source documentation: impact on measuring COVID-19 vaccine effectiveness. *Influenza Other Respir Viruses* 2022;16:1101–11. [PubMed: 35818721]
- [17]. Ogokeh CE, Campbell AP, Feldstein LR, Weinberg GA, Staat MA, McNeal MM, et al. Comparison of parental report of influenza vaccination to documented Records in Children Hospitalized with Acute Respiratory Illness, 2015-2016. *Journal of the Pediatric Infectious Diseases Society* 2021;10:389–97. [PubMed: 33043965]
- [18]. Brown C, Clayton-Boswell H, Chaves SS, Prill MM, Iwane MK, Szilagyi PG, et al. Validity of parental report of influenza vaccination in young children seeking medical care. *Vaccine* 2011;29:9488–92. [PubMed: 22015394]
- [19]. Jackson ML. Use of self-reported vaccination status can bias vaccine effectiveness estimates from test-negative studies. *Vaccine: X* 2019;1:100003.

- [20]. Price AM, Olson SM, Newhams MM, Halasa NB, Boom JA, Sahni LC, et al. BNT162b2 protection against the omicron variant in children and adolescents. *N Engl J Med* 2022;386:1899–909. [PubMed: 35353976]
- [21]. ATSDR. CDC/ATSDR Social Vulnerability Index (CDC/ATSDR SVI): Overview. 2024.
- [22]. Saelee R, Zell E, Murthy BP, Castro-Roman P, Fast H, Meng L, et al. Disparities in COVID-19 vaccination coverage between urban and rural counties - United States, December 14, 2020-January 31, 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:335–40. [PubMed: 35239636]
- [23]. Olson SM, Newhams MM, Halasa NB, Price AM, Boom JA, Sahni LC, et al. Effectiveness of BNT162b2 vaccine against critical Covid-19 in adolescents. *N Engl J Med* 2022;386:713–23. [PubMed: 35021004]
- [24]. Simeone R, Zambrano LD, Newhams MM, Halasa NB, Fleming-Dutra KE, Orzel A, et al. Maternal Participation in Enrollment Interview and Risk of Bias in a Multicenter Pediatric Network Evaluating COVID-19 Vaccine Effectiveness in Infants. *Open Forum Infect Dis* 2023;496:10.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

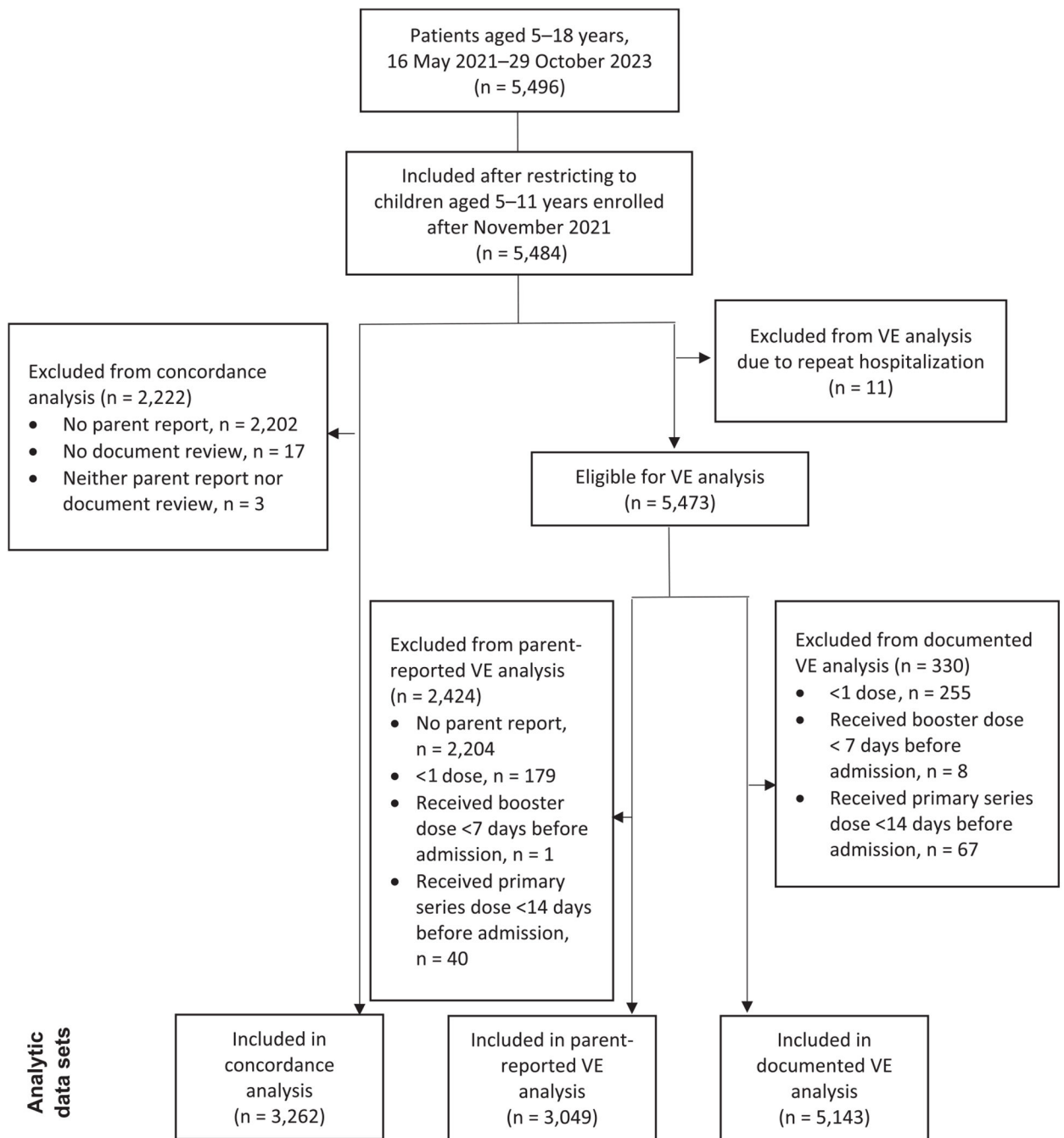


Fig. 1. Flow diagram of hospitalized patients aged 5–18 years in concordance and COVID-19 vaccine effectiveness analyses, 16 May 2021–29 October 2023, $n = 5,496$. Abbreviations: VE, vaccine effectiveness.

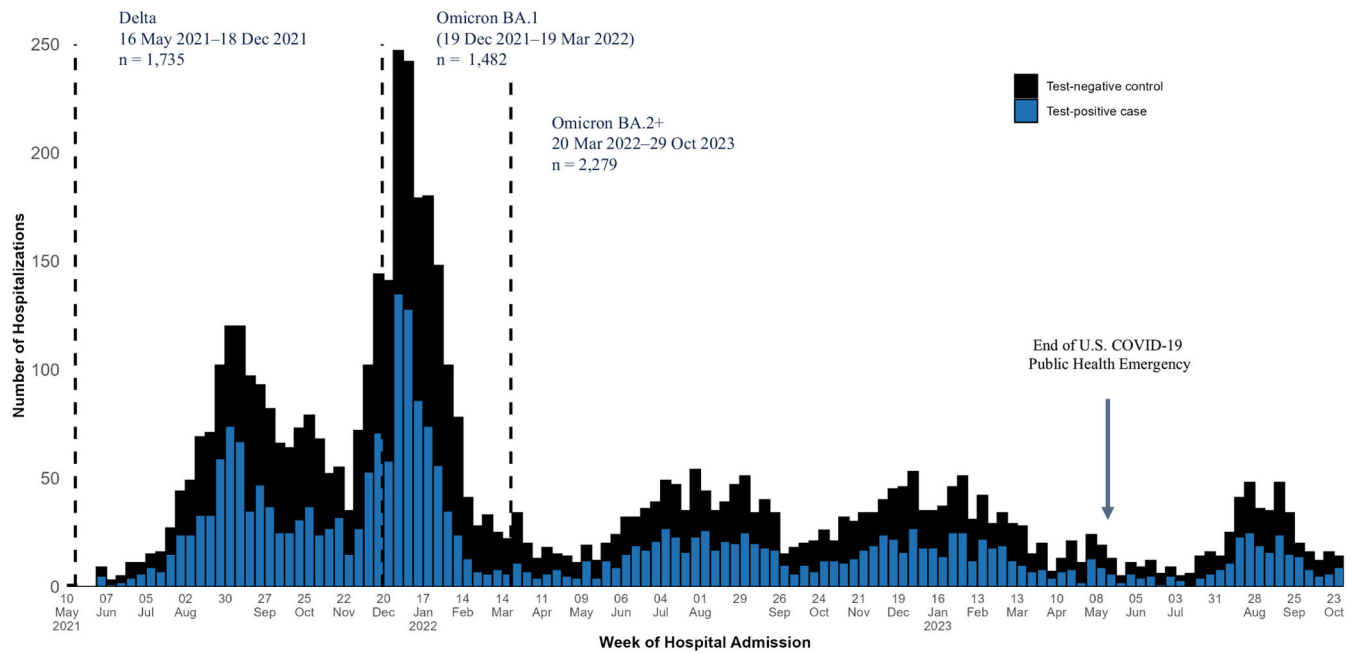


Fig. 2.

Weekly number of patients aged 5–18 years hospitalized with a COVID-19–like illness and a positive SARS-CoV-2 test result (case-patients) or a negative SARS-CoV-2 test result (control-patients) in the Overcoming COVID-19 network— 35 hospitals, 25 states (n = 5496), 16 May 2021–26 October 2023.

Table 1

Characteristics of hospitalized patients aged 5–18 years in concordance analysis of parent-reported versus documented COVID-19 vaccination status — 35 hospitals, 25 states (*n* = 3262) 16 May 2021–29 October 2023.

Characteristic	Total, No.(%)	Vaccinated ≥ 1 dose, No. (%)	Parent-report Documented*	Unvaccinated, No. (%)	Parent-report Documented*
Median age, yrs. [IQR]	(<i>n</i> = 3262) 13 [9, 16]	(<i>n</i> = 1274) 14 [10, 16]	(<i>n</i> = 1068) 14 [11, 16]	(<i>n</i> = 1988) 13 [8, 16]	(<i>n</i> = 2194) 13 [8, 16]
Female sex	1583 (49)	625 (49)	520 (49)	958 (48)	1063 (48)
Race/ethnicity					
White, Non-Hispanic	1220 (37)	451 (35)	393 (37)	769 (39)	827 (38)
Black, Non-Hispanic	819 (25)	289 (23)	241 (23)	530 (27)	578 (26)
Asian, Non-Hispanic	107 (3)	74 (6)	62 (6)	33 (2)	45 (2)
Hispanic/Latino	679 (21)	277 (22)	225 (21)	402 (20)	454 (21)
Multiple/other races	374 (11)	158 (12)	130 (12)	216 (11)	244 (11)
Unknown	63 (2)	25 (2)	17 (2)	38 (2)	46 (2)
Median SVI [IQR] [†]	0.6 [0.3, 0.8]	0.6 [0.3, 0.8]	0.5 [0.3, 0.7]	0.6 [0.3, 0.8]	0.5 [0.3, 0.7]
U.S. Census Bureau region [§]					
Northeast	360 (11)	179 (15)	156 (15)	181 (9)	204 (9)
Midwest	807 (25)	267 (21)	238 (22)	540 (27)	569 (26)
South	1379 (42)	488 (38)	408 (38)	891 (45)	971 (44)
West	716 (22)	340 (27)	266 (25)	376 (19)	450 (21)
Underlying medical conditions					
≥1 condition	2479 (76)	987 (77)	833 (78)	1495 (75)	1649 (75)
Respiratory	1217 (37)	475 (37)	407 (38)	743 (37)	811 (37)
Cardiac	353 (11)	148 (12)	125 (12)	205 (10)	228 (10)
Neurologic/ neuromuscular	798 (24)	345 (27)	295 (28)	453 (23)	503 (23)
Oncologic disorder	233 (7)	98 (8)	83 (8)	135 (7)	150 (7)
Non-oncologic immunosuppressive disorder [¶]	207 (6)	95 (7)	84 (8)	112 (6)	123 (6)
Endocrine	419 (13)	167 (13)	150 (14)	252 (13)	269 (12)
Obesity	341 (10)	123 (10)	108 (10)	218 (11)	233 (11)
COVID-19 vaccination status					

Characteristic	Total, No.(%)		Vaccinated ≥ 1 dose, No. (%)		Unvaccinated, No. (%)	
	Parent-report	Documented*	Parent-report	Documented*	Parent-report	Documented*
1 dose	180 (14)	168 (16)	—	—	—	—
Primary series only	842 (66)	721 (68)	—	—	—	—
≥ 3 doses	252 (20)	179 (17)	—	—	—	—
Vaccine type, if vaccinated						
Pfizer-BioNTech	1193 (94)	1060 (99)	—	—	—	—
Moderna	18 (1)	4 (0)	—	—	—	—
Mixed Pfizer-BioNTech/Moderna	8 (1)	2 (0)	—	—	—	—
Unknown	50 (4)	2 (0)	—	—	—	—
SARS-CoV-2 RT-PCR result						
Positive	510 (40)	403 (38)	1615 (50)	1105 (56)	1212 (55)	
Negative	764 (60)	665 (62)	1647 (50)	883 (44)	982 (45)	

Abbreviations: SVI, social vulnerability index.

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or jurisdictional Immunization Information Systems.

[†]SVI is a scale (range = 0–1), reflecting a composite score of socioeconomic status, household characteristics, racial and ethnic minority status, and housing type and transportation. A lower score indicates lower social vulnerability, whereas a higher score indicates higher social vulnerability, which might predispose a population to worse health outcomes. SVI was calculated based on ZIP code of patient’s residence.

[§]https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

[¶]Non-oncologic immunosuppressive disorders include solid organ transplant, HIV or AIDS, primary immunodeficiency, bone marrow transplant for nononcologic disease, and other disorder requiring treatment that suppresses the immune system.

Table 2

Characteristics of test-positive SARS-CoV-2 case-patients and test-negative control-patients aged 5–18 years in concordance analysis of parent-reported versus documented* COVID-19 vaccination status — 35 hospitals, 25 states (*n* = 3262), 16 May 2021–29 October 2023.

Characteristic	Case-patients, No. (Col %) ^{**}	Control-patients, No. (Col %) ^{**}
Age (years), median [IQR]	(<i>n</i> = 1615) 13.6 [9.6, 15.8]	(<i>n</i> = 1647) 13.0 [8.3, 15.4]
Female sex	768 (47.6)	815 (49.4)
Race and ethnicity		
White, Non-Hispanic	575 (35.6)	645 (39.2)
Black, Non-Hispanic	415 (25.7)	404 (24.5)
Asian, Non-Hispanic	55 (3.4)	52 (3.2)
Hispanic/Latino	337 (20.9)	342 (20.8)
Multiple/other races	200 (12.4)	174 (10.6)
Unknown race/ethnicity	33 (2.0)	30 (1.8)
Median SVI [†] [IQR]	0.6 [0.4, 0.8]	0.6 [0.3, 0.8]
U.S. Census Bureau Region[‡]		
Northeast	183 (11.3)	177 (10.7)
Midwest	388 (24.0)	419 (25.4)
South	679 (42.0)	700 (42.5)
West	365 (22.6)	351 (21.3)
Underlying medical condition		
≥1 underlying medical condition	1290 (79.9)	1189 (72.2)
Respiratory	596 (36.9)	621 (37.7)
Asthma	358 (22.2)	419 (25.4)
Cardiac	196 (12.1)	157 (9.5)
Neurologic/neuromuscular	431 (26.7)	367 (22.3)
Oncologic disorder	135 (8.4)	98 (6.0)
Non-oncologic immunosuppressive disorder [§]	124 (7.7)	83 (5.0)
Endocrine	239 (14.8)	180 (10.9)
Diabetes	64 (4.0)	67 (4.1)
Obesity	214 (13.3)	127 (7.7)

Characteristic	Case-patients, No. (Col %)**	Control-patients, No. (Col %)**
COVID-19 vaccination status (parental report)		
Unvaccinated	1105 (68.4)	883 (53.6)
1 dose	87 (5.4)	93 (5.6)
Primary series only	309 (19.1)	533 (32.4)
≥3 doses	114 (7.1)	138 (8.4)
COVID-19 vaccination status (documented source)¶		
Unvaccinated	1212 (75.0)	982 (59.6)
1 dose	67 (4.1)	101 (6.1)
Primary series only	248 (15.4)	473 (28.7)
≥3 doses	88 (5.4)	91 (5.5)

Abbreviations: SVI, social vulnerability index; IQR, interquartile range.

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or Jurisdictional Immunization Information Systems.

** Data are presented as number (column %) for all variables, except for age and SVI, which are presented as median (IQR).

† SVI is a scale (range = 0–1), reflecting a composite score of socioeconomic status, household characteristics, racial and ethnic minority status, and housing type and transportation. A lower score indicates lower social vulnerability; whereas a higher score indicates higher social vulnerability, which might predispose a population to worse health outcomes. SVI was calculated based on ZIP code of patient’s residence.

‡ https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

§ Non-oncologic immunosuppressive disorders include solid organ transplant, HIV or AIDS, primary immunodeficiency, bone marrow transplant for nononcologic disease, and other disorder requiring treatment that suppresses the immune system.

¶ Among those who received 1 dose, 2 received a bivalent dose. Of those who completed the primary series, 4 received a bivalent dose, and among those who received 3 or more doses, 4 received a bivalent dose. All other doses were of the original monovalent formula.

Table 3

Comparison of parental report and documented* sources for COVID-19 vaccination status (≥ 1 dose vs. none) among hospitalized patients aged 5–18 years ($n = 3262$), stratified by SARS-CoV-2 variant predominant period and test result, 16 May 2021–29 October 2023.

	All participants	Test-positive case-patients	Test-negative controls
	% (95 % CI) **	% (95 % CI) **	% (95 % CI) **
Overall (16 May 2021–29 Oct 2023)	$n = 3262$	$n = 1615$	$n = 1647$
Percent agreement	88.0 (86.9–89.1)	89.0 (87.5–90.5)	87.0 (85.4–88.7)
Kappa statistic	0.77 (0.75–0.79)	0.76 (0.73–0.79)	0.78 (0.75–0.81)
Sensitivity [†]	98.2 (97.1–98.8)	97.3 (95.2–98.6)	98.6 (97.5–99.4)
Specificity [‡]	89.7 (88.3–90.9)	90.3 (88.4–91.9)	88.9 (86.8–90.8)
Positive Predictive Value [§]	82.2 (80.0–84.2)	76.9 (73.0–80.3)	85.8 (83.1–88.1)
Negative Predictive Value [¶]	99.0 (98.5–99.3)	99.0 (98.2–99.4)	99.0 (98.1–99.5)
Delta (16 May 2021–18 Dec 2021)	$n = 1139$	$n = 572$	$n = 564$
Percent agreement	89.6 (87.8–91.3)	92.5 (90.3–94.6)	86.9 (84.1–89.7)
Kappa statistic	0.77 (0.74–0.81)	0.66 (0.62–0.70)	0.77 (0.72–0.82)
Sensitivity [†]	98.7 (96.6–99.6)	98 (89.3–99.9)	98.8 (96.5–99.8)
Specificity [‡]	90.6 (88.4–92.4)	92.7 (90.1–94.8)	86.7 (82.5–90.3)
Positive Predictive Value [§]	78.9 (74.4–82.6)	56.3 (45.9–66.3)	85.8 (81.0–89.1)
Negative Predictive Value [¶]	99.5 (98.7–99.7)	99.8 (98.8–100.0)	98.9 (96.9–99.6)
Omicron BA.1 (19 Dec 2021–19 Mar 2022)	$n = 926$	$n = 420$	$n = 506$
Percent agreement	91.1 (89.3–93.0)	92.9 (90.4–95.3)	89.7 (87.1–92.4)
Kappa statistic	0.84 (0.80–0.87)	0.84 (0.79–0.90)	0.82 (0.77–0.88)
Sensitivity [†]	98.5 (96.6–99.5)	96.7 (91.8–99.1)	99.5 (97.5–100.0)
Specificity [‡]	94.2 (92.0–95.9)	95.3 (92.2–97.4)	93.0 (89.4–95.7)
Positive Predictive Value [§]	90.8 (87.5–93.4)	89.4 (83.0–93.6)	91.6 (87.4–94.5)
Negative Predictive Value [¶]	99.1 (97.9–99.6)	98.6 (96.5–99.5)	99.6 (97.9–100.0)
Omicron BA.2+ (20 Mar 2022–29 Oct 2023)	$n = 1200$	$n = 623$	$n = 577$
Percent agreement	84.1 (82.0–86.1)	83.1 (80.2–86.1)	85.1 (82.2–88.0)
Kappa statistic	0.72 (0.69–0.76)	0.72 (0.67–0.77)	0.73 (0.68–0.78)

	All participants	Test-positive case-patients	Test-negative controls
Sensitivity [†]	97.4 (95.4–98.7)	97.4 (94.4–99.0)	97.4 (94.1–99.2)
Specificity [‡]	85.4 (82.8–87.8)	83.2 (79.1–86.7)	87.7 (84.0–90.8)
Positive Predictive Value [§]	78.6 (74.9–81.9)	77.3 (72.2–81.8)	80.2 (74.6–84.7)
Negative Predictive Value [¶]	98.4 (97.1–99.1)	98.2 (96.1–99.2)	98.5 (96.6–99.4)

Abbreviations: CI, confidence interval.

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or jurisdictional Immunization Information Systems.

** Data are presented as % (95 % CI) for all variables, except for kappa statistics, where the kappa statistic and its 95 % CI are shown.

[†] Sensitivity is the proportion of patients documented as having ≥1 COVID-19 vaccine dose (denominator) whose parents reported that they had received ≥1 COVID-19 vaccine dose (numerator).

[‡] Specificity is the proportion of patients documented as being unvaccinated (denominator) whose parents reported that they were unvaccinated (numerator).

[§] Positive predictive value is the proportion of patients reported as having ≥1 COVID-19 vaccine dose by parents (denominator) who had documented receipt of ≥1 COVID-19 vaccine dose (numerator).

[¶] Negative predictive value is the proportion of patients reported as being unvaccinated (denominator) who had no documentation of vaccination (numerator).

Table 4

Comparison of parent-reported versus documented* COVID-19 vaccination among hospitalized patients aged 5–18 years (*n* = 3262), 16 May 2021–29 October 2023.

Parent-reported vaccine doses	Documented vaccine doses, no.						
	unvaccinated	1 dose	2 doses	3 doses	4 doses	5 doses	Total
unvaccinated	1968	6	11	1	2	0	1988
1 dose	69	105	6	0	0	0	180
2 doses	126	52	655	9	0	0	842
3 doses	27	5	47	121	8	1	209
4 doses	4	0	1	8	23	0	36
5 doses	0	0	1	2	4	0	7
Total	2194	168	721	141	37	1	3262
Discordant, <i>n</i> (%) [†]	226 (10)	63 (38)	66 (9)	20 (14)	14 (38)	1 (100)	390 (12)

[†] Discordant refers to the number of patients for whom the number of vaccine doses reported by parents differs from the documented number of COVID-19 vaccine doses, which is considered the gold standard.

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or jurisdictional Immunization Information Systems.

Table 5

Discordance between number of COVID-19 vaccines reported by parents and number recorded in documented* sources by demographic and clinical characteristics of patients aged 5–18 years (n = 3262), 16 May 2021–29 October 2023.

Characteristic	Proportion of discordant vaccine reports (n/N)	Crude Discordance Ratio (95% CI)	Adjusted [†] Discordance Ratio (95% CI)
Age group, yrs			
5–11	152/1277 (11.9)	1.0 (0.8–1.2)	1.0 (0.8–1.2)
12–18	238/1985 (12.0)	Ref	Ref
Sex [‡]			
Female	201/1583 (12.7)	1.1 (0.9–1.4)	1.1 (0.9–1.4)
Male	188/1677 (11.2)	Ref	Ref
Race/ethnicity			
Black Non-Hispanic	92/819 (11.2)	1.1 (0.8–1.4)	1.0 (0.7–1.3)
Asian Non-Hispanic	18/107 (16.8)	1.6 (1.0–2.5)	1.3 (0.8–2.1)
Hispanic	85/679 (12.5)	1.2 (0.9–1.5)	1.1 (0.8–1.4)
Multiple or Other race	55/374 (14.7)	1.4 (1.0–1.9)	1.0 (0.7–1.4)
Unknown race	11/63 (17.5)	1.7 (0.9–2.9)	1.0 (0.5–2.1)
White Non-Hispanic	129/1220 (10.6)	Ref	Ref
Social vulnerability index [§]			
low (≤ 0.32)	74/721 (10.3)	0.8 (0.6–1.0)	0.8 (0.6–1.1)
medium (0.33–0.66)	138/1150 (12)	0.9 (0.8–1.2)	1.0 (0.8–1.2)
high (> 0.66)	178/1388 (12.8)	Ref	Ref
U.S. Census Bureau region**			
Northeast	55/360 (15.3)	1.4 (1.0–1.8)	1.9 (1.4–2.5)
Midwest	63/807 (7.8)	0.7 (0.5–0.9)	0.9 (0.7–1.2)
West	117/716 (16.3)	1.5 (1.2–1.8)	1.9 (1.4–2.4)
South	155/1379 (11.2)	Ref	Ref
Underlying medical condition			
≥ 1 underlying condition	293/2479 (11.8)	1.0 (0.8–1.2)	0.9 (0.7–1.1)
no underlying conditions	97/783 (12.4)	Ref	Ref
Days from admission to parent interview**			
≤ 7	65/1003 (6.5)	0.3 (0.3–0.4)	0.3 (0.2–0.4)
8–50	97/962 (10.1)	0.5 (0.4–0.6)	0.5 (0.4–0.6)
> 50	192/976 (19.7)	Ref	Ref
Infection status			
SARS-CoV-2 positive by PCR	178/1615 (11.0)	0.9 (0.7–1.0)	1.0 (0.9–1.3)
SARS-CoV-2 negative by PCR	212/1647 (12.9)	Ref	Ref

0.2 2.0
Adjusted Discordance ratio (95% CI)
Higher discordance

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or jurisdictional Immunization Information Systems.

[†] Adjusted log binomial models included age group, sex, race and ethnicity, social vulnerability index, census region, presence of ≥ 1 underlying condition, days from hospital admission to parent interview (categorical), and SARS-CoV-2 infection status at admission; n=325 observations were deleted due to missingness.

[§] Two participants had missing sex.

[¶] Social Vulnerability Index (SVI) is a scale (range = 0–1), reflecting a composite score of socioeconomic status, household characteristics, racial and ethnic minority status, and housing type and transportation. A lower score indicates lower social vulnerability, whereas a higher score indicates higher social vulnerability, which might predispose a population to worse health outcomes. SVI was calculated based on ZIP code of patient’s residence. Three participants had unknown SVI.

^{***} https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

^{††} 321 participants had missing date of interview.

TABLE 6

Characteristics of hospitalized patients aged 5–18 years in vaccine effectiveness analysis using parental reports and documented* COVID-19 vaccination status — 35 hospitals, 25 states ($n = 5215$), 16 May 2021–29 October 2023.

Characteristic	Parent-report, No. (%)**	Documented, No. (%)**
	N = 3049	N = 5143
Age (years), median [IQR]	13.3 [9.0–15.7]	13.1 [8.7–15.7]
Female sex	1487 (48.8)	2461 (47.9)
Race/ethnicity		
White, Non-Hispanic	1157 (37.9)	1950 (37.9)
Black, Non-Hispanic	756 (24.8)	1217 (23.7)
Asian, Non-Hispanic	94 (3.1)	159 (3.1)
Hispanic/Latino	638 (20.9)	979 (19.0)
Multiple/other races	348 (11.4)	611 (11.9)
Unknown race/ethnicity	56 (1.8)	227 (4.4)
Median SVI[†][IQR]	0.6 [0.3–0.8]	0.6 [0.3–0.8]
U.S. Census Bureau region[§]		
Northeast	331 (10.8)	663 (12.9)
Midwest	770 (25.2)	1326 (25.8)
South	1274 (41.8)	1949 (37.9)
West	674 (22.1)	1205 (23.4)
Underlying medical conditions		
≥1 underlying medical condition	2318 (76.0)	3878 (75.4)
Respiratory	1139 (37.4)	1976 (38.4)
Asthma	727 (23.8)	1315 (25.6)
Cardiac	332 (10.9)	556 (10.8)
Neurologic/neuromuscular	737 (24.2)	1204 (23.4)
Oncologic disorder	214 (7.0)	336 (6.5)
Non-oncologic immunosuppressive disorder [¶]	198 (6.5)	303 (5.9)
Endocrine	389 (12.8)	596 (11.6)
Diabetes	119 (3.9)	188 (3.7)
Obesity	324 (10.6)	507 (9.9)
COVID-19 vaccination status^{††}		
Unvaccinated	1996 (65.5)	3664 (71.2)
Primary series only	803 (26.3)	1164 (22.6)
≥3 doses	250 (8.2)	315 (6.1)
Vaccine type, if vaccinated		
Pfizer-BioNTech	990 (94.0)	1466 (99.1)
Moderna	17 (1.6)	6 (0.4)
Mixed Pfizer-BioNTech/Moderna	8 (0.8)	4 (0.3)
Unknown	38 (3.6)	3 (0.2)
SARS-CoV-2 positive by RT-PCR	1514 (49.7)	2446 (47.6)

Abbreviations: SVI, social vulnerability index.

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or jurisdictional Immunization Information Systems.

*** Data are presented as number (column %) for all variables, except for age and SVI, which are presented as median (IQR). Percentages for vaccine type use the number vaccinated as the denominator.

[†] SVI is a scale (range = 0–1), reflecting a composite score of socioeconomic status, household characteristics, racial and ethnic minority status, and housing type and transportation. A lower score indicates lower social vulnerability, whereas a higher score indicates higher social vulnerability, which might predispose a population to worse health outcomes SVI was calculated based on ZIP code of patient's residence.

[§] https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

[¶] Non-oncologic immunosuppressive disorder include solid organ transplant, HIV or AIDS, primary immunodeficiency, bone marrow transplant for non-oncologic disease, and other disorder requiring treatment that suppresses the immune system).

^{††} Among those with documented vaccination status, ≥1 bivalent dose was received by 4/315 who received ≥3 doses and 9/1164 who received 2 doses. All others received the original monovalent formula. Patients who received only 1 vaccine dose were not included in the vaccine effectiveness analysis.

Table 7

COVID-19 vaccine effectiveness against hospitalization in patients aged 5–18 years according to parent-reported and independently documented* vaccination status — 35 hospitals, 25 states ($n = 5215$), 16 May 2021–29 October 2023.

Vaccination status	Test-positive cases	Test-negative controls	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	VE† (95% CI)
Overall					
Independent documentation	1917	1747	ref	ref	ref
Unvaccinated	385	779	0.5 (0.4–0.5)	0.4 (0.4–0.5)	57.8 (49.5–64.7)
2-dose primary series	529	950	0.5 (0.4–0.6)	0.5 (0.4–0.5)	54.3 (46.8–60.7)
Parent-report					
Unvaccinated	1108	888	ref	Ref	ref
2-dose primary series	294	509	0.5 (0.4–0.5)	0.4 (0.3–0.5)	59.5 (50.3–67.0)
≥2 doses	406	647	0.5 (0.4–0.6)	0.4 (0.3–0.5)	56.9 (47.5–64.5)
Delta (16 May 2021–18 Dec 2021)**					
Independent documentation	762	525	ref	Ref	ref
Unvaccinated	41	269	0.1 (0.1–0.1)	0.1 (0.1–0.1)	89.9 (85.6–92.9)
2-dose primary series	41	278	0.1 (0.1–0.1)	0.1 (0.1–0.1)	90.2 (85.8–93.2)
Parent-report					
Unvaccinated	490	279	ref	Ref	ref
2-dose primary series	55	219	0.1 (0.1–0.2)	0.1 (0.1–0.2)	86.2 (80.6–90.2)
≥2 doses	55	243	0.1 (0.1–0.2)	0.1 (0.1–0.2)	87.4 (82.4–91.1)
Omicron BA.1 (19 Dec 2021–19 Mar 2022)**					
Independent documentation	480	487	ref	Ref	ref
Unvaccinated	119	243	0.5 (0.4–0.6)	0.4 (0.3–0.6)	56.5 (39.3–68.9)
2-dose primary series	133	270	0.5 (0.4–0.6)	0.4 (0.3–0.6)	55.6 (39.4–67.5)
Parent-report					
Unvaccinated	289	267	ref	Ref	ref
2-dose primary series	88	160	0.5 (0.4–0.7)	0.4 (0.3–0.6)	60.1 (44.1–71.5)
≥2 doses	105	194	0.5 (0.4–0.7)	0.4 (0.3–0.5)	62.1 (46.4–73.2)
Omicron BA.2 + (20 Mar 2022–29 Oct 2023)**					
Independent documentation	675	735	ref	ref	ref
Unvaccinated	225	267	0.9 (0.7–1.1)	0.9 (0.7–1.1)	12.2 (-6.3–27.4)
2-dose primary series	355	402	0.9 (0.8–1.1)	0.9 (0.7–1)	13.9 (-0.3–26.1)
Parent-report					
Unvaccinated	329	342	ref	ref	ref
2-dose primary series	151	130	1.2 (0.9–1.6)	1.1 (0.8–1.4)	-7.6 (-39.0–16.8)
≥2 doses	246	210	1.2 (1–1.6)	1 (0.8–1.3)	-1.4 (-26.7–18.9)

-60 -40 -20 0 20 40 60 80 100
Vaccine Effectiveness (%)

Abbreviations: CI, confidence interval; VE, vaccine effectiveness; OR, odds ratio.

Abbreviations: CI, confidence interval; VE, vaccine effectiveness; OR, odds ratio.

* Documentation comprised vaccine cards, electronic medical records, pediatrician records, or jurisdictional Immunization Information Systems.

** Among patients who received ≥2 doses, the median (IQR) days from last COVID-19 vaccine dose to hospitalization was 98 (59–139) in the Delta period, 124 (46–193) in the Omicron BA.1 period, and 280 (158–408) when Omicron BA.2 became predominant.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

[†]VE was estimated using logistic regression comparing the odds of being vaccinated versus being unvaccinated in SARS-CoV-2-positive case-patients and SARS-CoV-2-negative control-patients using the eq. $VE = 100 \times (1 - \text{adjusted odds ratio})$. Models included hospital site as a repeated effect using generalized estimating equations and were adjusted for the presence of one or more underlying medical conditions including obesity, date of hospital admission (bimonthly interval), U.S. Department of Health and Human Services region of hospital (https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf), social vulnerability index, age in years, and race/ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic of any race, other/unknown).