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Adverse Outcomes Are Increased with Exposure to Added Combinations of Infant Vaccines

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Abstract

This study evaluates 1,542,076 vaccine combinations administered to infants (less than 1 year of age at time of vaccination) between July 1st, 1991 and May 31st, 2011. All patients received a minimum of DTaP, HIB, and IPV at each administration (Base N=227,231). Vaccines additionally administered form the 7 cohorts of this study: HepB (N=321,296); PNC (pneumococcal) (N=319,420); Rota (N=10,139); HepB-PNC (N=531,516); HepB-Rota (rotavirus)(N=22,800); PNC- Rota (N=35,882); HepB-PNC-Rota (N=73,792). We produce a systematic analysis of the 7 cohorts and discover adverse outcomes associated with vaccine combinations, as well as describe adverse trends based on the increasing number of vaccines administered. All findings reported meet the highest bar of scientific scrutiny, p- value<0.0001 post-Bonferroni correction. This study is limited to diagnoses made within 30-days of vaccination (excluding day-of vaccination) of respiratory, developmental, and suspected infectious disease.

Keywords: *adverse outcome discovery, DTaP, HIB, pneumococcoccal, rotavirus, polio, hepatitis B, developmental diseases, infectious diseases, respiratory diseases, sepsis, suspected infection*

Introduction

Sufficiently sized vaccine combination studies have not been performed. Health safety agencies claim product safety based on isolated vaccine administrations. Studies that do address safety of concomitant administrations lack the cohort sizes (and thus statistical power) to detect clinically relevant interference or safety issues that may occur in fewer than one-in-a-hundred (Fortunato, 2022). In practice, except for the hepatitis B vaccine recommended in the first 24 hours of life, infants rarely receive a single vaccine temporally and clinically isolated from other vaccines. The CDC infant/child schedule (Wodi, 2024) adherence leads to five or six vaccine and vaccine combinations (RV5 has five variants, DTaP is 3-in-1, PCV has 15, 20, or 23 variants) at each 2-month, 4-month, and 6-month pediatrician visit. The result is that, though health safety agencies may claim safety of individual vaccines, claims to safety of vaccine combinations are unfounded.

rotavirus vaccine has been shown to reduce severe diarrhea (Burnett, 2018). Though introduced in 1998 in the United States, it was withdrawn in 1999 due to severe adverse events (intussusception — a life-threatening form of intestinal blockage). It was reintroduced in 2007, temporarily suspended in 2010 for the presence of porcine circovirus types 1 and 2 DNA that led to shedding and possible foreign DNA replication in infants (Mijatovic-Rustempasic et al., 2017). It is used in over 100 countries, and is given routinely in 80 countries. Pneumococcal conjugate vaccine is a polyvalent vaccine designed to create immunity for the bacterium Streptococcus pneumoniae, first licensed in the US in 2000 (Pinkbook: Pneumococcal disease, 2022). The hepatitis B vaccine was the first recombinant DNA vaccine for humans, licensed in the US in 1986, replacing the blood-derived vaccine (Pinkbook: Hepatitis B, 2022).

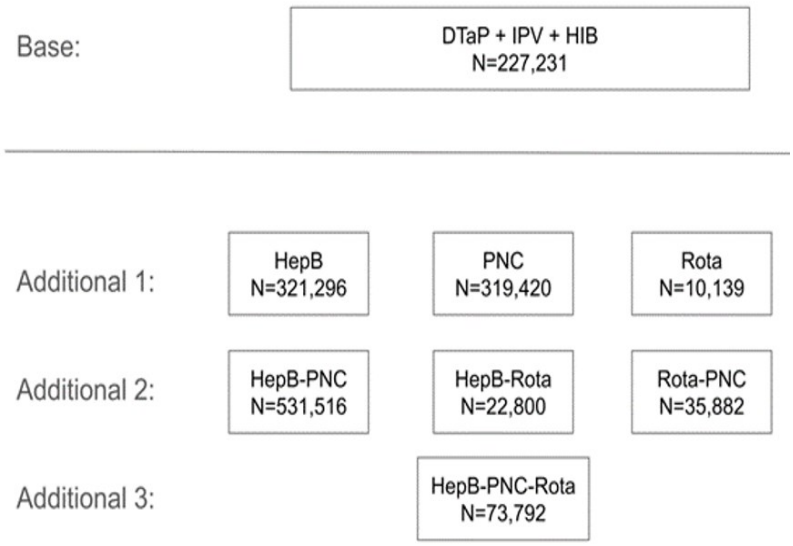

Figure 1. Experimental design depicting the base cohort (those who received only DTaP+IPV+HIB) and the 7 cohort combinations for administration of three additional vaccinations (HepB, PNC, Rota).

2 Methods

2.1 Experimental Design

This study evaluated vaccine combinations for infants between July 1st 1991 thru May 31st 2011. Total vaccine combinations administered number 1,542,076 (Figure 1) from the Florida Medicaid Database. The database constitutes over 460 million diagnosed claims from over 10 million individuals over a 20 year period. The study's basis of comparison (further referred to as "Base" as shown in Figure 1) include 227,231 vaccine combinations where infants received only DTaP, HIB, and IPV vaccines as the control or reference group. The comparing cohorts (also shown in Figure 1) include: HepB (base+HepB; N=321,296); PNC (base+PNC; N=319,420); Rota (base+Rota; N=10,139); HepB-PNC (base+HepB+PNC; N=531,516); HepB-Rota (base+HepB+Rota; N=22,800); PNC-Rota (base+PNC+Rota; N=35,882); HepB-PNC-Rota (base+HepB+PNC+Rota; N=73,792). Medical diagnoses (ICD-9-CM codes) were assessed through 30-days after vaccination exclusive of the day-of-vaccination.

2.2 Statistical Methods

Relative risk is assessed via the Bayesian probability by normalizing the posterior base-cohort ratio by the prior base-cohort ratio, and the 95% confidence intervals are calculated accordingly. This study implements a Python package (scipy.stats.fisher exact package) for a two-tailed Fisher's exact test to derive the *p*-value. The adjusted *p*-value is a Bonferroni correction where the *p*-value is multiplied by the performed number of statistical tests, to mitigate type-I (false positive) errors.

3 Results

The composite of statistically significant (p-value < 0.0001, post-Bonferroni adjustment) diseases along with relative risk and its 95% confidence interval may be seen in Table 1. Detailed within are 45 different diagnoses with the most recurring conditions being of respiratory diseases. Acute bronchiolitis due to other infectious organisms (ICD-9-CM: 466.19), acute upper respiratory infections of unspecified site (ICD-9-CM: 465.9), cough (ICD-9-CM: 786.2), and obstructive chronic bronchitis with acute bronchitis (ICD-9-CM: 491.22) have each appeared as elevated risk in 5 different combinations of vaccines. Obstructive chronic bronchitis with acute bronchitis reaches the highest of these respiratory relative risk of 25.331 (95% CI: 24.601-26.061) in the PNC-Rota combination, which interprets as an infant who receives DTaP + IPV + HIB + PNC + Rota is 2,433% more likely to be diagnosed as such within 30-days post-vaccination than an infant who only received DTaP + IPV + HIB.

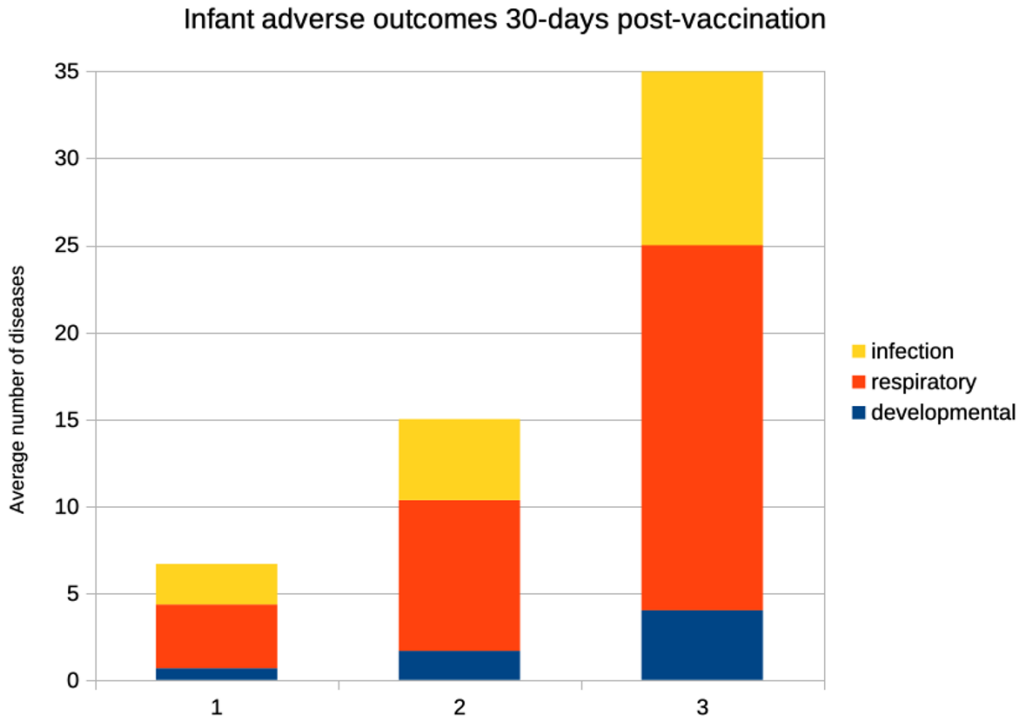

Figure 2.The average number of different diseases detected increases exponentially with every added vaccine.

Table 1

Thirty-day Relative Risk of Infant Vaccination Diagnoses Concerning Respiratory, Developmental, and Suspected Infectious Disease.

Category	ICD-9-CM code	ICD-9-CM Description	DTaP+IPV+HIB (N=227,231)	DTaP+IPV+HIB+HepB (N=321,296)	Bonferroni adjusted p-value	RR (95%CI)
Respiratory	491.22	Obstructive chronic bronchitis with acute bronchitis	9	80	<0.0001	6.287 (5.597-6.976)
				DTaP+IPV+HIB+PNC (N=319,420)		
Developmental	783.40	Lack of normal physiological development, unspecified	135	385	<0.0001	2.029 (1.833-2.225)
	783.41	Failure to thrive	107	290	<0.0001	1.928 (1.706-2.150)
Respiratory	786.2	Cough	2360	4536	<0.0001	1.367 (1.318-1.417)
	770.81	Primary apnea of newborn	140	452	<0.0001	2.297 (2.107-2.486)
	465.9	Acute upper respiratory infections of unspecified site	10630	16515	<0.0001	1.105 (1.081-1.129)
	466.19	Acute bronchiolitis due to other infectious organisms	2758	4697	<0.0001	1.212 (1.165-1.258)
	786.07	Wheezing	555	1094	<0.0001	1.402 (1.300-1.504)
Suspected Infection	472.2	Chronic nasopharyngitis	25	190	<0.0001	5.407 (4.99-5.823)
	009.1	Colitis, enteritis, and gastroenteritis of presumed infectious origin	215	605	<0.0001	2.002 (1.846-2.157)
	461.9	Acute sinusitis, unspecified	184	425	<0.0001	1.643 (1.470-1.816)
				DTaP+IPV+HIB+Rota (N=10,139)		
Respiratory	786.2	Cough	2360	561	<0.0001	4.304 (4.216-4.392)
	466.19	Acute bronchiolitis due to other infectious organisms	2758	321	<0.0001	2.337 (2.223-2.450)
	465.9	Acute upper respiratory infections of unspecified site	10630	737	<0.0001	1.453 (1.381-1.525)
	491.22	Obstructive chronic bronchitis with acute bronchitis	9	11	<0.0001	12.326 (11.591-13.062)
	493.90	Asthma, unspecified type, unspecified	1155	103	<0.0001	1.835 (1.635-2.035)
Suspected Infection	079.99	Unspecified viral infection	2362	197	<0.0001	1.725 (1.582-1.869)
	077.99	Unspecified diseases of conjunctiva due to viruses	14	13	<0.0001	10.791 (10.129-11.452)
	599.0	Urinary tract infection, site not specified	715	73	<0.0001	2.076 (1.837-2.315)
	380.10	Infective otitis externa, unspecified	116	25	<0.0001	3.974 (3.549-4.399)
				DTaP+IPV+HIB+HepB+PNC (N=531,516)		
Respiratory	466.1	Acute bronchiolitis	22	1307	<0.0001	25.398 (24.977-25.820)
	770.8	Other respiratory problems after birth	57	568	<0.0001	4.260 (3.988-4.532)
Suspected Infection	079.9	Unspecified viral and chlamydial infections	57	375	<0.0001	2.813 (2.534-3.091)

				DTaP+IPV+HIB+HepB+Rota (N=22,800)		
Developmental	783.41	Failure to thrive	107	42	<0.0001	3.912 (3.555-4.269)
	783.42	Delayed milestones	51	23	<0.0001	4.495 (4.002-4.987)
	783.40	Lack of normal physiological development, unspecified	135	40	<0.0001	2.953 (2.600-3.306)
Respiratory	786.2	Cough	2360	1123	<0.0001	4.742 (4.673-4.812)
	465.9	Acute upper respiratory infections of unspecified site	10630	1561	<0.0001	1.464 (1.412-1.515)
	466.19	Acute bronchiolitis due to other infectious organisms	2758	507	<0.0001	1.832 (1.738-1.926)
	519.11	Acute bronchospasm	12	30	<0.0001	24.916 (24.246-25.585)
	770.81	Primary apnea of newborn	140	57	<0.0001	4.058 (3.750-4.365)
	519.19	Other diseases of trachea and bronchus	5	16	<0.0001	31.892 (30.888-32.896)
	466.11	Acute bronchiolitis due to respiratory syncytial virus (RSV)	1144	202	<0.0001	1.760 (1.611-1.909)
	786.07	Wheezing	555	115	<0.0001	2.065 (1.865-2.265)
	491.22	Obstructive chronic bronchitis with acute bronchitis	9	15	<0.0001	16.610 (15.784-17.437)
Suspected Infection	077.99	Unspecified diseases of conjunctiva due to viruses	14	38	<0.0001	27.051 (26.439-27.664)
	288.60	Leukocytosis, unspecified	2	20	<0.0001	99.663 (98.209-101.116)
	790.8	Viremia, unspecified	17	19	<0.0001	11.139 (10.485-11.793)
	079.99	Unspecified viral infection	2362	347	<0.0001	1.464 (1.352-1.576)
	599.0	Urinary tract infection, site not specified	715	127	<0.0001	1.770 (1.582-1.958)
				DTaP+IPV+HIB+PNC+Rota (N=35,882)		
Developmental	783.41	Failure to thrive	107	62	<0.0001	3.669 (3.357-3.982)
	315.9	Unspecified delay in development	497	149	<0.0001	1.899 (1.716-2.081)
Respiratory	786.2	Cough	2360	1621	<0.0001	4.350 (4.287-4.412)
	466.19	Acute bronchiolitis due to other infectious organisms	2758	1163	<0.0001	2.670 (2.603-2.738)
	465.9	Acute upper respiratory infections of unspecified site	10630	2814	<0.0001	1.676 (1.636-1.716)
	770.81	Primary apnea of newborn	140	117	<0.0001	5.292 (5.047-5.538)
	519.11	Acute bronchospasm	12	43	<0.0001	22.692 (22.052-23.332)
	786.07	Wheezing	555	218	<0.0001	2.487 (2.331-2.644)
	491.22	Obstructive chronic bronchitis with acute bronchitis	9	36	<0.0001	25.331 (24.601-26.061)
	466.11	Acute bronchiolitis due to respiratory syncytial virus (RSV)	1144	297	<0.0001	1.644 (1.517-1.771)
	493.90	Asthma, unspecified type, unspecified	1155	297	<0.0001	1.628 (1.501-1.755)
	493.01	Extrinsic asthma with status asthmaticus	19	25	<0.0001	8.333 (7.736-8.929)
	793.1	Nonspecific (abnormal) findings on radiological and other examination of lung field	36	31	<0.0001	5.453 (4.973-5.933)
	519.19	Other diseases of trachea and bronchus	5	16	<0.0001	20.265 (19.261-21.269)
	799.02	Hypoxemia	10	18	<0.0001	11.399 (10.626-12.172)
	493.02	Extrinsic asthma with (acute) exacerbation	16	21	<0.0001	8.312 (7.661-8.962)
	491.9	Unspecified chronic bronchitis	28	26	<0.0001	5.880 (5.347-6.414)
Suspected Infection	079.99	Unspecified viral infection	2362	652	<0.0001	1.748 (1.662-1.834)
	288.60	Leukocytosis, unspecified	2	25	<0.0001	79.159 (77.719-80.599)
	599.0	Urinary tract infection, site not specified	715	225	<0.0001	1.993 (1.843-2.142)
	372.00	Acute conjunctivitis, unspecified	415	148	<0.0001	2.258 (2.071-2.446)

	460	Acute nasopharyngitis [common cold]	613	191	<0.0001	1.973 (1.811-2.135)
	461.9	Acute sinusitis, unspecified	184	82	<0.0001	2.822 (2.562-3.082)
	472.0	Chronic rhinitis	424	128	<0.0001	1.912 (1.714-2.109)
	009.1	Colitis, enteritis, and gastroenteritis of presumed infectious origin	215	80	<0.0001	2.356 (2.100-2.613)
				DTaP+IPV+HIB+HepB+PNC+Rota (N=73,792)		
Developmental	783.41	Failure to thrive	107	162	<0.0001	4.662 (4.418-4.906)
	783.40	Lack of normal physiological development, unspecified	135	124	<0.0001	2.828 (2.585-3.072)
	783.42	Delayed milestones	51	62	<0.0001	3.744 (3.373-4.114)
	315.9	Unspecified delay in development	497	273	<0.0001	1.691 (1.544-1.839)
Respiratory	786.2	Cough	2360	3136	<0.0001	4.092 (4.039-4.145)
	465.9	Acute upper respiratory infections of unspecified site	10630	5409	<0.0001	1.567 (1.535-1.599)
	466.19	Acute bronchiolitis due to other infectious organisms	2758	1862	<0.0001	2.079 (2.021-2.137)
	786.07	Wheezing	555	520	<0.0001	2.885 (2.766-3.004)
	770.81	Primary apnea of newborn	140	239	<0.0001	5.257 (5.048-5.465)
	799.02	Hypoxemia	10	71	<0.0001	21.863 (21.201-22.525)
	519.11	Acute bronchospasm	12	62	<0.0001	15.910 (15.292-16.528)
	519.19	Other diseases of trachea and bronchus	5	51	<0.0001	31.409 (30.491-32.328)
	793.1	Nonspecific (abnormal) findings on radiological and other examination of lung field	36	74	<0.0001	6.330 (5.932-6.728)
	466.11	Acute bronchiolitis due to respiratory syncytial virus (RSV)	1144	602	<0.0001	1.620 (1.522-1.719)
	491.22	Obstructive chronic bronchitis with acute bronchitis	9	45	<0.0001	15.397 (14.681-16.112)
	786.1	Stridor	55	72	<0.0001	4.031 (3.680-4.382)
	493.90	Asthma, unspecified type, unspecified	1155	555	<0.0001	1.480 (1.379-1.581)
	493.02	Extrinsic asthma with (acute) exacerbation	16	40	<0.0001	7.698 (7.119-8.278)
	770.89	Other respiratory problems after birth	9	31	<0.0001	10.607 (9.865-11.349)
	079.6	Respiratory syncytial virus (RSV)	219	152	<0.0001	2.137 (1.931-2.344)
	786.03	Apnea	413	234	<0.0001	1.745 (1.585-1.905)
	493.92	Asthma, unspecified type, with (acute) exacerbation	105	85	<0.0001	2.493 (2.207-2.779)
	786.09	Other respiratory abnormalities	911	421	<0.0001	1.423 (1.308-1.538)
	770.82	Other apnea of newborn	12	27	<0.0001	6.929 (6.249-7.608)
	786.05	Shortness of breath	189	123	<0.0001	2.004 (1.777-2.231)
Suspected Infection	079.99	Unspecified viral infection	2362	1175	<0.0001	1.532 (1.462-1.601)
	288.60	Leukocytosis, unspecified	2	43	<0.0001	66.206 (64.788-67.624)
	790.8	Viremia, unspecified	17	48	<0.0001	8.695 (8.142-9.248)
	372.00	Acute conjunctivitis, unspecified	415	261	<0.0001	1.937 (1.782-2.091)
	460	Acute nasopharyngitis [common cold]	613	341	<0.0001	1.713 (1.581-1.845)
	461.9	Acute sinusitis, unspecified	184	143	<0.0001	2.393 (2.175-2.612)
	599.0	Urinary tract infection, site not specified	715	370	<0.0001	1.594 (1.468-1.719)
	375.56	Stenosis of nasolacrimal duct, acquired	129	104	<0.0001	2.483 (2.224-2.741)
	372.30	Conjunctivitis, unspecified	739	362	<0.0001	1.508 (1.383-1.634)
	995.91	Sepsis	9	26	<0.0001	8.896 (8.138-9.654)

abbreviations: relative risk (RR); 95% confidence interval (95%CI); diphtheria, tetanus, acellular pertussis vaccine (DTaP); inactivated polio vaccine (IPV); haemophilus influenzae type b vaccine (HIB); hepatitis b vaccine (HepB); pneumococcal vaccine (PNC); rotavirus vaccine (Rota)

The highest respiratory relative risk of the study is 'other diseases of trachea and bronchus' (ICD-9-CM: 519.19) with an RR=31.409 (95%CI: 30.491-32.328), where infants who received all three vaccines in addition to the base were 3,041% more likely to be diagnosed as such within 30-days post-vaccination than an infant who only received DTaP+IPV+HIB. The highest developmental relative risk in the study is 'failure to thrive' (ICD-9-CM: 783.41) with an RR=4.662 (95% CI: 4.418-4.906) in infants who received all three vaccines in addition to the base. The highest suspected relative risk of infection in this study is for leukocytosis (ICD-9-CM: 288.60; elevated white blood cell count) with an RR = 99.663 (98.209-101.116) in infants who receive the HepB-Rota in addition to the base vaccinations.

The more vaccines administered to an infant results in more diagnoses within 30-days. Administration of one vaccine in addition to Base results in an average of 7 diseases increased relative to the Base cohort (1 developmental, 4 respiratory, and 2 suspected cases of infectious disease). Two vaccines in addition to Base results in an average of 15 diseases increased relative to the Base cohort (2 developmental, 9 respiratory, and 5 suspected cases of infectious disease). Three vaccines administered in addition to Base results in 35 diseases increased relative to the Base cohort (4 developmental, 21 respiratory, and 10 suspected cases of infectious disease).

4 Discussion

Following from Table 1, each additional vaccine more than doubles the diseases diagnosed. All three categories of diseases (developmental, respiratory, or suspected infectious disease) are true to the exponential trend with each additional vaccine doubling or more than doubling the average number of diseases diagnosed.

Respiratory diseases represent the largest cluster of diagnoses associated with the combinations examined. They highlight a maladapted immune response and a poor adaptation to environmental factors. The respiratory constellation of diseases is the clearest evidence put forth that the increase in diseases diagnosed is associated with the increase in the number of vaccines in the combination. Roué, et al. (2018) analyzed the rotavirus vaccine from the French IVANHOE study (Gagneur et al., 2011) of 7,150 preterm and full term infants and found 1.9% and 1.8%, respectively, were diagnosed with severe adverse events possibly related to the vaccine (though the authors dismissed the finding by noting only that the two groups had relative safety, while ignoring the alarming implications of such a high incidence of severe adverse events). The diagnoses only concerned the respiratory conditions of bronchiolitis, bronchopneumonia, and rhinitis.

"Failure to thrive" is consequential with the dysregulated respiratory and immune systems. The diagnosis is represented in the cohorts of: PNC; HepB+Rota; PNC+Rota; HepB+PNC+Rota as compared to the base of DTaP+IPV+HIB only.

Vaccine derived immune dysregulation may also be responsible for the diagnosis of sepsis as seen in the HepB+PNC+Rota cohort. Sepsis is, in essence, a dysregulated response to an infection. The detection of an infection begins the immune pro-inflammatory response to assist in destroying damaged tissue and pathogenic organisms. An anti-inflammatory response concludes the immune reaction. If this conclusion is not successful (or biochemically not perceived to be successful) in containing the damage and pathogen, a pro-inflammatory response becomes systemic and recruits system wide immune defenses. An anti-inflammatory response becomes systemic to down-regulate the systemic pro-inflammatory response. This constitutes the cytokine storm which, if not brought

into regulation, will result in organ dysfunction, organ failure, shock, suppression of the immune system, multiple organ dysfunction, and eventually death. Severe sepsis has a mortality rate of 25%, and septic shock has a mortality rate of 50% (Mayr et al., 2014).

5 Conclusion

This study set out to establish the foundation of vaccine combination safety, which resulted in the discovery of adverse outcomes associated with those combinations. By examining all 7 combinations of 3 vaccines (HepB, PNC, and Rota) in context of the base and widely administered set of 3 others (DTaP, HIB, and IPV) we describe contextually relevant diseases pertaining to development, respiratory, and suspected infectious disease. We additionally go on to describe adverse outcome frequency trends with the increasing number of vaccines. The pattern shown in Table 1 follows that, chiefly, the greater the number of vaccines in the combination yields an exponentially greater number of disease diagnoses.

Limitations

Though a surprising practice, it is generally recommended that preterm infants receive more vaccinations and earlier than full-term infants (Gagneur et al., 2015). This may influence the results to overemphasize pre-term complications in the context of vaccination.

The examined vaccines were administered over a 20 year period. Diagnosable conditions and diagnosing practices that are temporally biased may affect the outcome of the analysis where vaccination practices are likewise temporally affected.

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Data and code availability. All data used is in the public domain and is derived from the Agency for Health Care Administration (https://ahca.myflorida.com/). This project utilized the Python programming language and PostgreSQL code, which will be made available upon request.

Declaration

The authors have no conflicting or competing interests to declare.

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