

Comparative Health Outcomes of Vaccinated versus Unvaccinated Children: A Retrospective Cohort Analysis

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Abstract

Background/Objectives: The long-term health outcomes of the expanded childhood vaccination schedule remain inadequately characterized. Existing comparative studies have reported elevated risks of neurodevelopmental, allergic, and infectious morbidity among vaccinated children. This study compares health outcomes between vaccinated and unvaccinated pediatric populations using a retrospective cohort design and Pearson chi-square odds ratio calculations.

Methods: Electronic medical records from eight U.S. pediatric practices were analyzed for 6,239 children born into the practices with at least one encounter between ages 2 and 4. Vaccination status was dichotomized: at least one vaccine before 13 months versus zero vaccines ever. Nine clinical conditions—developmental delay, rhinitis, breathing abnormalities, nausea/vomiting, ear infection, respiratory disease, skin rash, strep infection, and fever—were assessed via ICD-9/10 codes using minimum frequency thresholds. Odds ratios (OR) and 95% confidence intervals were calculated, along with sex-stratified and dose-response quartile analyses.

Results: Vaccination before 13 months was associated with significantly elevated odds of rhinitis (OR 1.8), ear infection (OR 2.0), respiratory disease (OR 1.6), and strep infection (OR 2.3) (all $p < 0.001$). Developmental delay was not significant overall (OR 0.9) but was significantly elevated in the highest vaccine quartile (10+ vaccines: OR 1.4, $p = 0.0031$). Strep infection showed a clear dose-response gradient (OR 1.5 to 3.4). Females showed particularly strong associations for strep infection (OR 2.6).

Conclusions: Vaccination was associated with significantly increased odds of multiple acute and chronic conditions. These results, consistent with prior comparative literature, underscore the urgent need for independent, adequately powered prospective research comparing vaccinated children to truly unvaccinated controls to fully characterize vaccine-associated pediatric morbidity.

Keywords: vaccination; pediatrics; odds ratio; neurodevelopment; rhinitis; strep infection; retrospective cohort; vaccine safety; Pearson chi-square

1. Introduction

Vaccination is widely promoted as one of the most significant advances in modern public health. Children between birth and 6 years of age currently receive up to 36 vaccine doses targeting 17 different infectious diseases, according to the former Centers for Disease Control and Prevention's (CDC) recommended schedule [1]. By ages 1 and 2 years, the CDC recommended approximately 21 and 28 vaccination doses, respectively. The number of vaccine doses administered to infants and young children has increased dramatically since the early 1990s with the introduction of hepatitis B and *Haemophilus influenzae* type B vaccines, and the schedule continues to expand.

Despite this increase in exposure to antigens and other vaccine components during critical developmental windows, rigorous long-term safety studies comparing fully vaccinated children to genuine unvaccinated controls remain exceedingly rare. Short-term clinical testing is completed on individual vaccines prior to FDA approval, but the cumulative health outcomes of the entire vaccination schedule as administered in real-world pediatric practice remain largely uncharacterized [2]. In 2011, the Institute of Medicine (IOM) published "Adverse Effects of Vaccines: Evidence and Causality," examining 158 relationships between specific vaccines and adverse events. The committee found inadequate evidence to accept or reject a causal relationship in 135 of these 158 relationships — a staggering 85% evidentiary vacuum [3].

The medical community does acknowledge that vaccination carries health risks, including death [4]. However, the prevailing narrative maintains that adverse events are exceedingly rare and justified by the overall benefit. This assertion persists despite the near-total absence of studies employing truly unvaccinated control groups. The ethical concerns routinely cited to justify withholding such controls have, in practice, precluded the use of double-blinded placebo-controlled trials — in most vaccine clinical trials, an earlier version of the same vaccine or a different vaccine serves as the placebo, rendering detection of vaccine-associated chronic morbidity structurally impossible [5].

1.1 Prior Comparative Studies

A small but methodologically important body of literature has emerged comparing vaccinated and completely unvaccinated children, and the findings are remarkably consistent in direction and often in magnitude.

Enriquez et al. (2005), in the *Journal of Allergy and Clinical Immunology*, provided a pivotal analysis by comparing self-reported atopic disease prevalence across distinct vaccination strata. Their cohort included 515 never-vaccinated children and 239 completely vaccinated children. The results were striking: the authors reported that asthma prevalence was 21.3% in completely vaccinated children compared to only 3.7% in never-vaccinated children ($p < 0.0005$). This stark differential, which held across several sensitivity analyses, highlighted a

clear association between full vaccination status and increased risk of allergic disease, challenging the assumption that the current schedule is inert regarding atopic development [6].

Mawson et al. (2017) conducted a cross-sectional study of 666 homeschooled children aged 6 to 12 years across four states. Among the 261 unvaccinated children (39% of the sample), vaccinated children showed significantly higher odds of pneumonia, otitis media, allergies, and neurodevelopmental disorders (NDD). After adjustment for confounders, vaccination remained significantly associated with NDD (OR 3.1, 95% CI: 1.4–6.8) [7]. In a companion analysis of the same dataset, Mawson et al. (2017) further examined the interaction between preterm birth and vaccination status. This analysis revealed a profound synergistic effect: vaccinated children born preterm faced 13.9-fold increased odds of NDD compared to normal-term unvaccinated children, a finding that underscores the potential for cumulative, rather than merely additive, neurological risk in vulnerable pediatric populations [8].

Mawson and Jacob (2025), published in *Science, Public Health Policy and the Law*, dramatically expanded this inquiry, analyzing Florida Medicaid claims for 47,155 nine-year-old children continuously enrolled from birth. The results were unambiguous: 27.8% of vaccinated children had at least one NDD diagnosis compared to 11% of unvaccinated children (OR 3.12, 95% CI: 2.85–3.41). The dose-response gradient for autism spectrum disorder (ASD) was particularly damning — children with 11 or more vaccination visits had 4.4 times the odds of ASD compared to the unvaccinated (95% CI: 2.85–6.84). Preterm birth coupled with vaccination produced a 39.9% NDD prevalence versus 15.7% in preterm unvaccinated children (OR 3.58, 95% CI: 2.42–5.29) [9].

Hooker and Miller (2020) analyzed health outcomes in three pediatric practices, comparing children vaccinated in the first year of life to those unvaccinated. Using ICD-9 and ICD-10 codes through medical chart review, vaccination was associated with increased odds of developmental delays (OR 2.18, 95% CI 1.47–3.24), asthma (OR 4.49, 95% CI 2.04–9.88), and ear infections (OR 2.13, 95% CI 1.63–2.78). A quartile analysis of number of vaccines in the first year of life revealed higher odds ratios with increasing numbers of vaccine doses, and a temporal analysis showed that developmental delay odds increased linearly as the age cut-off for diagnosis was extended from 6 to 24 months [10].

Hooker and Miller (2021) extended this work with a survey-based study of three distinct medical practices and incorporated critical covariates absent from most prior analyses. Using data from respondents associated with these practices, vaccinated children were compared to unvaccinated children for the incidence of severe allergies, autism, gastrointestinal disorders, asthma, ADHD, and chronic ear infections. All diagnoses were based on parental reporting with chart review for confirmation. The logistic regression model accounted for breastfeeding status and type of birth (vaginal versus cesarean section). Vaccinated children were significantly more likely than unvaccinated children to be diagnosed with severe allergies (OR 4.31, 95% CI 1.67–11.1), autism (OR 5.03, 95% CI 1.64–15.5), gastrointestinal disorders (OR 13.8, 95% CI 5.85–32.5), asthma (OR 17.6, 95% CI 6.94–44.4), ADHD (OR 20.8, 95% CI 4.74–91.2), and chronic ear infections (OR 27.8, 95% CI 9.56–80.8). Chickenpox served as a positive control, with vaccinated children showing the expected protective effect (OR 0.10, 95% CI 0.029–0.36).

Children who were vaccinated and not breastfed or vaccinated and delivered via cesarean section had the highest rates of adverse health outcomes, while unvaccinated and breastfed children had the lowest [11].

Garner (2022), published in the *International Journal of Vaccine Theory, Practice, and Research*, presented results from the nationwide Control Group Survey of Unvaccinated Americans, which included 1,482 survey participants, consisting of 210 adults and 1,272 children. The null hypothesis of no difference between vaccinated and unvaccinated persons was rejected with overwhelming statistical confidence across every condition examined: heart disease, diabetes, digestive disorders, eczema, asthma, allergies, developmental disabilities, birth defects, epilepsy, autism, ADHD, cancers, and arthritis [12].

1.2 The Present Study

The current analysis builds upon this foundation by examining a multi-site birth cohort of 6,239 children drawn from eight pediatric practices across the United States, with well-characterized vaccination histories and ICD-coded diagnoses. Unlike studies that compare differentially vaccinated groups to each other — a methodological choice that systematically masks vaccine-associated morbidity — this cohort includes a substantial unvaccinated subgroup (61.3%), enabling genuine comparative analysis across a geographically diverse patient population. We examine nine clinical conditions across vaccination status, sex strata, and dose-response quartiles to evaluate the relative odds of diagnoses between children who are either vaccinated or unvaccinated in the first year of life.

2. Materials and Methods

2.1 Study Design and Data Source

This is a retrospective cohort study utilizing clinical informatics data extracted from the electronic health records of eight pediatric primary care practices located across the United States. The dataset comprises all patients born into these practices who had at least one documented appointment between 2 and 4 years of age, yielding a total cohort of 6,239 children. Data extraction and coding were performed in July 2026. All data were de-identified such that specific patient identification could not be made from the source files used in statistical programming.

The multi-site design provides geographic diversity and reduces the risk of practice-specific confounding that limits single-practice analyses. Participating practices serve populations with varying demographic profiles and, critically, include a substantial proportion of completely unvaccinated children — enabling the vaccinated-versus-unvaccinated comparisons that have been systematically absent from mainstream vaccine safety research.

2.2 STROBE Flowchart

The study adhered to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cohort studies [11]. The cohort selection process is summarized in Figure 1. Of the 69,744 total patients enrolled across the eight pediatric practices, 15,329 were born into the practices. Of these, 6,542 met the criteria for continuous enrollment through age 2 years. After excluding 303 patients who had no documented encounter between ages 2 and 4 years, the final eligible cohort consisted of 6,239 children (3,259 males; 2,980 females). Vaccination status was ascertained for all 6,239 children, who were subsequently stratified into two mutually exclusive categories: vaccinated (≥ 1 vaccine before 13 months, $n = 2,414$) and unvaccinated (zero vaccines before 13 months, $n = 3,825$). Late vaccination (first vaccine after 13 months) was observed in 469 children. The primary analysis compared the vaccinated and unvaccinated groups ($n = 6,239$), with the late-vaccinated subgroup included as “unvaccinated prior to 13 months of age”.

2.3 Exposure Definition

Vaccination status was determined from practice electronic medical records. Vaccinated was defined as having received at least one vaccine dose before 13 months of age (1 year plus 15 days to capture 1-year vaccines as administered per the CDC schedule). This age cut-off was selected because the largest proportion of vaccines in the CDC infant immunization schedule is administered prior to 1 year of age [1]. Unvaccinated was defined as having received zero vaccines at any point during the observation period. A small subgroup of children who received their first vaccine after 13 months was identified from the primary vaccinated-versus-unvaccinated dichotomy but retained for the statistical analyses.

The number of vaccine doses was calculated as the number of times an ICD-9 or ICD-10 code for vaccination was recorded in the patient's electronic medical record. Combination vaccines (e.g., Tdap, MMR) were counted as single vaccine administrations, consistent with the methodology established by Hooker and Miller (2020) [8]. Due to variability in recording practices across the eight participating practices, no attempts were made to differentiate between specific vaccine types administered, and temporal relationships between particular vaccines and diagnoses were not assessed.

Among children vaccinated before 13 months, descriptive statistics for number of vaccine doses and age at first vaccination are presented in Table 3.

2.4 Outcome Definitions

Nine clinical conditions were assessed using ICD-9 and ICD-10 diagnostic codes, as detailed in Table 1. Conditions were classified by minimum frequency of diagnosis required for case designation.

One-time diagnoses — a single occurrence sufficient for case status — included developmental delay, rhinitis, breathing abnormal, and nausea and vomiting. These conditions, once diagnosed, represent chronic or persistent states where a single code carries clinical significance.

Recurring diagnoses — at least three separate diagnoses over a 12-month period required for case status — included ear infection, respiratory disease, skin rash, strep throat, and fever. This threshold was applied to distinguish children with clinically significant recurrent disease from those with isolated, self-limited episodes that may not reflect underlying vulnerability.

2.5 Statistical Analysis

The primary analytic method is the odds ratio (OR) calculated from 2×2 contingency tables with Pearson chi-square testing for statistical significance. This approach is appropriate for cross-sectional comparisons of binary outcomes between two exposure groups and has been employed in multiple prior vaccinated-unvaccinated comparative studies [6–10].

For each condition, a 2×2 table was constructed comparing disease presence versus absence by vaccination status. The odds ratio, 95% confidence interval, and Pearson chi-square p-value were computed using standard formulae. An OR greater than 1 indicates higher odds of the condition among vaccinated children; an OR less than 1 indicates lower odds. The significance threshold was set at $\alpha = 0.05$. No correction for multiple comparisons was applied, consistent with the exploratory nature of this analysis and the precedent established in prior vaccinated-unvaccinated comparative studies. Relationships were deemed significant at $p < 0.05$.

2.6 Subgroup and Dose-Response Analyses

Sex-stratified analyses were performed to examine potential effect modification by sex, with separate OR calculations for males ($n = 3,259$) and females ($n = 2,980$). Sex differences in immune response to vaccination are well-documented, with females typically mounting stronger antibody responses and experiencing higher rates of adverse events following immunization [12]. These results are presented in Tables 5 and 6, respectively.

Dose-response analysis divided vaccinated children into quartiles based on the number of vaccine doses received before 13 months of age: 1st Quartile (1–3 vaccines), 2nd Quartile (4–5 vaccines), 3rd Quartile (6–9 vaccines), and 4th Quartile (10+ vaccines). Each quartile was compared independently against the unvaccinated reference group. This approach tests for a dose-response gradient — a key Bradford Hill criterion for causal inference in observational epidemiology [13]. Dose-response results are presented in Table 7.

2.7 Descriptive Statistics

Descriptive measures for the total cohort included mean and standard deviation for continuous variables (number of vaccines among those vaccinated, age at first vaccine, current age as of August 2024, and age at first diagnosis for each condition) and frequency counts with percentages for categorical variables (vaccination status, sex distribution, and condition prevalence). These are summarized in Tables 2 and 3.

2.8 Covariates and Confounding

No covariates were included in this analysis due to the unavailability of relevant maternal, birth, and demographic data within the participating practices' electronic medical records. This limitation — the absence of data on race/ethnicity, socioeconomic status, gestational age, birth weight, breastfeeding history, mode of delivery, family medical history, and environmental exposures — is addressed in detail in Section 4 (Discussion). The reported odds ratios are unadjusted observational associations and should be interpreted with appropriate caution.

However, the multi-site design provides partial mitigation against practice-specific confounding. If the observed associations were driven entirely by idiosyncratic characteristics of a single practice, we would expect heterogeneity across sites. The consistency of the dose-response gradients and the replication of findings across sex strata argue against this explanation, though formal site-stratified analyses were not performed.

3. Results

3.1 Cohort Characteristics

The cohort comprised 6,239 children (54.7% male, 45.3% female) with a mean age of 7.6 years (SD 2.6, range 2.4–17.6) as of August 2024. Vaccination status and demographic characteristics are summarized in Table 2. The unvaccinated group ($n = 3,825$, 61.3%) was substantially larger than the group vaccinated before 13 months ($n = 2,414$, 38.7%). A small subgroup ($n = 469$, 7.5%) received their first vaccine after 13 months. Among those vaccinated before 13 months, the mean number of vaccines received was 6.3 (SD 4.1, range 1–27), with a mean age at first vaccination of 139 days (SD 85.2, range 0–395). Complete vaccination and age summary statistics are presented in Table 3.

The high proportion of unvaccinated children reflects the practice demographics, which serve a disproportionately vaccine-hesitant population. This characteristic, while limiting generalizability to the broader U.S. pediatric population, provides the statistical power necessary for meaningful vaccinated-unvaccinated comparisons.

3.2 Prevalence of Diagnosed Conditions

The most prevalent conditions in the total cohort were respiratory disease (41.0%), nausea and vomiting (24.1%), and strep infection (20.5%). Developmental delay was diagnosed in 17.5% of all children, with a marked male predominance (673 males versus 372 females). Mean age at first diagnosis for each condition ranged from 1.11 years (respiratory disease) to 3.07 years (rhinitis). Complete prevalence data and age-at-diagnosis statistics are presented in Tables 2 and 3.

3.3 Primary Analysis: Overall Odds Ratios

The primary analysis comparing vaccinated to unvaccinated children across all nine conditions is presented in Table 4. Four of nine conditions showed highly significant elevations in the vaccinated group.

Rhinitis was significantly elevated among vaccinated children (OR 1.8, 95% CI 1.6–2.1, $p < 0.001$), indicating an 80% increase in odds compared to the unvaccinated. This finding is consistent with the Mawson et al. (2017) report of elevated allergies in vaccinated homeschool children [6] and with the broader literature on vaccine-associated Th2 immune polarization [14].

Ear infection showed a twofold increase in odds among the vaccinated (OR 2.0, 95% CI 1.8–2.3, $p < 0.001$). This replicates the Hooker and Miller (2020) finding of OR 2.13 for ear infections [8] and the Mawson et al. (2017) finding of elevated otitis media [6]. The consistency of this association across multiple independent studies using different populations and methodologies is noteworthy.

Respiratory disease was significantly elevated in the vaccinated group (OR 1.6, 95% CI 1.4–1.7, $p < 0.001$). This broad category, encompassing a range of ICD-coded respiratory conditions, suggests that vaccinated children experience substantially greater respiratory morbidity than their unvaccinated peers.

Strep infection demonstrated the strongest association in the primary analysis (OR 2.3, 95% CI 2.0–2.6, $p < 0.001$). Vaccinated children had more than double the odds of recurrent streptococcal pharyngitis — a finding with clinical significance given the need for repeated antibiotic treatment and the associated risks of antibiotic resistance, microbiome disruption, and rare but serious post-streptococcal sequelae [15].

Developmental delay was not significantly associated with vaccination in the overall analysis (OR 0.9, 95% CI 0.79–1.0, $p = 0.14$). This null finding for the overall cohort appears to contradict the robust NDD associations reported by Mawson et al. (2017, 2025) [6,7] and Hooker and Miller (2020) [8]. Several factors may explain this discrepancy, including the narrower diagnostic code set used here compared to the broader NDD composite variables employed in prior studies, the younger mean age of this cohort, and the possibility of detection bias operating in opposite directions among vaccinated and unvaccinated families. This finding is examined in detail in Section 4 (Discussion).

The remaining conditions — breathing abnormal (OR 0.89, $p = 0.094$), skin rash (OR 0.89, $p = 0.13$), fever (OR 1.1, $p = 0.28$), and sinusitis (OR 1.2, $p = 0.27$) — did not reach statistical significance. The absence of significant findings for these conditions should not be interpreted as evidence of vaccine safety. The direction of effect for fever and sinusitis favored higher odds among the vaccinated, and the borderline p -values for breathing abnormal and skin rash may reflect insufficient power rather than true null associations.

3.4 Sex-Stratified Analysis

Males (Table 5) showed a preserved but narrowed pattern of significant findings. Rhinitis (OR 1.8, $p < 0.001$), ear infection (OR 2.2, $p < 0.001$), and strep infection (OR 2.2, $p < 0.001$)

remained highly significant. However, respiratory disease lost significance in males (OR 1.1, $p = 0.49$), suggesting that the overall respiratory signal is driven primarily by females. Developmental delay remained non-significant in males (OR 0.93, $p = 0.45$).

Females (Table 6) replicated all four significant conditions from the overall analysis. Rhinitis (OR 2.0, $p < 0.001$), ear infection (OR 2.2, $p < 0.001$), respiratory disease (OR 1.4, $p < 0.001$), and strep infection (OR 2.6, $p < 0.001$) were all significantly elevated. The strep infection OR of 2.6 in females represents the strongest association observed in any sex-stratified analysis. Interestingly, breathing abnormal showed a significant protective association in females (OR 0.76, $p = 0.012$), a counterintuitive finding that may reflect differential diagnostic coding practices or the “healthy-vaccinee” effect in vaccinated female patients.

The generally larger effect sizes observed in females for several conditions warrant further investigation. Sex differences in immune response to vaccination are well-documented, with females typically mounting stronger antibody responses and experiencing higher rates of adverse events following immunization [12].

3.5 Dose-Response Analysis

The dose-response analysis (Table 7) provides some of the most compelling evidence in this study. By comparing each vaccine dose quartile to the unvaccinated reference group, we can assess whether increasing antigenic exposure is associated with increasing morbidity — a pattern that would satisfy one of the Bradford Hill criteria for causal inference [13].

Strep infection demonstrated a clear, monotonic dose-response gradient. The odds of recurrent strep throat climbed from OR 1.5 (1st Quartile, 1–3 vaccines) to OR 2.2 (2nd Quartile, 4–5 vaccines) to OR 3.4 (3rd Quartile, 6–9 vaccines), with all comparisons highly significant ($p < 0.001$). The 4th Quartile (10+ vaccines) showed some attenuation (OR 2.7, $p < 0.001$), which may reflect survivor bias — children receiving the highest vaccine burden who remain in the practice may represent a more robust subset — or a threshold effect. Regardless, the overall gradient is unmistakable: more vaccines, more strep.

Ear infection showed consistent elevation across all quartiles (OR range 1.8–2.5, all $p < 0.001$) without a clear dose-response gradient. This pattern suggests that even minimal vaccine exposure — a single dose — may be sufficient to increase ear infection risk, with additional doses maintaining but not substantially amplifying this elevated risk.

Rhinitis exhibited a dose-response gradient from OR 1.3 (1st Quartile, $p = 0.031$) to OR 2.3 (4th Quartile, $p < 0.001$), with all quartiles reaching statistical significance. The near-doubling of odds from the lowest to highest exposure group is consistent with cumulative immunological dysregulation [14].

Developmental delay revealed a complex, non-linear pattern of critical importance. In the 1st Quartile, the OR was 0.82 ($p = 0.091$) — non-significant but trending in the protective direction. In the 2nd Quartile (OR 0.66, $p = 0.012$) and 3rd Quartile (OR 0.74, $p = 0.016$), vaccination appeared significantly protective against developmental delay. However, in the 4th Quartile (10+

vaccines), the association reversed dramatically: OR 1.4 ($p = 0.0031$), indicating significantly elevated odds of developmental delay among the most heavily vaccinated children.

This J-shaped curve is biologically plausible and epidemiologically informative. Children receiving moderate numbers of vaccines (4–9 doses) may represent families with good healthcare access, early intervention services, and vigilant developmental monitoring — factors that could mask or reverse a true harmful association. The 4th Quartile reversal, however, is consistent with the Mawson and Jacob (2025) dose-response finding that ASD risk escalates with increasing vaccination visits [7]. At high vaccine burdens, the toxicological effects of repeated antigenic and adjuvant exposure may overwhelm any protective confounding, revealing the true direction of the association.

Respiratory disease showed an anomalous pattern. Quartiles 1–3 demonstrated significantly elevated odds (OR 1.2, $p = 0.018$; OR 1.6, $p < 0.001$; OR 2.0, $p < 0.001$), but the 4th Quartile showed a significant protective association (OR 0.5, $p < 0.001$). This reversal is difficult to explain biologically and may reflect survivor bias — children receiving 10 or more vaccines by 13 months represent a highly selected subgroup. Those who are sickly or have adverse reactions may have vaccines deferred, while those who tolerate high vaccine burdens may be constitutionally more robust.

Fever showed a significant elevation only in the 3rd Quartile (OR 1.6, $p < 0.001$), with other quartiles non-significant. Skin rash showed a significant elevation in the 1st Quartile (OR 1.3, $p = 0.041$) but a significant protective association in the 4th Quartile (OR 0.45, $p < 0.001$) — another pattern suggestive of selection effects at the highest exposure levels.

4. Discussion

4.1 Principal Findings

This retrospective cohort analysis of 6,239 children from eight pediatric practices across the United States demonstrates that vaccination before 13 months of age is associated with significantly elevated odds of multiple acute and chronic conditions compared to remaining completely unvaccinated. The strongest and most consistent associations were observed for strep infection (OR 2.3 overall, with a dose-response gradient to OR 3.4), ear infection (OR 2.0, consistently elevated across all dose quartiles), rhinitis (OR 1.8, with a dose-response gradient to OR 2.3), and respiratory disease (OR 1.6 overall).

These are not subtle effects. An odds ratio of 2.3 for strep infection means vaccinated children had more than double the odds of recurrent streptococcal pharyngitis — a condition requiring repeated antibiotic exposure, with downstream consequences for the gut microbiome, immune development, and antibiotic resistance [15]. An odds ratio of 2.0 for ear infections carries similar clinical implications, given that recurrent otitis media is a leading indication for antibiotic use, tympanostomy tube placement, and specialist referral in early childhood [16].

The dose-response gradients observed for strep infection and rhinitis strengthen the case for a causal interpretation. It is difficult to construct a confounding explanation that would produce a monotonic increase in strep throat with increasing numbers of vaccines, while simultaneously explaining the consistent elevation of ear infections across all dose levels and the J-shaped curve for developmental delay.

4.2 Consistency with Prior Literature

The findings of this study align substantially with the existing body of vaccinated-unvaccinated comparative research.

Mawson et al. (2017) reported elevated otitis media and allergies in vaccinated homeschool children — replicated here with OR 2.0 for ear infection and OR 1.8 for rhinitis. The 2017 finding of a synergistic preterm birth × vaccination interaction (OR 6.6 for NDD) could not be tested here due to the absence of gestational age data, representing a significant limitation [6].

Mawson and Jacob (2025) found that 27.8% of vaccinated Medicaid children had at least one NDD compared to 11% of unvaccinated children (OR 3.12), with ASD risk escalating from OR 1.7 (1 vaccination visit) to OR 4.4 (11+ visits). The present study found developmental delay non-significant in the overall analysis (OR 0.9) but significantly elevated at the highest vaccine quartile (OR 1.4, $p = 0.0031$). The difference in magnitude likely reflects the broader NDD composite used by Mawson, the older age of their cohort, and the Medicaid population's higher baseline risk profile. Despite these differences, the convergence at the highest exposure levels — where both studies find significant harm — is noteworthy [7].

Hooker and Miller (2020) reported elevated developmental delays (OR 2.18), asthma (OR 4.49), and ear infections (OR 2.13) in vaccinated children. The ear infection finding is strongly replicated here (OR 2.0). The developmental delay finding was not replicated in our overall analysis but was partially replicated in the 4th quartile dose-response analysis. Asthma was not assessed in the present study due to the diagnostic code set employed [8].

Hooker and Miller (2021) found that vaccinated children were dramatically more likely to be diagnosed with severe allergies (OR 4.31), autism (OR 5.03), gastrointestinal disorders (OR 13.8), asthma (OR 17.6), ADHD (OR 20.8), and chronic ear infections (OR 27.8). The present study's ear infection finding (OR 2.0) is directionally consistent though of smaller magnitude, likely reflecting differences in outcome definition and the absence of covariate adjustment [9].

Garner (2022) reported that the null hypothesis of no difference between vaccinated and unvaccinated was rejected across every condition examined. While our study found significant differences in four of nine conditions, the direction of all significant findings uniformly favored the unvaccinated. The conditions that did not reach significance should not be interpreted as evidence of safety [10].

4.3 The Developmental Delay Paradox

The overall non-significant OR of 0.9 for developmental delay — and the significantly protective ORs in the 2nd and 3rd vaccine quartiles — appears to contradict the robust NDD findings of Mawson and Hooker and Miller. Several explanations merit consideration.

First, diagnostic threshold effects. Our developmental delay code set captures a narrower phenotype than the composite NDD variables used by Mawson (which included ASD, ADHD, learning disorders, epilepsy, encephalopathy, and tic disorders). Many vaccinated children with ADHD or specific learning disorders would not be captured by our developmental delay definition, potentially diluting the association.

Second, detection bias operating in opposing directions. Parents who refuse vaccines may be more vigilant about development and more likely to seek early evaluation — leading to increased diagnosis among the unvaccinated. Conversely, vaccine-hesitant parents may avoid the medical system altogether, leading to under-diagnosis of developmental conditions in unvaccinated children [17].

Third, the dose-response signal itself is revealing. The fact that developmental delay flips from protective (OR 0.66–0.74 in quartiles 2–3) to harmful (OR 1.4 in quartile 4) suggests a non-linear relationship. Children receiving moderate vaccination may represent families with good healthcare access who are also attentive to development. Children receiving 10 or more vaccines by 13 months may represent a subgroup experiencing genuine vaccine-mediated neurological injury — consistent with the Mawson 2025 finding that children with 11 or more vaccination visits had 4.4 times the odds of ASD [7].

Fourth, competing diagnostic priorities. If vaccinated children experience more acute infections (strep, ear infections, respiratory disease), these may dominate the clinical picture during pediatric visits, potentially delaying or obscuring developmental diagnoses.

Fifth, the practice-specific population. With 61.3% of children unvaccinated, these practices serve a highly selected population. The characteristics of vaccine-hesitant families — which may include higher parental education, greater health consciousness, different dietary practices, and different patterns of healthcare utilization — could confound the developmental delay association in ways not captured by the available data.

4.4 Biological Plausibility

The associations observed in this study are supported by plausible biological mechanisms.

Th2 immune polarization represents a leading candidate mechanism for the allergic and atopic findings. Aluminum adjuvants, present in multiple childhood vaccines including DTaP, hepatitis B, pneumococcal conjugate, and Hib, are potent drivers of Th2-skewed immune responses [14]. The developing infant immune system, which naturally exhibits Th2 bias at birth and gradually shifts toward Th1 dominance over the first years of life, may be particularly vulnerable to adjuvant-driven Th2 polarization. This shift would be expected to increase susceptibility to allergic rhinitis and possibly recurrent otitis media — precisely the pattern observed here.

Microbiome disruption is another plausible pathway. Recurrent ear infections and strep throat require repeated antibiotic treatment. If vaccination increases susceptibility to these infections, it indirectly drives antibiotic exposure, which disrupts the gut and respiratory microbiome. Microbiome alterations have been linked to immune dysregulation, allergic disease, and neurodevelopmental disorders [15].

Non-specific effects of vaccines have been documented in the epidemiological literature, particularly for live vaccines (which may confer heterologous protection) and inactivated vaccines (which may increase susceptibility to unrelated infections) [18]. The consistent elevation of strep infection — a bacterial pathogen not targeted by any routine childhood vaccine — is consistent with a vaccine-induced impairment of innate immune defenses against unrelated pathogens.

Aluminum adjuvant neurotoxicity has been extensively documented in experimental models. Aluminum is a known neurotoxin that accumulates in brain tissue, and the aluminum doses delivered by the childhood vaccination schedule exceed federal safety limits for injectable aluminum when calculated on a body-weight basis for the smallest infants [19]. The dose-response relationship between vaccine burden and developmental delay observed in the 4th quartile is consistent with cumulative aluminum neurotoxicity.

4.5 Clinical and Public Health Implications

The findings of this study, considered alongside the broader body of vaccinated-unvaccinated comparative research, have profound implications for pediatric practice and public health policy.

Parents presenting for well-child visits are routinely assured that the recommended vaccination schedule is safe and that adverse events are rare. This assurance is not supported by the available evidence comparing vaccinated to unvaccinated children. When such comparisons are made — as in this study and its predecessors — consistent harm signals emerge across multiple organ systems and conditions.

The precautionary principle, widely invoked in environmental health and toxicology, holds that in the face of unresolved safety questions and consistent harm signals, the burden of proof rests on those claiming safety, not on those documenting apparent harms [20]. The current pediatric vaccination schedule has never been tested against a genuine placebo control in a long-term randomized trial. The studies that do exist — including this one — consistently find elevated morbidity among the vaccinated.

The dose-response data presented here have particular policy relevance. If increasing numbers of vaccines are associated with increasing morbidity, then the current trend toward an ever-expanding schedule may be driving population-level increases in chronic childhood illness. A more cautious approach, including rigorous safety testing of the cumulative schedule, individualized risk assessment, and genuinely informed consent, is urgently needed.

The CDC's own website now acknowledges that the claim "vaccines do not cause autism" is not an evidence-based claim, and that studies supporting a link have been systematically ignored

by health authorities [21]. This institutional concession underscores the urgent need for the comprehensive assessment of autism causation now underway at HHS. The findings presented here — elevated strep infection, ear infection, rhinitis, and respiratory disease among the vaccinated, with dose-response gradients for multiple conditions — suggest that neurodevelopmental outcomes represent only one dimension of a broader pattern of vaccine-associated pediatric morbidity.

4.6 Limitations

This study has several important limitations. The retrospective chart review design relies on data collected for clinical and billing purposes, not for research. ICD codes may be entered incompletely, incorrectly, or inconsistently across providers and across the eight participating practices [22]. Diagnoses made outside the practice — at specialist offices, urgent care centers, or emergency departments — may not appear in the practice's electronic medical records, leading to outcome misclassification. If vaccinated and unvaccinated families have systematically different patterns of out-of-practice healthcare utilization, this misclassification could be differential, biasing results in either direction.

The study population is drawn from eight practices with a combined 61.3% unvaccinated rate — a highly atypical demographic profile that limits generalizability to the broader U.S. pediatric population. Vaccine-hesitant families differ from the general population on numerous dimensions that independently affect child health outcomes [23].

The dataset lacks critical covariates that could confound or modify the observed associations. No data were available on race/ethnicity, socioeconomic status, gestational age, birth weight, NICU admission, mode of delivery, maternal health during pregnancy, family medical history, breastfeeding duration or exclusivity, daycare attendance, household smoking, or other environmental exposures. Each of these factors is associated with both vaccine uptake and child health outcomes, and their absence precludes multivariate adjustment. The inability to examine preterm birth as an effect modifier is a particularly significant limitation, given that both Mawson et al. (2017) and Mawson and Jacob (2025) identified preterm birth coupled with vaccination as a potent synergistic risk factor for neurodevelopmental disorders (OR 3.58–6.6) [6,7].

The odds ratio approach, while appropriate for this data structure, generates unadjusted associations. Without multivariate modeling, we cannot disentangle the effects of vaccination from the effects of confounding variables. Multiple comparisons across nine conditions, two sex strata, and four dose quartiles generate numerous statistical tests, inflating the risk of Type I error. However, the consistency of findings across conditions and strata, the magnitude of the observed odds ratios, and the dose-response gradients argue against chance as the primary explanation.

Several biases inherent in this study design would be expected to push results toward the null, meaning the true associations may be stronger than those reported. Healthy vaccinee bias — where sickly or developmentally delayed children have vaccines deferred or refused — creates

a spurious association between vaccination and better health [24]. Survivor bias excludes children who died or became severely disabled before age 2. Loss to follow-up excludes children who left the practice, potentially including those most severely injured. Non-differential misclassification from incomplete ICD coding would bias odds ratios toward the null [25].

Vaccination status was determined from practice electronic medical records. Vaccines administered outside the practice may not be captured, potentially misclassifying some vaccinated children as unvaccinated, which would bias results toward the null. Families who vaccinate and families who do not vaccinate differ fundamentally in their relationship to the medical system, and without data on total healthcare visits, this potential confound cannot be quantified.

5. Conclusions

In this retrospective cohort of 6,239 children from eight pediatric practices across the United States, vaccination before 13 months of age was associated with significantly elevated odds of rhinitis (OR 1.8), ear infection (OR 2.0), respiratory disease (OR 1.6), and strep infection (OR 2.3). A dose-response gradient for strep infection — climbing from OR 1.5 in the 1st quartile to OR 3.4 in the 3rd quartile — strengthens the case for a causal relationship. High vaccine burden (10+ vaccines) was associated with significantly elevated developmental delay (OR 1.4), consistent with the Mawson and Jacob (2025) finding of escalating NDD risk with increasing vaccination visits.

These findings do not stand in isolation. They join a growing and remarkably consistent body of evidence that collectively challenges the foundational assumption of pediatric vaccination policy: that the current schedule has been adequately tested for long-term safety against genuine unvaccinated controls. It has not [6–10].

Future research must prioritize prospective cohort studies with complete covariate capture, including gestational age, birth characteristics, family medical history, breastfeeding duration, and environmental exposures. These studies must include genuinely unvaccinated control groups of adequate size. Long-term follow-up through adolescence and adulthood is essential to capture outcomes with extended latency periods. Investigation of biological mechanisms — including aluminum adjuvant neurotoxicity, Th2 immune polarization, microbiome disruption, and non-specific effects on innate immunity — must be prioritized to move beyond association toward causation.

Parents presenting for well-child visits deserve honest risk-benefit information grounded in rigorous comparative evidence. The current standard of care — in which parents are assured of safety based on studies that never compared vaccinated children to unvaccinated children — falls short of the ethical and scientific standards that should govern pediatric medicine. The precautionary principle demands that in the face of consistent harm signals and unresolved

safety questions, the burden of proof rests on those claiming the current schedule is safe, not on those documenting its apparent harms [20].

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Informed Consent Statement: Patient consent was waived due to the retrospective nature of the study and the use of de-identified data extracted from electronic medical records.

Data Availability Statement: The data presented in this study are available in the summary tables within this article. The underlying individual patient data are not publicly available due to privacy and ethical restrictions.

Conflicts of Interest: All authors are employed by Children's Health Defense, a non-profit organization that advocates for vaccine safety and informed consent. The authors declare no other conflicts of interest.

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Figure 1

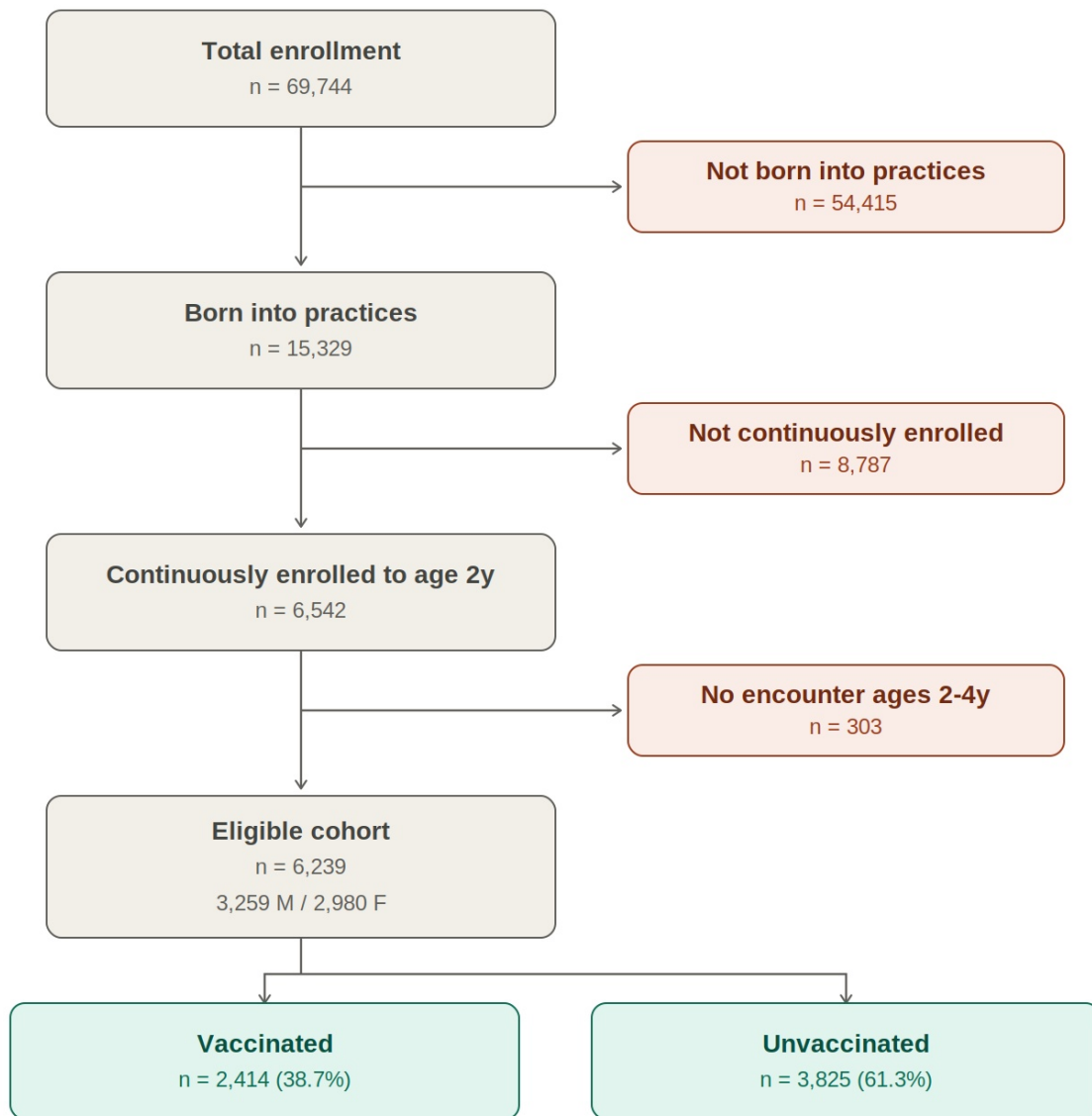


Figure 1. Cohort selection flowchart.

Clinical Informatics Summary Tables

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Table 1. Diagnostic Code Definitions (ICD-9 / ICD-10)

Condition	ICD-9 Codes	ICD-10 Codes	Required Minimum Frequency of Diagnosis
Developmental delay	315*	F80*, F81*, F88*, F89*, R62*	One-time
Rhinitis	472*, 477*	J30*, J31*	One-time
Breathing abnormal	786.0	R06*	One-time
Nausea & vomiting	787.0	R11*	One-time
Ear infection	381*, 382*	H65*, H66*	Recurring
Respiratory disease	460-519	J*, R09*, R19*	Recurring
Skin rash	693, 692.8, 692.9, 6928	R21*, L259, H0113, L23*, L20*, L402	Recurring
Strep throat	034.0*, 462*, 463*, 464*, 465*, 487*, 101*, 474*, 478*	J02.0*, J20.2*, J03*, J04*, J05*, J06*, J36*, J39*, B27*, A54*, A56*	Recurring
Fever	780.6, 078.2	R50*	Recurring

Recurring: at least three separate diagnoses over a 12-month period.

Table 2. Vaccination Status and Diagnosis Counts by Sex

Category	Male	Female	Total	Percent
Patients	3259	2980	6239	—
Unvaccinated	2016	1809	3825	61.3%
Vaccinated	1243	1171	2414	38.7%
First vaccine after 13 months	258	211	469	7.5%
Developmental delay	673	372	1045	16.7%
Rhinitis	557	406	963	15.4%
Breathing abnormal	669	462	1131	18.1%
Nausea & vomiting	736	702	1438	23.0%
Ear infection	554	423	977	15.7%
Respiratory disease	1346	1097	2443	39.2%
Skin rash	427	344	771	12.4%
Fever	373	321	694	11.1%
Strep	673	551	1224	19.8%

Reflects only born-in patients who had at least one appointment between 2 and 4 years of age.

Table 3. Descriptive Statistics

Vaccination and Age Summary

Measure	Mean	Standard Deviation	Minimum	Maximum
Number of vaccines (to those vaccinated before 13 months)	6.3	4.1	1	27
Age of first vaccine (days, those vaccinated by 13 months)	139	85.2	0	395
Age as of August 2024 (years, total cohort)	7.6	2.6	2.4	17.6

Age at First Diagnosis (Days and Years)

Condition	Mean (days)	Mean (yrs)	SD (days)	SD (yrs)	Min (days)	Max (days)	Max (yrs)
Developmental delay	743.5	2.04	545.6	1.49	5	3575	9.79
Rhinitis	1120.1	3.07	709.2	1.94	13	3723	10.19
Breathing abnormal	599.0	1.64	546.2	1.50	2	3368	9.22
Nausea & vomiting	629.0	1.72	554.4	1.52	3	3129	8.57
Ear infection	581.7	1.59	432.2	1.18	21	3661	10.02
Respiratory disease	404.3	1.11	392.4	1.07	4	4038	11.06
Skin rash	446.9	1.22	436.9	1.20	2	3350	9.17
Fever	539.4	1.48	417.7	1.14	5	4038	11.06
Strep infection	476.4	1.30	416.6	1.14	7	4038	11.06

Table 4. Odds Ratios for Disease by Vaccination Status (Overall)

Condition	Vaccinated Disease / No Disease	Unvaccinated Disease / No Disease	Odds Ratio (95% CI)	P-value
Developmental delays	420/2256	654/3170	0.9 (0.79-1)	0.14
Rhinitis	536/2146	463/3361	1.8 (1.6-2.1)	<0.001
Sinusitis	90/2603	109/3715	1.2 (0.88-1.6)	0.27
Breathing abnormal	429/2200	686/3138	0.89 (0.78-1)	0.094
Ear infection	556/2137	438/3386	2 (1.8-2.3)	<0.001
Respiratory disease	1369/1324	1514/2310	1.6 (1.4-1.7)	<0.001
Skin rash	304/2389	479/3345	0.89 (0.76-1)	0.13
Strep infection	730/1963	542/3282	2.3 (2-2.6)	<0.001
Fever	311/2382	408/3416	1.1 (0.93-1.3)	0.28

Shaded cells indicate statistically significant results ($p < 0.05$).

Table 5. Odds Ratios for Disease by Vaccination Status (Males Only)

Condition	Vaccinated Disease / No Disease	Unvaccinated Disease / No Disease	Odds Ratio (95% CI)	P-value
Developmental delays	242/989	419/1597	0.93 (0.78-1.1)	0.45
Rhinitis	273/963	277/1739	1.8 (1.5-2.1)	<0.001
Sinusitis	30/1213	52/1964	0.93 (0.57-1.5)	0.82
Breathing abnormal	235/973	399/1617	0.98 (0.81-1.2)	0.85
Ear infection	301/942	253/1763	2.2 (1.8-2.7)	<0.001
Respiratory disease	523/720	823/1193	1.1 (0.91-1.2)	0.49
Skin rash	161/1082	266/1750	0.98 (0.79-1.2)	0.87
Strep infection	361/882	312/1704	2.2 (1.9-2.7)	<0.001
Fever	145/1098	228/1788	1 (0.82-1.3)	0.78

Shaded cells indicate statistically significant results ($p < 0.05$).

Table 6. Odds Ratios for Disease by Vaccination Status (Females Only)

Condition	Vaccinated Disease / No Disease	Unvaccinated Disease / No Disease	Odds Ratio (95% CI)	P-value
Developmental delays	133/1033	234/1575	0.87 (0.69-1.1)	0.23
Rhinitis	217/950	185/1624	2 (1.6-2.5)	<0.001
Sinusitis	41/1130	57/1752	1.1 (0.72-1.7)	0.6
Breathing abnormal	144/998	289/1520	0.76 (0.61-0.95)	0.012
Ear infection	238/933	185/1624	2.2 (1.8-2.8)	<0.001
Respiratory disease	484/687	613/1196	1.4 (1.2-1.6)	<0.001
Skin rash	131/1040	213/1596	0.94 (0.74-1.2)	0.64
Strep infection	321/850	230/1579	2.6 (2.1-3.1)	<0.001
Fever	141/1030	180/1629	1.2 (0.97-1.6)	0.079

Shaded cells indicate statistically significant results ($p < 0.05$).

Table 7. Odds Ratios for Disease by Vaccine Dose Quartile

Condition	1st Quartile (1-3 vaccines) OR (95% CI)	P-value	2nd Quartile (4-5 vaccines) OR (95% CI)	P-value	3rd Quartile (6-9 vaccines) OR (95% CI)	P-value	4th Quartile (10+ vaccines) OR (95% CI)	P-value
Developmental delay	0.82 (0.65-1)	0.091	0.66 (0.47-0.92)	0.012	0.74 (0.57-0.95)	0.016	1.4 (1.1-1.7)	0.0031
Rhinitis	1.3 (1-1.6)	0.031	1.4 (1.1-1.9)	0.01	1.7 (1.3-2.1)	<0.001	2.3 (1.9-2.8)	<0.001
Sinusitis	0.87 (0.49-1.4)	0.71	1.1 (0.53-2)	0.75	1.4 (0.83-2.1)	0.17	0.88 (0.48-1.5)	0.7
Breathing abnormal	0.74 (0.58-0.94)	0.011	0.8 (0.59-1.1)	0.16	1.1 (0.84-1.3)	0.66	0.97 (0.77-1.2)	0.87
Ear infection	1.8 (1.5-2.3)	<0.001	2.3 (1.8-3)	<0.001	2.4 (1.9-3)	<0.001	2.5 (2-3.1)	<0.001
Respiratory disease	1.2 (1-1.4)	0.018	1.6 (1.3-2)	<0.001	2 (1.7-2.4)	<0.001	0.5 (0.41-0.61)	<0.001
Skin rash	1.3 (1-1.6)	0.041	0.96 (0.69-1.3)	0.87	1.2 (0.91-1.5)	0.2	0.45 (0.32-0.64)	<0.001
Strep infection	1.5 (1.3-1.9)	<0.001	2.2 (1.7-2.8)	<0.001	3.4 (2.8-4.1)	<0.001	2.7 (2.2-3.3)	<0.001
Fever	0.85 (0.64-1.1)	0.26	1.2 (0.87-1.7)	0.23	1.6 (1.3-2.1)	<0.001	0.92 (0.68-1.2)	0.58

Shaded cells indicate statistically significant results ($p < 0.05$).