Increased Mortality Associated with 2-Month Old Infant Vaccinations

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Article

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Abstract

The Louisiana Department of Health provided a dataset of 1,775 children who died before their 3rd birthday, between 2013 and 2024, and were matched to an immunization record. This study analyzes the children vaccinated in their 2nd month of life (60-90 days old) and the outcome of dying in the 3rd month of life (90-120 days old). Children vaccinated in their 2nd month of life were between 29%-74% (depending on vaccine) more likely to die in their 3rd month, between 28%-74% if black, and between 52%-98% if female. Compared collectively, children who received all 6 recommended 2-month vaccines were 68% (68% for blacks and 112% for females) more likely to die in their 3rd month. Not only are these mortality rates elevated, but the causes of death present differently based on vaccination. CDC recommendation-compliant female children were more likely to die of non-leading causes of death, and, in this analysis, included 3 infectious disease and 4 nervous system related mortalities in the vaccinated and zero, in either, for the unvaccinated.

Keywords: infant mortality; SIDS; vaccination; respiratory syncytial virus; hepatitis B; rotavirus; diphtheria; tetanus; pertussis; haemophilus influenza type B; pneumococcal; poliovirus

Introduction

Communicable disease is voraciously addressed with the public health practice of childhood vaccination. This practice administers an intervention to a healthy child with the motivation of preventing or diminishing a future disease. There are two dynamics to consider, and sometimes they are opposed: the health of the public and the health of the individual. To paraphrase Jeremy Bentham, the father of modern utilitarianism, "the greatest health for the greatest number". It is the definition of "healthy" for a society to maximize health, but health choices break down to individual choices. "Do no harm" is not a matter of perspective, it is an ethical edict. So a healthy choice for the public must, necessarily, also be a healthy choice for the individual - and the evidence to support those choices must, necessarily, be clear.

During the study period (2013-2024) the Centers for Disease Control and Prevention (CDC) recommended immunization schedule [1] includes seven different immunizations for the age of 2-months. A CDC compliant child could expect to be immunized for respiratory syncytial virus, hepatitis B, rotavirus (up to 5 live viruses), diphtheria, tetanus, pertussis (3- or 4-antigens), haemophilus influenza type B, pneumococcal (up to 20 different strains), and poliovirus (all 3 strains, though two are now eradicated [2]). It is the largest single-day antigenic assault a person is ever likely going to encounter in their lifetimes, and may be accompanied with 1.225 mg of aluminum adjuvant (DTaP 0.625mg [3] (revised down to 0.5mg in 2023 [4]), Hib 0.225mg [5], PCV 0.125mg [6], HepB 0.25mg [7]) even though the (baseless [8]) maximum per-dose limit allowable by the Food and Drug Administration (FDA) is 0.85mg [9].

The infant mortality rate in the United States is approximately 1-in-200 (in 2023 there were 20,162 deaths per 3,596,017 births with a rate of 5.61 per thousand [10]). In what amounts to one of the greatest health hazards in the entire country, and a national injustice, the infant mortality rate in the United States for babies born to a Black of African American mother is approximately 1-in-100, almost

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twice that of the national rate (in 2023 there were 5,844 deaths per 554,733 births with a rate of 10.53 per thousand).

Sudden Infant Death Syndrome (SIDS) is an unexplained sudden death in the first year of life. With the support of the CDC and the American Academy of Pediatrics (AAP), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the U.S. National Institutes of Health (NIH), has led and funded the "Safe to Sleep" campaign (formerly known as "Back to Sleep"). The campaign has been widely perceived to be successful. "A dramatic decline in SIDS incidence has been observed in many countries after the introduction of "Back to Sleep" campaigns for prevention of SIDS. All infants should be placed to sleep in a safe environment including supine position, a firm surface, no soft objects and loose bedding, no head covering, no overheating, and room-sharing without bed-sharing." [11]

Methods

This study meets criteria for exemption by the Louisiana Department of Health (LDH) Institutional Review Board (IRB) (FWA00026681). The LDH Office of Public Health (OPH) utilized the Louisiana Electronic Event Registration System (LEERS), a vital records database, and Louisiana Immunization Network (LINKS), an immunization information system, to match immunization records (including CVX [12] code for the vaccine and the day-of-life it was administered) to death records (including cause of death) of children who died under the age of 36 months. Of the approximately 5,800 children who died before their 3rd birthday between 2013 and 2024, 1,775 deceased children could be exactly matched to their immunization record. This analysis excludes the 550 children who died before an age of 90 days (Figure 1).

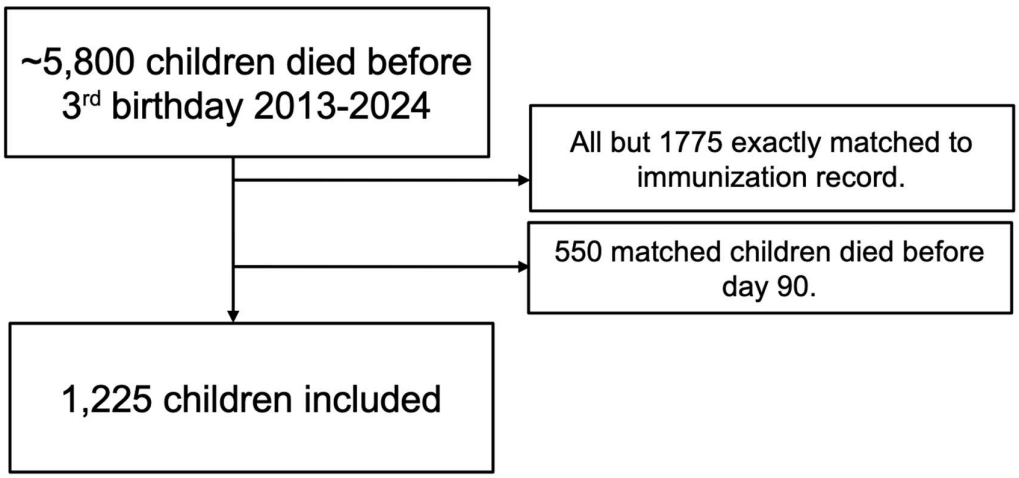

Figure 1. Inclusion and exclusion criteria. Of the ~5,800 children who died before their third birthday, 1,775 were exactly matched to their immunization schedule. The 550 children who died before day 90 were excluded, leaving 1,225 children to be considered for this study.

The analysis of the Louisiana child death and immunization data was undertaken in three parts. The mortality rates of individual vaccines, in general combination of 5 (DTaP, rotavirus, HIB, polio, and pneumococcal) and 6 (HepB) vaccines, and the specific formulations of marketed combination vaccines (GlaxoSmithKline's Pediarix® [CVX code 110], Sanofi Pasteur's Pentacel® [CVX code 120], and MSP Vaccine Company's (a joint venture between Merck and Sanofi Pasteur) Vaxelis® [CVX code 146]) were assessed.

A child was considered to be vaccinated if they were documented as receiving the vaccine between day 60 and day 90 of life, and unvaccinated if they did not meet that criteria. A child was considered to have 'died' if they died between day 90 and day 120, and considered 'alive' if they died

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after day 120. Since this is a mortality dataset, all children represented herein died before their 3rd birthday.

For individual vaccine considerations, children were excluded if the first vaccination was before 60 days of life, and numbered for: DTaP=84; HIB=80; polio=85; pneumococcal=85; rotavirus=77, with 67 in common for all five vaccines. No HepB children were excluded for earlier vaccinations as they abided by CDC recommendations.

Data on national infant mortality is obtained from the National Center for Health Statistics. The linked birth/infant death records, 2017–2023 expanded [Data set] is hosted by the CDC.

Statistical computations were made using the SciPy (v1.10.1) library package running on Python (v3.8.10).

Results

The 1,225 children represented by the dataset, Table 1, were more likely to be: male (57.0%); black (58.6%); non-hispanic (94.1%). The year 2015 saw the greatest number of deaths in this dataset (10.4%). To appear in this dataset, a child must minimally have been immunized at least once and died within their first 3 years of life. When inspecting vaccination between days 60 and 90 of life, Table 2, the lowest mortality rate is that of the unvaccinated (15.16%) and the greatest mortality rate is associated with Vaxelis [13] (30.65%), a hexa-valent vaccine containing 0.319 mg aluminum from aluminum slats used as adjuvants (both aluminum phosphate and amorphous aluminum hydroxyphosphate sulfate). The vaccine contains 11 antigens, one for each diphtheria, tetanus, hepatitis B, HIB, each of the 3 types of poliovirus, and 4 for pertussis.

Table 1. Demographics.

Category	Sub-Category	N	%
Total		1225	
Sex	Male	698	57.0%
	Female	527	43.0%
Race	Black	718	58.6%
	White	465	38.0%
	Asian	7	0.6%
	AIAN	5	0.4%
	other	30	2.4%
Ethnicity	Non-Hispanic	1153	94.1%
	Hispanic	50	4.1%
	missing	22	1.8%
Year of Death	2013	116	9.5%
	2014	107	8.7%
	2015	127	10.4%
	2016	116	9.5%
	2017	104	8.5%
	2018	84	6.9%
	2019	87	7.1%
	2020	92	7.5%
	2021	97	7.9%
	2022	110	9.0%
	2023	104	8.5%
	2024	81	6.6%

Demographics for the 1,225 included individuals. AIAN=American Indian and Alaskan Native.

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Table 2. Mortalities by vaccinations administered between 60 and 90 days of life.

vaccinations between 60-90 days	N	Mortality	% Mortality
unvaccinated	343	52	15.16%
DTaP	777	151	19.43%
HepB	717	143	19.94%
HIB	772	149	19.30%
polio	772	148	19.17%
pneumococcal	759	148	19.50%
rotavirus	611	133	21.77%
DTaP+Rota+HIB+polio+Pneu	589	131	22.24%
DTaP+Rota+HIB+polio+Pneu+HepB	536	124	23.13%
Pediarix®+HIB	408	80	19.61%
Pentacel®+HepB	214	40	18.69%
Vaxelis®	62	19	30.65%

The number of children, the assessed mortality, and the mortality rate based on vaccinations administered between 60 and 90 days of life. Mortality is defined as a death between 90 and 120 days of life. Described here are the unvaccinated, the individual 6 vaccines recommended for 2-month old infants by the CDC, a combination of the 5 first given at 2-months (DTaP+Rota+HIB+polio+pneumococcal), a combination of all 6 (DTaP+Rota+HIB+polio+pneumococcal add HepB), and the 3 combination vaccines (Pediarix®+HIB, Pentacel®+HepB, Vaxelis®). [DTaP='diphtheria tetanus pertussis' treated in this manuscript as 1 vaccine; HepB='hepatitis B'; HIB='haemophilus influenzae type b'; Pneu short for pneumococcal; rota short for rotavirus].

Child Mortality Associated with Individual Vaccines

Children vaccinated in their 2nd month of life were more likely to die in their 3rd month of life (Figure 2). This is relative to the control group children who were unvaccinated in that same time window. The hazard for the vaccinated translated to an increase in mortality by: 42% for DTaP; 29% for HepB; 35% for HIB; 32% for polio; 41% for pneumococcal; 74% for rotavirus (reaching statistical significance OR=1.74 (1.26-2.41), p-value=0.0005). For every vaccine inspected, children who were not vaccinated in their 2nd month of life had a lower mortality rate than those who were vaccinated in that same time window.

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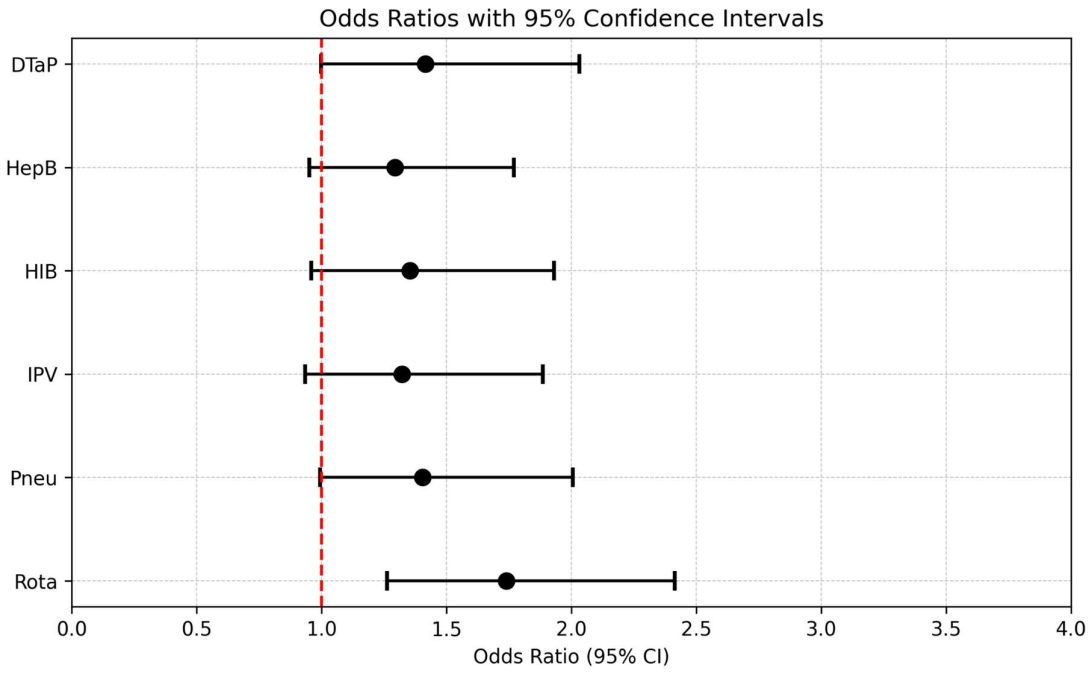

Figure 2. Mortality odds for individual 2-month vaccinations compared to unvaccinated infants. Vaccinated compared to unvaccinated for 6 CDC recommended vaccines at 2 months of age. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 (for the exception of HepB where such vaccination is recommended) were excluded.

Race Differences in Child Mortality Associated with Individual Vaccines

The increase in mortality odds was greater for black children than for white children for every individual vaccine inspected (Figure 3). This is relative to the race-specific control group children who were unvaccinated in that same time window. The increased mortality odds: for DTaP was 38% for blacks and 26% for whites; for HepB was 28% for blacks and 18% for whites; for HIB was 38% for blacks and 14% for whites; for polio was 33% for blacks and 12% for whites; for pneumococcal was 47% for blacks and 11% for whites; for rotavirus was a statistically significant 74% (OR=1.74 (1.14-2.68) p-value=0.0079) for blacks and 43% for whites. The differences show that black-vaccinated children (relative to black-unvaccinated children) are more likely to die than white-vaccinated children (relative to white-unvaccinated children). For every vaccine inspected, both black and white children who were not vaccinated in their 2nd month of life had a lower mortality rate than their vaccinated counterparts in that same time window.

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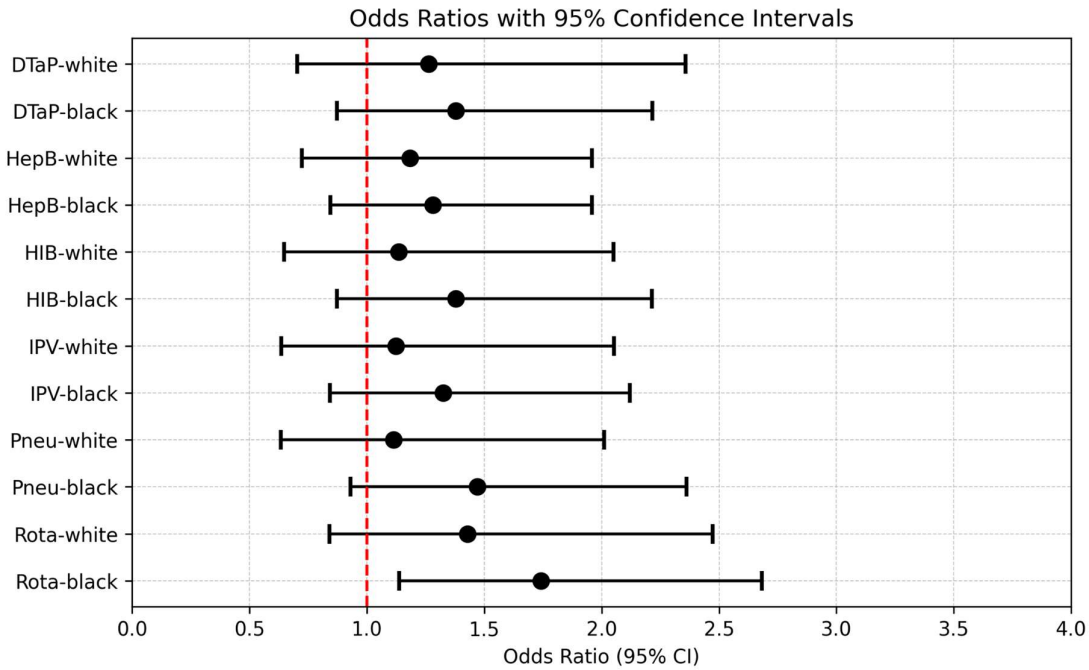

Figure 3. Mortality odds for individual 2-month vaccinations compared to unvaccinated infants by race. Vaccinated compared to unvaccinated for 6 CDC recommended vaccines at 2 months of age by race (black and white). The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 (for the exception of HepB where such vaccination is recommended) were excluded.

Sex Differences in Child Mortality Associated with Individual Vaccines

The vast majority of added mortality risk was borne by females (Figure 4). The increase in mortality odds was greater for female children than for male children for every individual vaccine inspected, and statistically significant for all but HepB (Figure 4). This is relative to the sex-specific control group children who were unvaccinated in that same time window. The increased mortality odds: for DTaP was 98% (OR=1.98 (1.13-3.63), p-value=0.0130) for females and 10% for males; for HepB was 52% for females and 14% for males; for HIB was 87% (OR=1.87 (1.08-3.38), p-value=0.0193) for females and 6% for males; for polio was 77% (OR=1.77 (1.03-3.17), p-value=0.0359) for females and 5% for males; for pneumococcal was 85% (OR=1.85 (1.07-3.30), p-value=0.0204) for females and 14% for males; for rotavirus was 89% (OR=1.89 (1.16-3.11) p-value=0.0088) for females and 62% (OR=1.62 (1.04-2.54), p-value=0.0277) for males. The differences show that female-vaccinated children (relative to female-unvaccinated children) are more likely to die than male-vaccinated children (relative to male-unvaccinated children). For every vaccine inspected, both male and female children who were not vaccinated in their 2nd month of life had a lower mortality rate than their vaccinated counterparts in that same time window.

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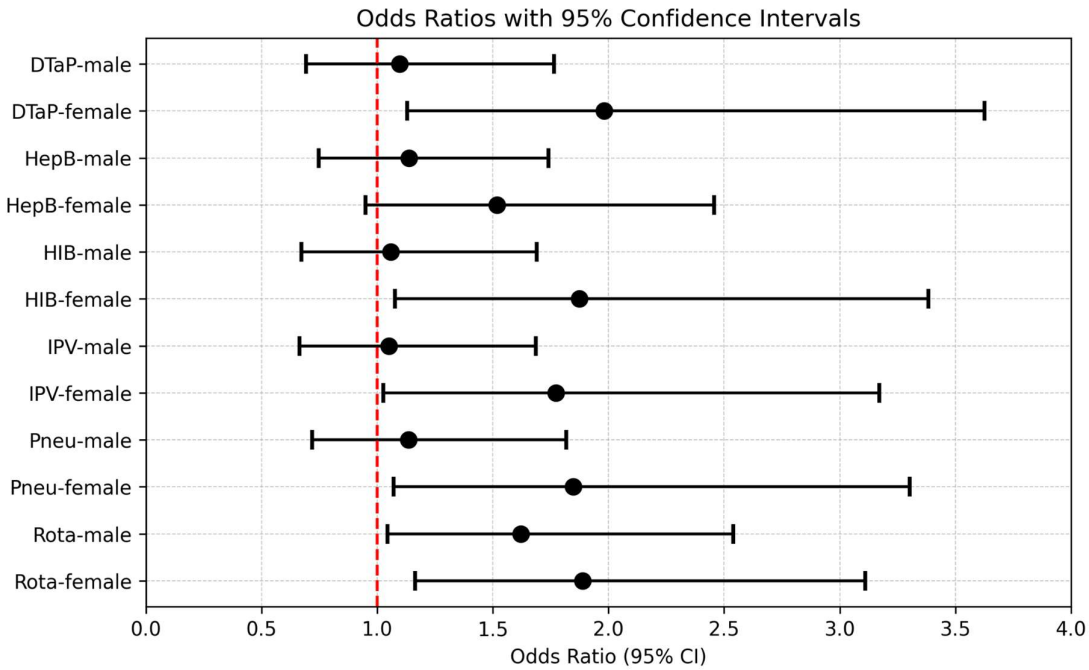

Figure 4. Mortality odds for individual 2-month vaccinations compared to unvaccinated infants by sex. Vaccinated compared to unvaccinated for 6 CDC recommended vaccines at 2 months of age by sex. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 (for the exception of HepB where such vaccination is recommended) were excluded.

Child Mortality Associated with Combinations of 5 and 6 Vaccines

In practice, children do not generally receive vaccinations individually but as a recommended regimen of multiple vaccinations. Children adhering to the CDC immunization schedule receive a HepB vaccine (up until very recently) and an RSV monoclonal antibody immunization shortly after birth. The 2-month recommendation represents the greatest single-day first-time vaccination likely to be experienced in childhood or adulthood, with the possible exception of those required for military service and readiness.

Children receiving all 5 first-time recommended vaccines for 2-month olds (DTaP, rotavirus, HIB, polio, and pneumococcal) were compared to children who did not receive any of the 5 vaccines in their second month of life (Figure 5). Children who received all five vaccines were 60% (OR=1.60 (1.12-2.32), p-value=0.0084) more likely to die in their 3rd month compared to the unvaccinated. Black children who received all five vaccines were 62% (OR=1.62 (1.01-2.64), p-value=0.0446) more likely to die in their 3rd month compared to unvaccinated blacks. Female children who received all five vaccines were 109% (OR=2.09 (1.17-3.89), p-value=0.0093) more likely to die in their 3rd month compared to unvaccinated females.

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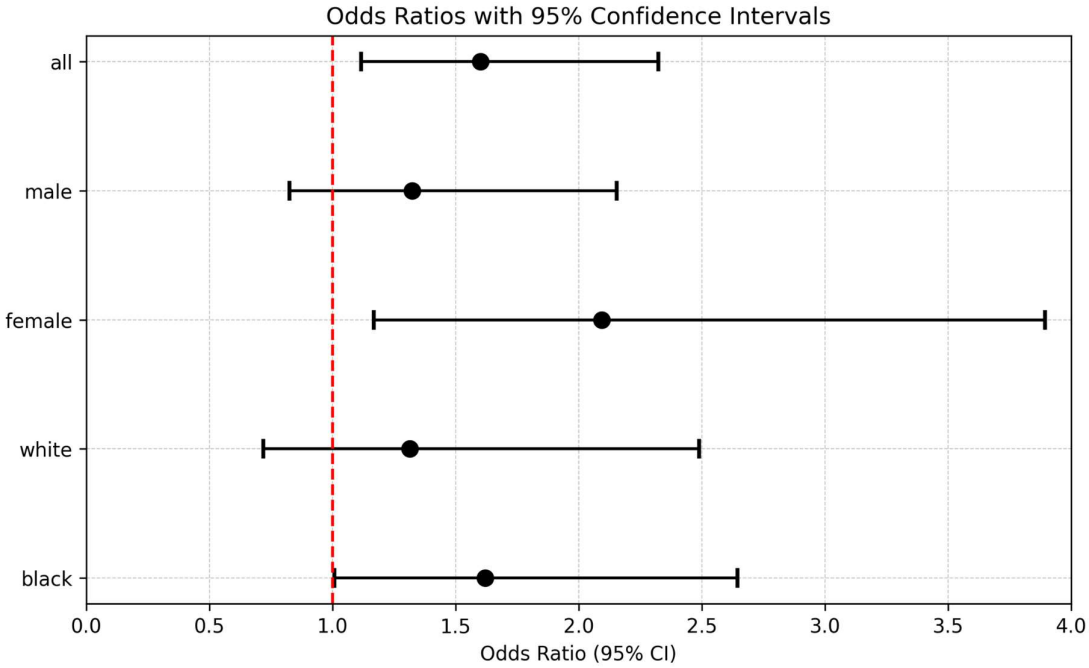

Figure 5. Mortality odds for children receiving 2-month DTaP, rotavirus, HIB, polio, and pneumococcal vaccines compared to unvaccinated infants. Vaccinated compared to unvaccinated all 5 first CDC recommended vaccines at 2 months of age. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 were excluded. Populations considered were: all, both sexes, and the two leading races (blacks and whites).

When including consideration for the HepB vaccine, children receiving all 6 recommended vaccines for 2-month olds (DTaP, rotavirus, HIB, polio, pneumococcal, and HepB) were compared to children who did not receive any of the 6 vaccines in their second month of life (Figure 6). Children who received all six vaccines were 68% (OR=1.68 (1.16-2.46), p-value=0.0043) more likely to die in their 3rd month compared to the unvaccinated. Black children who received all six vaccines were 68% (OR=1.68 (1.04-2.77), p-value=0.0311) more likely to die in their 3rd month compared to unvaccinated blacks. Female children who received all six vaccines were 112% (OR=2.12 (1.18-3.98), p-value=0.0083) more likely to die in their 3rd month compared to unvaccinated females.

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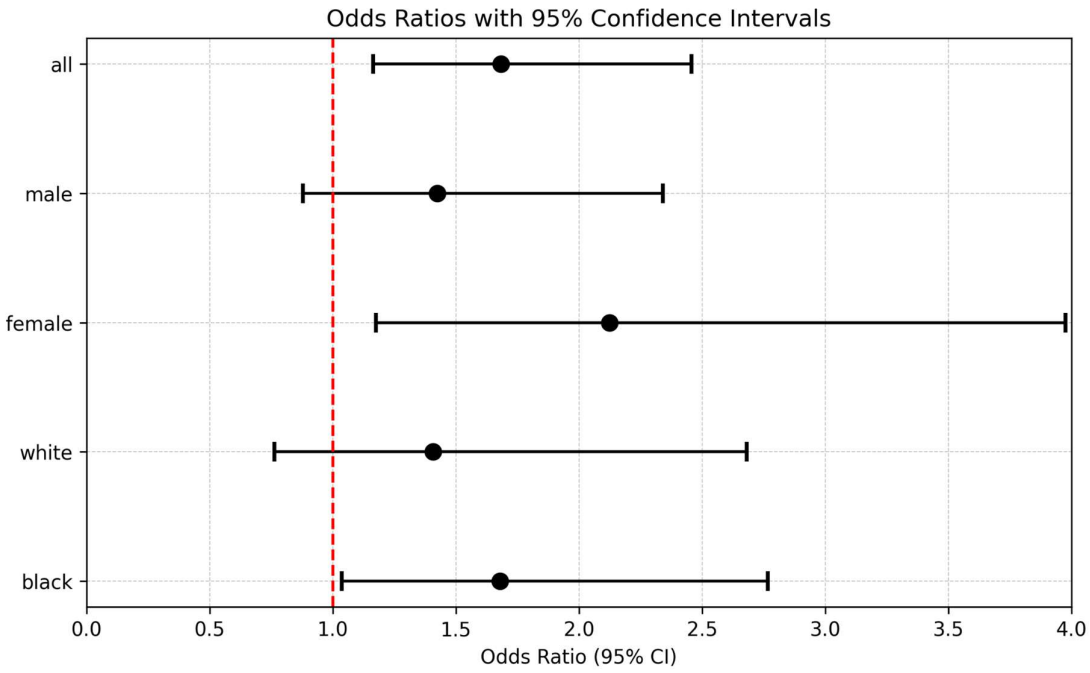

Figure 6. Mortality odds for children receiving 2-month DTaP, rotavirus, HIB, polio, pneumococcal, and HepB vaccines compared to unvaccinated infants. Vaccinated compared to unvaccinated all 6 CDC recommended vaccines at 2 months of age. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 were excluded (with the exception of the CDC recommendation compliant HepB). Populations considered were: all, both sexes, and the two leading races (blacks and whites).

Child mortality Associated with Formulated Combination Vaccines

Formulated combinations vaccines are widely used in the United States. GlaxoSmithKline manufactures Pediarix® [CVX code 110] and includes vaccinations for DTaP, HepB, and polio. Sanofi Pasteur manufactures Pentacel® [CVX code 120] and includes vaccinations for DTaP, HIB, and polio. MSP Vaccine Company (a joint venture between Merck and Sanofi Pasteur) manufactures Vaxelis® [CVX code 146] and includes vaccinations for DTaP, HepB, HIB, and polio.

Children who received GlaxoSmithKline's Pediarix® and a HIB vaccine were compared to children who did not receive any of the 4 vaccines in their second month of life (Figure 7). Vaccinated children were 40% more likely to die in their 3rd month compared to the unvaccinated. Black vaccinated children were 39% more likely to die in their 3rd month compared to unvaccinated blacks. Female vaccinated children were 96% (OR=1.96 (1.04-3.78), p-value=0.0295) more likely to die in their 3rd month compared to unvaccinated females.

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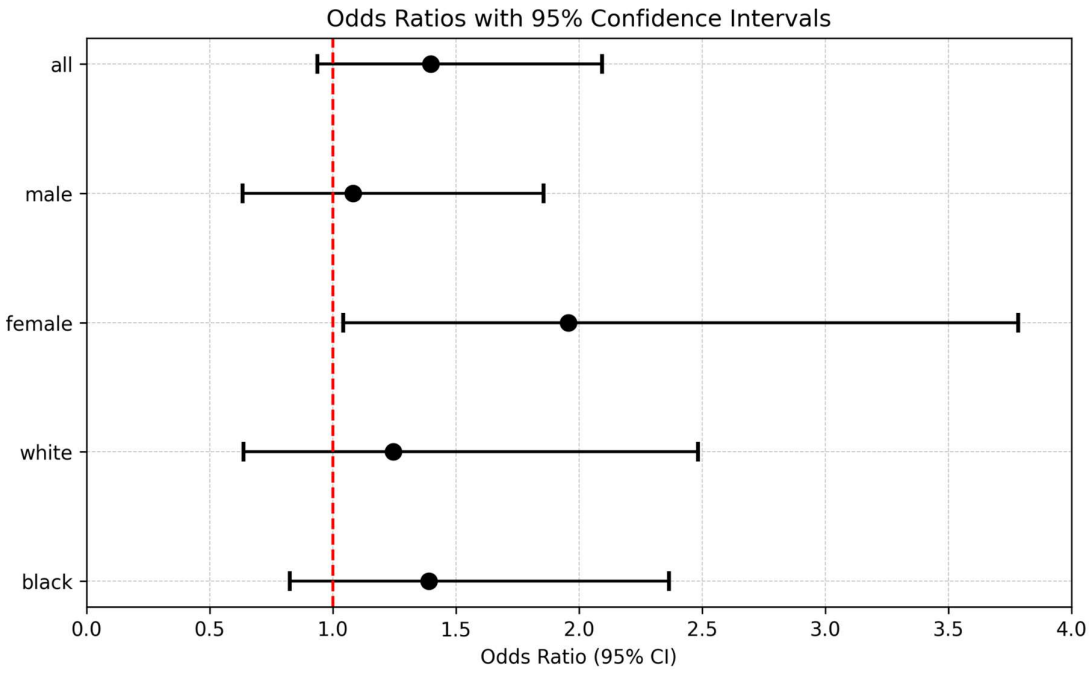

Figure 7. Mortality odds for children receiving Pediarix® and HIB in their 2-month vaccinations compared to the unvaccinated. Vaccinated children where Pediarix® and HIB were included in their 2-month vaccination compared to unvaccinated. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 were excluded (with the exception of the CDC recommendation compliant HepB). Populations considered were: all, both sexes, and the two leading races (blacks and whites).

Children who received Sanofi Pasteur's Pentacel® and a HepB vaccine were compared to children who did not receive any of the 4 vaccines in their second month of life (Figure 8). Vaccinated children were 32% more likely to die in their 3rd month compared to the unvaccinated. Black vaccinated children were 21% more likely to die in their 3rd month compared to unvaccinated blacks. Female vaccinated children were 84% more likely to die in their 3rd month compared to unvaccinated females.

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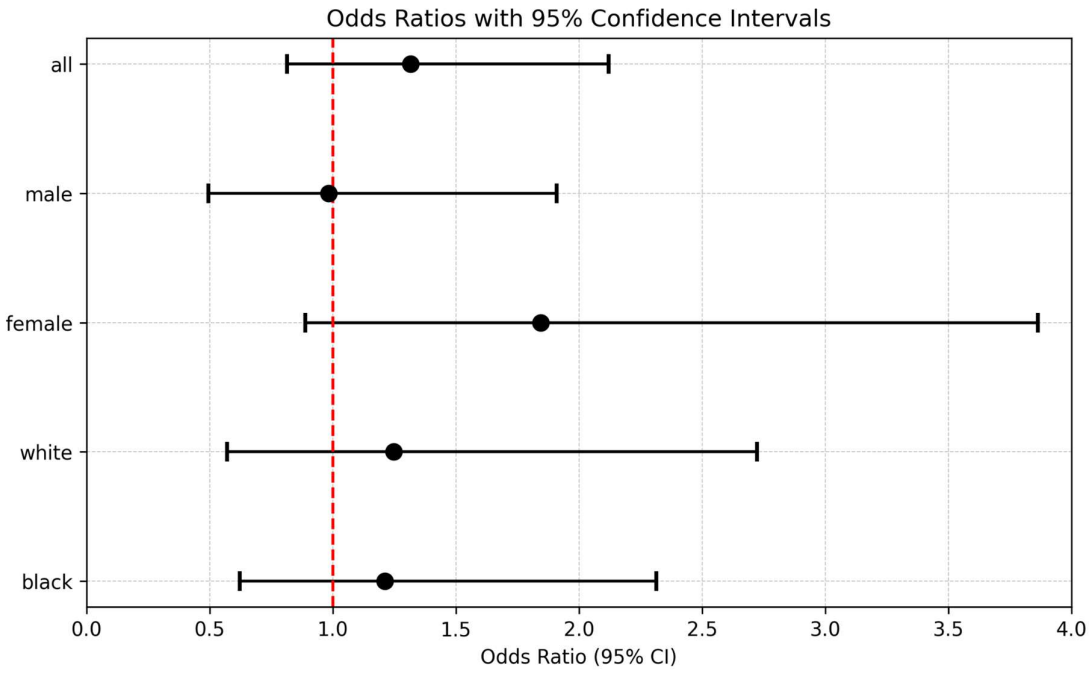

Figure 8. Mortality odds for children receiving Pentacel® and HepB in their 2-month vaccinations compared to the unvaccinated. Vaccinated children where Pentacel® and HepB were included in their 2-month vaccination compared to unvaccinated. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 were excluded (with the exception of the CDC recommendation compliant HepB). Populations considered were: all, both sexes, and the two leading races (blacks and whites).

Children who received MSP Vaccine Company's Vaxelis® vaccine were compared to children who did not receive any of the 4 vaccines in their second month of life (Figure 9). Vaccinated children were 153% (OR=2.53 (1.29-4.84), p-value=0.0054) more likely to die in their 3rd month compared to the unvaccinated. Black vaccinated children were 122% more likely to die in their 3rd month compared to unvaccinated blacks. Female vaccinated children were 150% more likely to die in their 3rd month compared to unvaccinated females.

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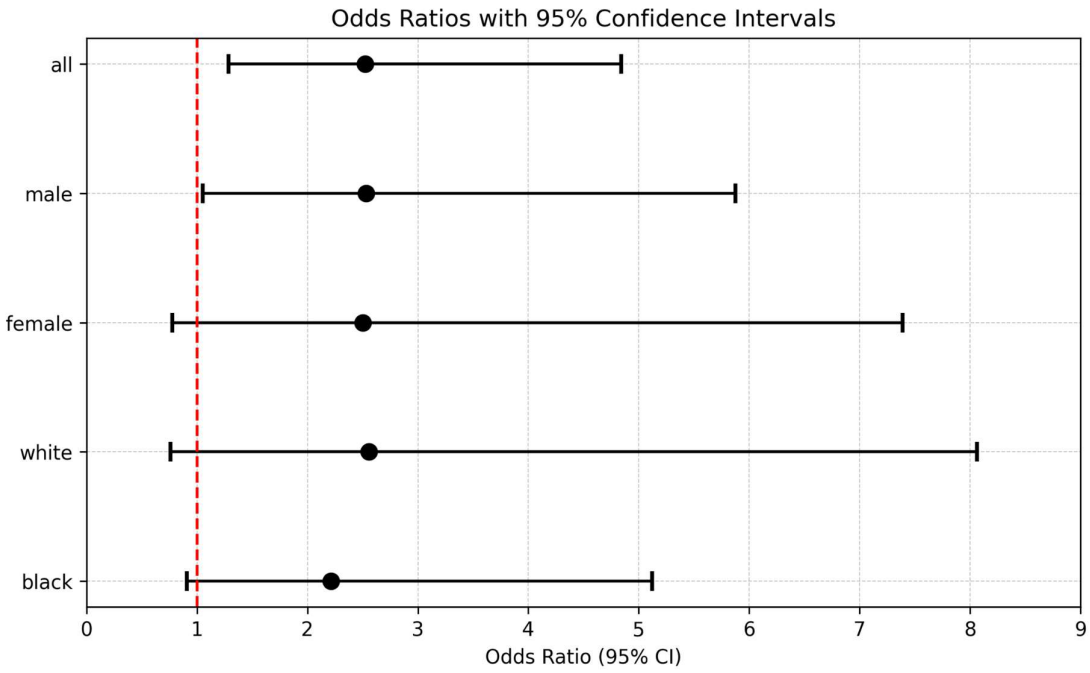

Figure 9. Mortality odds for children receiving Vaxelis® in their 2-month vaccinations compared to the unvaccinated. Vaccinated children where Vaxelis® was included in their 2-month vaccination compared to unvaccinated. The figure reflects the odds of an infant dying in their 3rd month of life if they were vaccinated in their second month of life. Children vaccinated before day 60 were excluded (with the exception of the CDC recommendation compliant HepB). Populations considered were: all, both sexes, and the two leading races (blacks and whites).

Cause of Death in Children Associated with Vaccines

For the last several decades the portion of infant mortality of those who died between 28 and 364 days of life has remained relatively constant (Figure 10). The medical and infant health advocacy community has heralded the decline of Sudden Infant Death Syndrome (SIDS) over those decades. Though the SIDS (ICD10:R95) rates have fallen, accidental suffocation and strangulation (ICD10:W75) and other ill-defined and unspecified (ICD10:R99) causes of death have commensurately risen.

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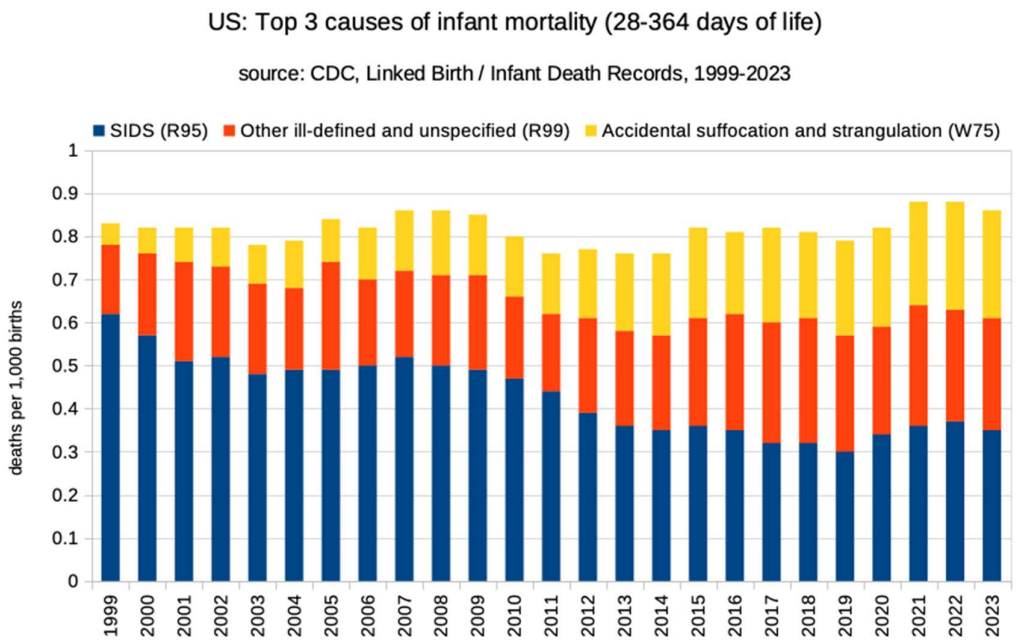

Figure 10. Leading Causes of Infant Death in the US. Top 3 causes of infant death in the United States at 28-364 days of life. Though Sudden Infant Death Syndrome (SIDS) (ICD10: R95) has been declining over the past decades, the other classified causes of other ill-defined and unspecified (ICD10: R99) and accidental suffocation and strangulation (ICD10: W75) has commensurately increased over the same time period. The resulting impact is that the top three causes of infant death have been held close to constant over the decades.

If vaccinations played no part in 3rd month mortalities, we would expect to see the proportion of the leading causes of death held constant. That is, of the 19 unvaccinated female children who died in their 3rd month, 14 of them (74%) died of a leading cause of death (defined as ICD10 chapters W and R) while the remaining (26%) died from various other causes. Since 37 vaccinated female children died of a leading cause, 13 mortalities from other causes are expected. However 25 are found, a 92% increase. Three vaccinated females died of an infectious disease compared to zero unvaccinated. Four vaccinated females died of a nervous system disease compared to zero unvaccinated.

Discussion

Data provided by LDH of 1,775 children and their immunizations reveal strong associations between 2-month old vaccinations and mortality. Those associations are stronger for blacks and strongest for females. Not only do vaccinated children die at a higher rate than unvaccinated children, they also die of different causes.

Compared to their unvaccinated counterparts, females were much more likely to die post-vaccination than males. The difference is so great, it is statistically significant almost everywhere it was measured. The strongest association for females has biological and medical plausibility. Fink & Klein [14] characterize sex differences in early life for immune systems and vaccinations as "[t]he observed combination of lower levels of BAFF [B cell-activating factor family] and higher proportions of CD5+ B cells in boys as compared with girls suggests that sex differences in the humoral immune response may be present at birth, with boys having a more immature/naïve immune system, in general." Klein & Flanagan [15] go on to show a greater immune response to vaccination for females and a greater rate of adverse reactions, when characterized, for vaccinated females.

The culmination of this study is a proof-of-concept, that it is possible to show statistically significant harm associated with vaccinations in infants in a dataset of 1,225 eligible children. To validate, generalize, and explore that harm further requires corroboration with additional sources of

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evidence. Every state, province, and country where an immunization registry may be matched with a death registry may provide that evidence.

Conclusion

Children who are vaccinated in their 2nd month of life are more likely to die in their 3rd month. Not only are these mortality rates elevated, but the causes of death are presented differently based on vaccination. CDC recommendation compliant female children were more likely to die of non-leading causes of death, and in this analysis included 3 infectious disease and 4 nervous system related mortalities in the vaccinated and zero, in either, for the unvaccinated.

Acknowledgments: The authors would like to thank the state of Louisiana, and all those who govern it, for making this data available.

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