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Attorneys for Petitioners

UNITED STATES DISTRICT COURT OF CALIFORNIA

EASTERN DISTRICT - SACRAMENTO

Joy Garner, individually and on behalf of The Control Group; Joy Elisse Garner, individually and as parent of J.S. and F.G.; Evan Glasco, individually and as parent of F.G.; Traci Music, individually and as parent of K.M. and J.S., Michael Harris, individually and as parent of S.H., Nicole Harris, individually and as parent of S.H.,

Petitioners,

v.

DONALD JOHN TRUMP, in his official capacity as PRESIDENT OF THE UNITED STATES OF AMERICA,

Respondent.

Case No.: 2:20−CV−02470−WBS−JDP

DECLARATION OF RACHEL WEST, DO IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION, OR IN THE ALTERNATIVE REQUEST FOR ORDER TO SHOW CAUSE

Date: February 22, 2021
Time: 1:30 PM
Courtroom: 5
Judge: William B. Shubb

Rachel West, DO Declaration

I, Rachel West, DO, hereby declare:

1. I am a licensed physician in the State of California, and board certified in Family Medicine, and practice Integrative Family Medicine. At my private clinic in Los Angeles, California, I treat patients of all ages, everyone from babies to elderly patients.

Professional Background & Medical Focus

2. Attached as Exhibit A is a true and correct copy of my Curriculum Vitae showcasing my extensive experience and certifications as a physician. On the basis of my education and experience, I am qualified to provide the professional opinion in this declaration.

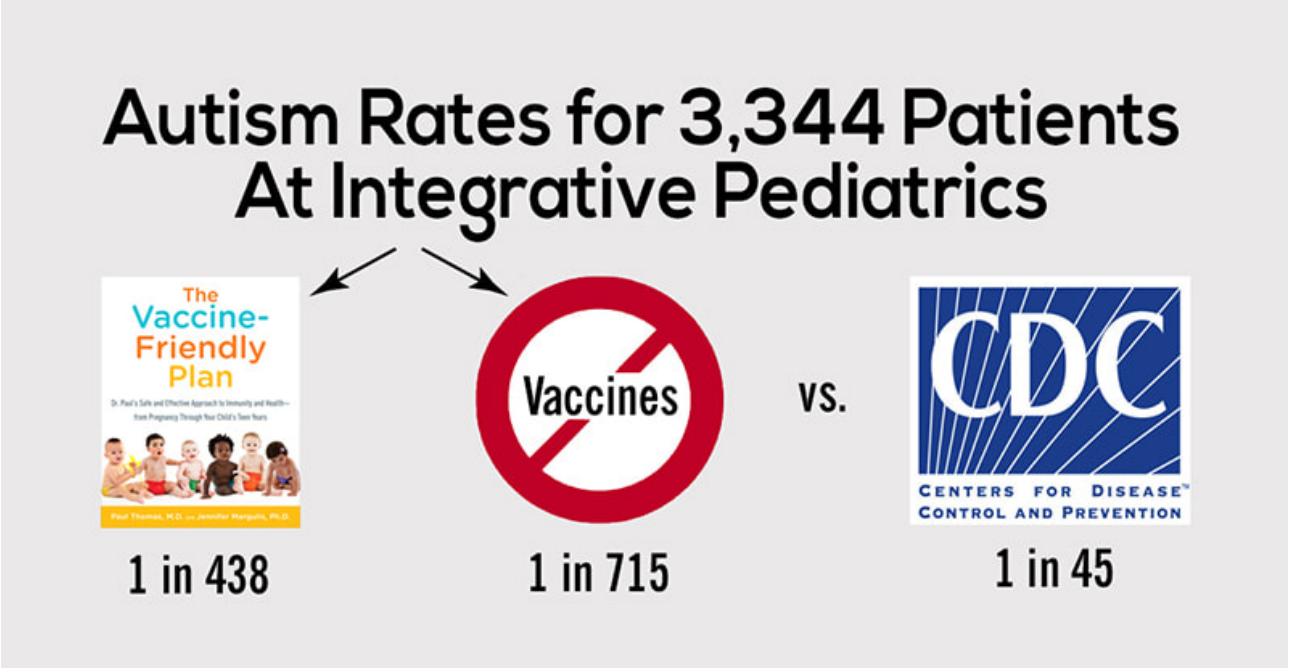
3. In particular I help patients with nutritional therapies, hormonal balancing, heavy metal detoxification, and oxidative medicine (MAH, UBI). For patients, this includes comprehensive testing to help address the root causes of illness, toward the goal of working with patients on recovering, maintaining, and promoting long-term health.

Clinically Evaluating Vaccinated versus Unvaccinated

4. Like many integrative physicians, I interface with both vaccinated and unvaccinated patients. My colleagues and I have observed that our unvaccinated patients are exponentially healthier than the vaccinated. Test results and examinations of the unvaccinated consistently show thriving immune system health, and a near absence of chronic illness.

5. I have learned to inquire with unvaccinated patients whether they received the Vitamin K shot at birth (due to harmful aluminum and benzyl alcohol), and also whether the mother was vaccinated during pregnancy, as these patients tend to present with higher rates of chronic illness and therefore require more work up and treatment options.

6. Although genetics is relevant, it is impossible that autism could be a “genetic disorder”; autism is caused primarily by vaccination. I have an autism spectrum disorder questionnaire that I use with new patients. My colleague Paul Thomas, MD has documented a similar phenomenon in his own practice:



As colleagues, this is the type of information we share in the normal course of our practices, because a key job of a physician is investigative. I've observed integrative physicians in particular are more likely to take respect this solemn responsibility by engaging in the laborious process of genuinely listening to patients, independently observing, and thinking critically. Debunking of the CDC vaccine schedules (children and adult) is widespread among my integrative physician colleagues, and it saddens us to observe the consequences of that CDC schedule in the daily harm to children and adults. Indeed, most of the patients that come to our integrative practices are more educated and/or exiles from conventional medical practices, because the patient families realized the folly of practices beholden to the recommendations of pharmaceutical manufacturers.

7. As a physician, I have personally observed multiple cases of blatantly obvious vaccine injury where the conventional physician who vaccinated denied the obvious causation. One case that comes to mind is a baby who immediately developed a gray area (i.e., necrosis) around the vaccine injection site. The gray area spread gradually to other parts of the body, and the hospital doctor silenced the mother (from reporting her observations) and instead diagnosed the baby with choking on the mother's breast milk. Firemen helped save the baby after the situation escalated. The mother promptly departed the conventional practice and the family comes to me for treatment. First

and foremost, the mother stopped vaccinating the baby. And that baby is now thriving today as a child.

8. Another key point is that reproduction is the best method to nullify the effects of vaccine damage, in the sense that once a mother decides to stop vaccinating herself, when she reproduces she can produce a healthier baby. And to the extent that baby remains unvaccinated, the child is (according to the Control Group pilot survey evidence) 97.75% likely to grow and thrive without contributing to the chronic illness pandemic. By contrast, per national data, if the child is vaccinated then the child is more than 50% likely to join the chronic illness pandemic destroying this Nation. This makes vaccination one of the worst health choices that a person can make for themselves and the Nation and the world, especially given the *de minimis* risks today of every single infectious disease that is the subject of CDC recommended vaccination, as highlighted by Dr. Kimmel and Petitioners' Requests for Judicial Notice (especially PRJN2, sections 43-44).

9. A recurring theme that patients report to me is their baby's regression (i.e., speech regression, health decline) immediately after vaccination. This is followed by taking the baby to the pediatrician who ignores any causal connection to vaccination and tends to blame the parents for their genetics or living habits. Many parents realize they are being lied to by the pediatrician, and in the process of seeking a second opinion, they realize their story is not an isolated account but rather is part of a consistent paradigm in conventional medicine: vaccine injury denial.

10. As confirmed by my Pediatric Health History Information Questionnaire that I give my pediatrics patients, I have learned to spot the common issues with vaccinated children: neurodevelopmental and learning disorders, allergies, asthmas, autoimmune disorders, diabetes, chronic inflammation, digestive disorders, organ disorders, seizures, and recurring infections.

11. By contrast, the unvaccinated do not routinely present with these same common issues found in the vaccinated. If an unvaccinated child presents with an issue, it tends to be isolated, mild, and easily treatable. I have also found that families of unvaccinated children tend to be better educated regarding how to spot signs of infectious disease and to take precautionary measures. In short, the unvaccinated are healthier and better equipped to prevent infectious disease.

12. The same phenomenon that I have observed with vaccinated versus unvaccinated children, I have also observed with vaccinated versus unvaccinated adults. However, the percentage of unvaccinated adults is lower, and is especially low when factoring the number of unvaccinated adults over age 30.

Petitioners Are Likely To Succeed On The Merits

13. In December 2020, I professionally examined the following materials filed in this lawsuit:

- Petitioners' Verified Petition
- Petitioners' Requests for Judicial Notice (Appendices 1-2)
- The Graph Exhibits Attached to Petitioners' Request to Utilize Demonstrative Evidence In Support of Motion for Preliminary Injunction
- The Declaration and Exhibits of Vicky Pebsworth, PhD in Support of Motion for Preliminary Injunction
- The Exhibits attached to the declaration of Petitioner Joy Garner In Support of Motion for Preliminary Injunction

14. For starters, the Control Group pilot survey results are consistent with my research and findings as a physician. If the pilot survey were repeated, as evidenced by the confidence intervals, we would expect to find the same results proving that vaccines are causing the chronic illness pandemic.

15. At 1,482 participants, the Control Group pilot survey population size was so large that the population pool inherently expressed many biological factors (i.e., dietary practices, sanitation practices, exercise practices, genetic makeup). None of these factors was the subject of the pilot survey because such factors are already the subject of myriad other population studies articulating the numerical impact of such factors on health outcomes. Indeed, for decades all such other studies have been wholly unable to identify the cause of the National health crisis of injured and dysfunctional immune systems. By contrast, vaccines are the obvious biological cause of the immune system health crisis because only vaccines are designed to cause, and do cause, permanent alterations to the immune system. And the results of this Control Group pilot survey describe such

causation with precise numerical accuracy, as confirmed by the 99% Confidence Interval [5.95-5.99] as well as the p-values.

16. Medical dictionaries and government documents confirm: vaccination is not immunization. The two terms are not synonymous.

17. New evidence shows entirely unvaccinated Americans as a population cohort are extraordinarily healthy (evidencing their robust immune systems), whilst vaccinated Americans as a population cohort are suffering the worst pandemic of chronic illness in American history (evidencing their weakened immune systems). The extent of the chronic illness pandemic, and its immune-mediated nature, is well documented in Petitioners' Requests for Judicial Notice, especially Appendix One.

18. Every individual's immune system and every vaccine must be accounted on its own merits, free of one-size-fits-all assumptions. For example, a healthy unvaccinated individual can acquire natural immunity to chicken pox with zero injuries whilst an unhealthy vaccinated person can suffer multiple serious injuries to the varicella vaccine that weakens their immune system to millions of other pathogens intruding their human biome.

19. Vaccine science is not settled. It is emerging daily. Vaccines remain one of the most controversial scientific subjects in the modern world, primarily because vaccines are manufactured with legally classified neurotoxins, and vaccines have never followed the scientific method for testing with true placebos or a control group of entirely unvaccinated individuals. Instead, vaccine regulatory approvals are supported by fake placebos (so-called "placebos" that contain neurotoxins), fake controls (so-called "controls" of people who are also vaccinated or otherwise receiving a non-inert substance such as aluminum), short-term testing windows (so-called "tests" with monitoring periods as short as 3-days), and long-term passive surveillance of vaccine injuries (so-called "surveillance" with an unknown to approximately 99% failure rate of reporting).

20. Thus, vaccine science has not even evolved enough to recognize the basic dictionary definition of words, let alone become advanced enough to reach the status of "settled science".

21. Every vaccine product insert (a document required by law) admits the lack of safety testing for that vaccine, and further admits the vaccine's list of known side effects. Likewise,

government documents and top scientific journals have also admitted the observed, but un-calculated, role of vaccination in America's chronic illness pandemic. To support without questioning the un-calculated numbers of vaccine injuries, credentialed professionals repeat empty phrases about vaccines in an echo-chamber, "vaccines are safe and effective", "side effects are rare". Such phrases are empty and dogmatic because they are mathematically unsupported. Quite literally, zero data supports these phrases.

22. For example, the Institute of Medicine (IOM) admitted that "studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted." Literally, zero studies, and yet the IOM dogmatically claims vaccines are "safe". Dogma is defined according to Merriam-Webster, "dogma: a point of view or tenet put forth as authoritative without adequate grounds".

23. As highlighted above, the passive surveillance system VAERS maintained by Health and Human Services (HHS) for monitoring vaccine injuries has an unknown to approximately 99% failure rate, which results in literally zero statistical confidence in its ability to report accurately on the number of vaccine injuries in the American populace.

24. The most accurate and lawful way to describe vaccination is that it is an experimental procedure that has been falsely labeled as "safe and effective". Vaccine side effects have been falsely labeled as "rare". Compare the Council for International Organizations of Medical Sciences Working Group III, which set forth the following definitions for drug adverse events:

> "Very common ≥ 1/10 (≥ 10%)
> "Common ≥ 1/100 and < 1/10 (≥ 1% and < 10%)
> "Uncommon ≥ 1/1000 and < 1/100 (≥ 0.1% and < 1%)
> "Rare ≥ 1/10,000 and < 1/1000 (≥ 0.01% and < 0.1%)
> "Very rare < 1/10,000 (< 0.01%)"

25. Vaccine adverse events are not "rare" by this scientific definition. Until vaccines are compared long-term against a large control group of entirely unvaccinated individuals, it is scientifically impossible to state that vaccines are "safe" or that vaccine side effects are "rare".

26. The Pilot Survey in this case is such a comparison, and the results show vaccine injury is very common.

27. The international pharmaceutical industry conducts studies of "vaccine hesitancy" (the reasons certain people decline vaccines). These studies consistently show that the population of individuals who avoid vaccination (the "vaccine hesitant") are better educated than those who submit to vaccination. Indeed, the international pharmaceutical industry publishes that increasing numbers of physicians are also rejecting vaccination for themselves and their families.

28. The international pharmaceutical industry's vaccination marketing campaigns are factually misleading and yet effective in frightening most Americans into submission to untested vaccination schedules. Consequently, today the number of individuals who remain entirely unvaccinated in America is small, estimated at less than 1% of our entire population.

29. The scientific method that respects control groups is in jeopardy due to both the overzealous international pharmaceutical industry and the health officials beholden to it. Many of these health officials have expressed publicly their desire to vaccinate 100% of the population within their jurisdiction. And Covid-19 has increased this overzealousness across the country.

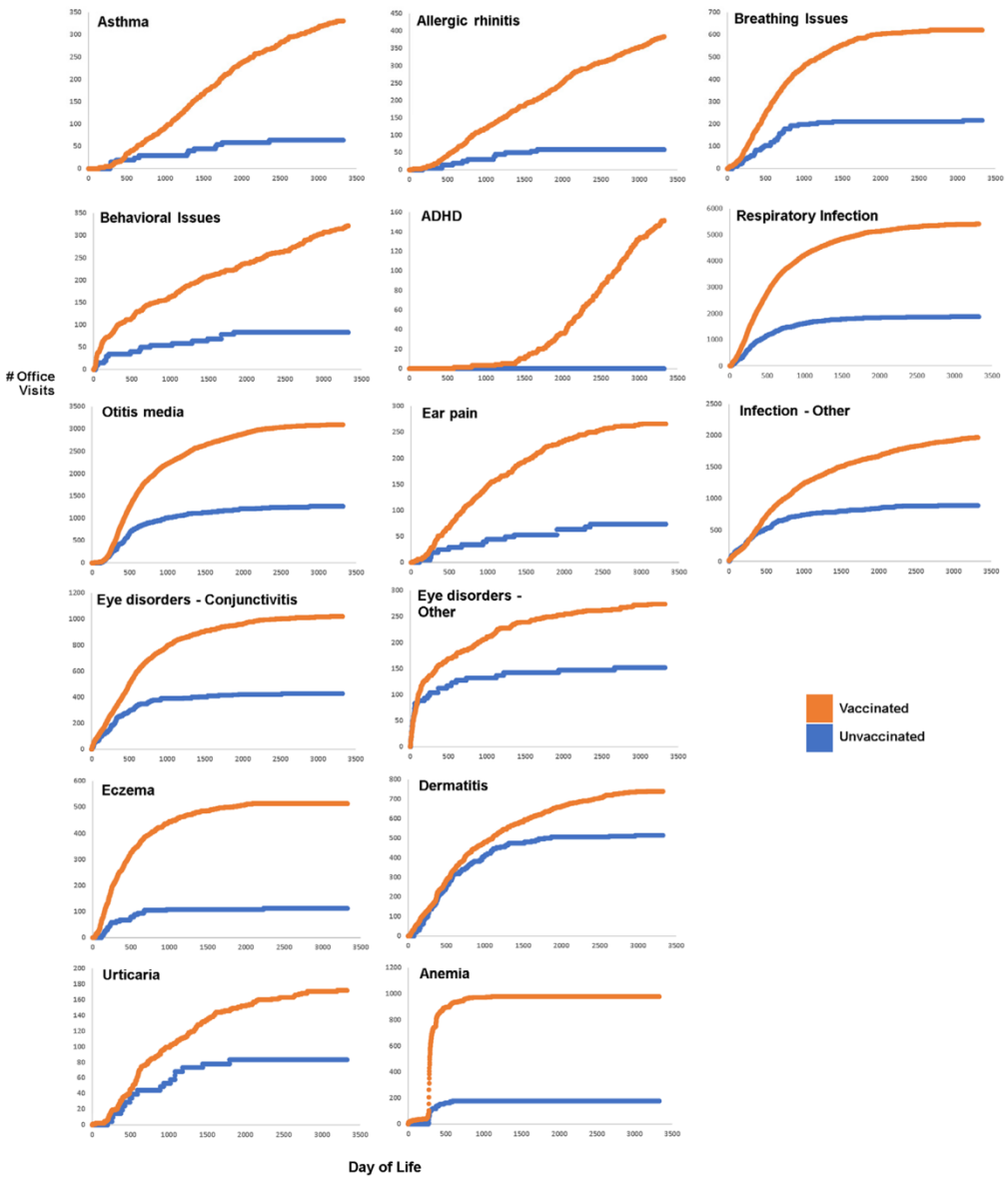
30. Even though "vaccine hesitancy" studies prove the overall nature of the unvaccinated population is pro-science, today this group of conscientious Americans are persecuted, isolated, ridiculed, and vilified by politicians, bureaucrats, and the mainstream media. This creates a legal predicament for unvaccinated and partially vaccinated Americans as they suffer threats to their fundamental rights, in particular their rights to informed consent and informed refusal.

31. The international pharmaceutical industry that produces vaccines has a long-history of scientific corruption and conflicts of interest. In short, it is a trillion dollar industry that uses aborted babies to manufacture certain vaccines, adds known neurotoxins such as aluminum and mercury to vaccines, specifically engineers newer vaccines to manipulate human DNA, and then summarily labels every single one of their finished products "safe", without any mathematical proof that would comply with the scientific method.

Corroboration Published November 22, 2020

32. Corroborating evidence for Petitioners' Control Group Survey data can be found in the recently published 'vaccinated versus unvaccinated' study by Paul Thomas and James Lyons-Weiler: Lyons-Weiler, J. and Thomas, P. (2020) Relative Incidence of Office Visits and Cumulative Rates of Billed Diagnoses Along the Axis of Vaccination. *Int. J. Environ. Res. Public Health* 2020, *17*(22), 8674; https://doi.org/10.3390/ijerph17228674. Attached as Exhibit B is a true and correct copy of such paper ("Thomas Paper").

33. The Thomas Paper is unique because it presents approximately 10-years of medical record data comparing the health of the vaccinated to the unvaccinated. Figure 5 in particular shows the unvaccinated are exponentially healthier than the vaccinated:



34. So the Thomas Study provides corroborating evidence for the TCG American Survey. But they are also different as follows:

A. In the Thomas Study, patients must have at least 2 office visits with the MD (first visit >60days before birth; last visit <60 days after birth). The authors acknowledge, "Future studies with less restrictive inclusion criteria that also avoid temporal confounding by matched DOC may help us better characterize these populations in the practice." Compare the TCG American Survey allowing all individuals to participate, including those who pursue holistic healthcare through Naturopathic practices, home births, and similar. In this manner, the TCG American Survey is likely more representative of the unvaccinated population.

B. In the Thomas Study, diagnoses were tagged to billing ("A related potential limitation includes that, because the data used were from billed diagnoses (in the case of outcomes) or billed vaccination, there may be some occurrences that were missed if insurance did not cover those events for a given patient (e.g., ASD diagnosed via a family counselor/psychologist/psychiatrist)."). Compare the TCG American Survey where diagnoses are written by the patient or parent regardless of any billing. Indeed, in the TCG American Survey the organizer Joy Garner received no money whatsoever for office visits, prescriptions, anything. Per her declaration, Ms. Garner simply received and recorded whatever the participant wrote on the form (which is also how the NSCH works).

C. In the Thomas Study, no information was provided on pregnancy vaccines or K-shot in the unvaccinated group. On page 62 of his book "The Vaccine Friendly Plan", Paul Thomas writes "nearly all of my patients get the [K] shot", which is likely because birthing at the hospital is most prevalent. Compare the TCG American Survey that examined these critical factors and stratified accordingly to show their risk values.

D. In the Thomas Study, most of the "vaccinated" group do not follow the CDC schedule because they follow Paul Thomas' delayed vaccine schedule. Compare The

TCG American Survey that was compared to National Averages where most follow the CDC schedule.

E. In the Thomas Study, information was not provided on the number of chronic illnesses per patient. Compare The TCG American Survey that tracked this information and therefore provided a metric for mildness/severity of injury to the immune system.

35. In further support for the corroborative evidential nature of the Thomas Study, some of the most helpful or instructive citations in the Thomas Study are as follows:

> "Pre-licensure clinical trials for vaccines cannot detect long-term outcomes since safety review periods following administration are typically 42 days or less [3]. Long-term vaccine safety science relies on post-market surveillance studies using databases such as the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC's) Vaccine Adverse Events Reporting System (VAERS) and the Vaccine Safety Datalink. VAERS [4] is a passive reporting system in which, according to Ross 2011 [5], "fewer than 1% of vaccine adverse events are reported." The Vaccine Safety Datalink (VSD) can, in principle, according to the Institute of Medicine (IOM, 2013) [6], be used to compare outcomes of vaccines and unvaccinated children. Based on the IOM's recommendation, in 2016, the CDC published a white paper (CDC, 2016 [7]; Glanz et al., 2016 [8]) on studying the safety of their recommended pediatric vaccine schedule. Unfortunately, to date, no studies have been published comparing a diversity of outcomes of vaccinated and unvaccinated children using the VSD.
>
> "There are serious limitations inherent to long-term vaccine safety studies as currently implemented. Post-licensure studies on vaccine safety typically employ an "N vs. N + 1" design of analysis, meaning they compare fully vaccinated children with fully vaccinated children missing only one vaccine. Despite reports of increases in vaccine cessation, virtually none of the post licensure- vaccine safety studies have included comparisons to groups completely unexposed to vaccines.
>
> "A few independent (non-CDC) studies do exist that have compared outcomes between vaccinated and unvaccinated children. A small survey study of 415 families with homeschooled children by Mawson et al., 2017 [9] that compared vaccinated with completely unvaccinated children reported increased risk of many diagnoses among the vaccinated children including (condition, fold- increase): allergic rhinitis (30.1), learning disabilities (5.2), attention deficit hyperactivity disorder (ADHD) (4.2), autism (4.2),

neurodevelopmental disorders (3.7), eczema (2.9), and chronic illness (2.4). The increased risk of neurodevelopmental disorders appeared to be higher in cases of preterm births. A study from Germany (Schmitz et al., 2011) [10] reported no increases in adverse outcomes other than atopy.

"A limitation of both of these studies is that they relied on parental surveys, and both had a small unexposed group. A further limitation in the German study [10] is that they also defined a child as unexposed to vaccines even if they received vaccination for varicella, rotavirus, pneumococcal, meningococcal, influenza, and/or others; the study, therefore, is not "vaccinated vs. unvaccinated". Studies of Diphtheria, Pertussis, and Tetanus (DTP) vaccine that had an unexposed group found an increased risk of mortality (Mogensen et al., 2017) [11] and asthma (McDonald et al., 2008) [12] in the vaccine exposed group. Gallagher and Goodman, 2008 [13] reported increased ASD in a hepatitis B vaccine-exposed group. Studies funded by the pharmaceutical industry or conducted by the CDC typically tend to find no harm associated with vaccination, while studies conducted without pharmaceutical industry funding have often found harm.

"Hooker and Miller 2020 [14] recently found an increase in odds ratio (OR) in developmental delay (OR 2.18), asthma (OR 4.49), and ear infection (OR 2.13) in vaccinated children compared to unvaccinated children in a study using data from three practices. In the current study, we assess the total outcomes of patients ranging in age from 2 months to 10.4 years of all children in a pediatric practice that have not been vaccinated compared to those who have been variably vaccinated based on medical records using a novel measure, the Relative Incidence of Office Visit (RIOV), and compare results from that measure to results obtained using odds ratios of incidence of diagnoses.

…

"We have found higher rates of office visits and diagnoses of common chronic ailments in the most vaccinated children in the practice compared to children who are completely unvaccinated. The data clearly show different odds of developing many of these adverse health conditions. We have demonstrated in many ways that most of the statistical associations found tend to be robust to age in cohort (days of care), vaccination range, and family history.

…

"Lifestyle differences between the vaccinated and unvaccinated groups in this practice cannot explain the large difference in outcomes, and if they do, then it would be objective to conclude that

> everyone should adopt the lifestyle followed by the unvaccinated if they want healthier children. That lifestyle choice includes, for many families, avoiding some or all vaccines, and thus, the lifestyle choice concern is inextricably linked to vaccine exposure.
>
> "Parents are almost universally told by their child's health care provider that the health issue was not due to the vaccine, in spite of growing evidence in the scientific literature that supports both plausible mechanisms of action for chronic illnesses including epidemiological associations. It is now apparent that the commonly reported lack of association of adverse events may be due to the use of a test statistic with low intrinsic power and due to problems including model misspecification and overadjustment bias and that further research is needed to update guidelines and recommendations via additional studies.
>
> "We could detect no widespread negative health effects in the unvaccinated other than the rare but significant vaccine-targeted diagnosis. We can conclude that the unvaccinated children in this practice are not, overall, less healthy than the vaccinated and that indeed the vaccinated children appear to be significantly less healthy than the unvaccinated.
>
> "We concur with Mawson et al., 2017 [9], who reported: 'Further research involving larger, independent samples is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children's health.'
>
> "We also concur with Hooker and Miller 2020 [14], who wrote: 'Further study is necessary to understand the full spectrum of health effects associated with childhood vaccination'."

37. Regarding the reference above to Mawson *et al.* (2017), there are several key caveats, most notably: (a) only 261 of the Mawson study participants were completely unvaccinated, and (b) 51% of the "vaccinated" group was only partially vaccinated rather than fully vaccinated, even though Mawson *et al* stated that in the American population approximately 95% of Kindergarten children are fully vaccinated. So, again, the TCG American Survey is likely more representative of a cross section of unvaccinated Americans.

38. Immediately after he published his paper (Thomas Paper), the Oregon Medical Board appears to have retaliated against Dr. Thomas by issuing an emergency suspension of his medical license. https://omb.oregon.gov/clients/ormb/OrderDocuments/e579dd35-7e1b-471f-a69a-

3a800317ed4c.pdf. This is yet example of the oppressive climate that American physicians face when they present evidence of systemic vaccine harm. My physician colleagues and I are all too aware of this climate, but we feel compelled to stick out our necks. To borrow a quote from Jean Valjean, "If I speak, I am condemned. If I stay silent, I am damned."

Petitioners Are Likely To Suffer Irreparable Harm In The Absence of Preliminary Injunction

39. Mandatory vaccination has been a thorn in the side of my unvaccinated patient families. Probably the most common problem in California is coerced vaccines for public and private school attendance (i.e., Cal. Health & Safety Code section 120325 *et seq.*, commonly known as SB277/276/714). This law is enforced by the California Department of Public Health, and it has forced a lot of families into homeschool situations.

40. I spoke with the SB277 bill co-author Senator Ben Allen, who promised for approximately 1-year that he was against SB276. Senator Allen told me face to face that he did not follow the CDC vaccine schedule for his own children because of the information he learned from activists opposed to vaccination. And yet, when SB276/714 came up for a vote, Senator Allen voted to mandate vaccinations that would not give the same choice he exercised for his family to other families.

41. Another recurring issue I see is exiled patients, those who are removed from conventional practices due to their choice to forego vaccines. A lot of these patient families had already received some vaccines, so they are experiencing a litany of health problems. Some come to my clinic like medical refugees needing immediate assistance.

42. The blatant vilification that the unvaccinated face in America is unfair. It is tantamount to medical discrimination. It is essentially blackballing for exercising the right of informed refusal.

43. Covid-19 has only exacerbated the discrimination and blackballing. My unvaccinated patient families are living in a state of fight or flight. The recent University of California flu shot mandate is an example. Many health freedom families have joined the exodus from California because of California's far-left politics that push mandatory vaccination. The evidence points to California bureaucrats continuing to push mandatory vaccination. And the

predictable result is that we will lose countless more unvaccinated participants for health surveys and studies. Mandatory vaccination has become an attack on the scientific method, to the detriment of our Country. I love America and want to see this Nation thrive.

44. I support Respondent but he has not abated these threats; rather Respondent has emboldened them by actively promoting Covid-19 vaccination without providing the Suspension or Order to safeguard the Nation, as stated in the Verified Petition. The evidence shows vaccines are responsible for the majority of chronic illnesses suffered by Americans today, and that vaccines are the single most serious public health threat this Nation has ever faced. Therefore, inaction is tantamount to destruction.

The Balance of Equities Weighs in Petitioners' Favor

45. I am a member of the nationwide nonprofit organization Physicians for Informed Consent (PIC). Attached as Exhibit C is an educational documents relating to the flu shot. And attached as Exhibit D are educational documents relating to measles and the MMR vaccine. The citations from each of these documents are mainstream/authoritative, and I refer to them here to further emphasize that mandatory vaccination is recognized as dangerous in my community of integrative physicians. I will also note it is a commonplace error of convenience when medical professionals and researchers refer to partially vaccinated patients as "unvaccinated", even though they really mean "not vaccinated with vaccine dose x, but still vaccinated with vaccines a, b, c…". This error of convenience perpetuates confusion among both experts and layman alike, so I am glad to see Petitioners' Request for Judicial Notice on the true meaning of unvaccinated. Like Petitioners, when I refer to the "unvaccinated" in this declaration, I am referring only to the true sense of the term: an individual who has received zero vaccines in their lifetime.

46. No government survey has been taken and no study has been conducted on the health of a very large number of unvaccinated Americans. This scientific vacuum amounts to nothing short of an ongoing human medical experiment that has no chance of advancing medical knowledge concerning the risks of vaccination, and accompanying long-term effects on public health.

47. Vaccinations are unavoidably unsafe. They cause "unavoidable" injury and death.

48. Surveying the health of unvaccinated patients is vital to the scientific method. If a nationwide survey of unvaccinated patients was performed, I would actively contact my patients to inform them of the opportunity. And I would certainly offer my services to faithfully participate as prescribed (i.e., performing physical exams, reviewing medical records). Notably, a comprehensive survey/study concerning vaccine safety and efficacy would benefit from access to the Vaccine Safety Data Link maintained by the CDC, but it is not necessary.

49. For this survey to be conducted scientifically, an unvaccinated control group must remain intact and be protected under the Constitution. The control group must remain free from discrimination with respect to each individual's life, liberty, education, religion and livelihood. Discrimination reduces and threatens to eliminate desired unvaccinated candidates for scientific survey.

50. Without a Court Order protecting Americans, the control group population of unvaccinated Americans is imminently threatened (especially by myriad local health officials' unscientific overreaction to Covid-19) to be reduced to statistically insignificant numbers, and/or to zero. This loss of evidence would represent a great and irreparable loss to our Nation. A recent example of the unscientific overreaction to Covid-19 is the veneer of campus-health protection recently stripped as the country embraces distance learning, while quizzically, vaccine mandates remain in full force.

51. In the balance of equities, the unvaccinated must prevail. They hold the "secret" to health. As a group they are not harming others. The unvaccinated courageously assert their Constitutional rights and yet public health policy shamefully hunts them down for injection like animals. The unvaccinated are an endangered population threatened with extinction. Forced vaccination is a tool of tyrants, as history will surely adjudge.

The Requested Relief is Genuinely in the Public Interest

52. The dissolution of America is imminent unless the unvaccinated are protected as holders of the cure to the chronic illness pandemic that is destroying this Nation.

53. America must no longer sustain 'separate but equal' public policies, where unvaccinated Americans are given second class rights: banned from public and private school, prohibited from gainful employment, denied the right to serve in the military, and more.

54. It is widely known and recognized among unvaccinated Americans that child welfare authorities are notorious for citing non-vaccination as a basis for medical neglect charges.

55. Living in a state of fear of child welfare authorities infringes unvaccinated Americans' zone of privacy in medical decision making. One consequence of this is an unnatural limit on choice of medical provider, which causes disruption to doctor-patient relationships.

56. Here in 2020, America is witnessing a biotechnology revolution by pharmaceutical companies advancing new vaccines unknown to previous generations:

a. Vaccines such as chickenpox and rubella that are cultured from aborted human fetal tissue,

b. Vaccines that manipulate human DNA,

c. Vaccines incorporating nanotechnology,

d. Vaccines manufactured from cancerous "immortal cell lines", and

e. Vaccines employing human tracking technology.

57. This biotechnology revolution cannot be ignored. The time has already come to remember Justice Harlan's caveat on his 1905 Supreme Court holding in *Jacobson v. Massachusetts*, "There is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will." Surely, if we are living in a Republic, then *Jacobson* was not intended to become an open door to unlimited technological advancements so long as a pharmaceutical company attaches its behavior to the word "vaccine".

58. Historically, many vaccines have been recalled and phased out as new discoveries revealed hidden dangers. We saw this recently with MMRV, where the number of vaccine-caused seizures was so obvious that even VAERS could not bury the evidence. When healthy parents choose to forego injecting their healthy children with whatever particular vaccine the government

happens to be promoting at that particular time and place, parents are frequently threatened by child protective services that their child custody will be stripped and their children will be taken away and given to strangers. This constitutes cruel and unusual punishment. Healthy families being separated and healthy people being ousted from society for their refusal to inject government-mandated biotechnology is a grossly disproportionate response to the parental choice of non-cooperation with human medical experimentation. The punishment is tortuous, degrading, and inhuman.

59. Mandatory and coerced biological alteration is cruel and unusual. Children, young people, and pregnant women have been especially victimized by vaccines that have not been fully studied and which permanently alter their DNA in unknown measure. It is cruel and unusual when health officials use State powers to give pharmaceutical companies unmeasured control over individual posterity.

60. The ability of the unvaccinated to independently protect themselves from vaccination as a form of human medical experimentation is routinely dismissed by local authorities who do not consider vaccination programs to be a form of human experimentation. It is therefore increasingly difficult for unvaccinated Americans to protect themselves from becoming experimental medical subjects, as a patchwork of ever-changing discriminatory laws, regulations, and policies are enforced against the unvaccinated.

61. Many unvaccinated Americans live under a justifiable constant threat that they can be quarantined, lose parental rights, and forcefully vaccinated simply for refusing a vaccination that gave rise to their quarantine order. In this manner, forced vaccination becomes a potentiality at the whim of a public official merely due to the unvaccinated American's initial refusal to submit to forced vaccination. Therefore, a patchwork of local authorities is able to assert it is unlawful to be peaceful and unvaccinated in the event of an emergency, provided that the public official decides to vaccinate any given population of individuals in his discretion. This prohibition on being peacefully natural jeopardizes the constitutionality of public health statutory schemes because the government is not permitted to criminalize innocent conduct.

62. The legislative and judicial branches have, thus far, primarily chosen to subjugate the people of this Nation for the benefit of the pharmaceutical/medical industrial complex. Beyond the

many obvious violations of individual human rights, this long-held pattern of Constitutional interpretation, enforced by legislative acts, has now placed our entire Nation in great peril. The collective "herd" which our legislatures claim to be protecting with an endless stream of coerced pharmaceuticals, delivered by the most invasive means possible, is very sick now. The number of disabled in our younger generations is exponentially higher than just 20 years ago. And the trajectory for the next decade is nothing short of catastrophic. Very soon, this "herd" will, in large part, be incapable of supporting any branches of government, no matter the increased taxation pressed upon the ones who remain semi-viable.

63. A rapidly growing number of children and young adults in the USA will never leave home, never work, never fall in love, never have a family. They will *instead* require the full-time support of their parents, and society, for their entire lives. I have observed this with vaccinated families in my medical practice, and I have observed the increasing trend over decades. The number of parents who have personally witnessed their perfectly healthy children seriously injured by pharmaceuticals is growing rapidly. In spite of attempted censorship their stories are reaching the masses. A storm is upon us. It will make landfall. Directing this storm to the correct shore is the only remaining option. If our Nation is to survive this storm, the culprits can no longer be protected by any branch of government, let alone rewarded for their acts against our Nation's people.

64. The stakes do not get any higher than they are in this case. The Verified Petition makes it clear that Petitioners seek to protect more than their individual rights here. They fight to protect their Nation from imminent and inevitable collapse.

I declare under threat of penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed on the date set forth below in Los Angeles, California.

DocuSigned by:
Rachel West, DO
409D789965B347C...

12/22/2020

Rachel West, DO — Date

Exhibit A

Rachel West, DO

2211 Corinth Avenue, Suite 204
Los Angeles, California 90064

Education & Residency

- Undergraduate: Northwestern University, Evanston IL. Graduated with a BA double major in 1994.
- Medical School: New York College of Osteopathic Medicine. Graduated in 1999.
- Internship in Family Medicine: Tucson General Osteopathic Program. Completed in 2000.
- Residency in Family Medicine: Union Hospital/ St. Barnabas Hospital System NJ. Completed in 2003.

Physician Experience

- 20+ years owning and operating a private clinical practice in integrative family medicine
- 5+ years managing other integrative physicians

Certifications

- Board certified by American College of Osteopathic Family Physicians
- Assistant clinical professor at College of Osteopathic Medicine of the Pacific
- Certified by American Academy for the Advancement of Medicine
- Certified in chelation therapy
- Certified in traditional osteopathy

Exhibit A

Exhibit B

International Journal of
Environmental Research and Public Health

MDPI

Article

Relative Incidence of Office Visits and Cumulative Rates of Billed Diagnoses Along the Axis of Vaccination

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Abstract: We performed a retrospective analysis spanning ten years of pediatric practice focused on patients with variable vaccination born into a practice, presenting a unique opportunity to study the effects of variable vaccination on outcomes. The average total incidence of billed office visits per outcome related to the outcomes were compared across groups (Relative Incidence of Office Visit (RIOV)). RIOV is shown to be more powerful than odds ratio of diagnoses. Full cohort, cumulative incidence analyses, matched for days of care, and matched for family history analyses were conducted across quantiles of vaccine uptake. Increased office visits related to many diagnoses were robust to days-of-care-matched analyses, family history, gender block, age block, and false discovery risk. Many outcomes had high RIOV odds ratios after matching for days-of-care (e.g., anemia (6.334), asthma (3.496), allergic rhinitis (6.479), and sinusitis (3.529), all significant under the Z-test). Developmental disorders were determined to be difficult to study due to extremely low prevalence in the practice, potentially attributable to high rates of vaccine cessation upon adverse events and family history of autoimmunity. Remarkably, zero of the 561 unvaccinated patients in the study had attention deficit hyperactivity disorder (ADHD) compared to 0.063% of the (partially and fully) vaccinated. The implications of these results for the net public health effects of whole-population vaccination and with respect for informed consent on human health are compelling. Our results give agency to calls for research conducted by individuals who are independent of any funding sources related to the vaccine industry. While the low rates of developmental disorders prevented sufficiently powered hypothesis testing, it is notable that the overall rate of autism spectrum disorder (0.84%) in the cohort is half that of the US national rate (1.69%). The practice-wide rate of ADHD was roughly half of the national rate. The data indicate that unvaccinated children in the practice are not unhealthier than the vaccinated and indeed the overall results may indicate that the unvaccinated pediatric patients in this practice are healthier overall than the vaccinated.

Keywords: pediatrics; vaccines; adverse events; relative incidence of office visit

1. Introduction

Vaccines are widely regarded as safe and effective within the medical community and are an integral part of the current American medical system. While the benefits of vaccination have been estimated in numerous studies, negative and nonspecific impact of vaccines on human health have not been well studied. Most recently, it has been determined [1,2] that variation exists in individual responses to vaccines, that differences exist in the safety profile of live and inactivated vaccines, and that simultaneous administration of live and inactivated vaccines may be associated with poor outcomes. Studies have not been published that report on the total outcomes from vaccinations, or the increase or decrease in total infections in vaccinated individuals.

Pre-licensure clinical trials for vaccines cannot detect long-term outcomes since safety review periods following administration are typically 42 days or less [3]. Long-term vaccine safety science relies on post-market surveillance studies using databases such as the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC's) Vaccine Adverse Events Reporting System (VAERS) and the Vaccine Safety Datalink. VAERS [4] is a passive reporting system in which, according to Ross 2011 [5], "fewer than 1% of vaccine adverse events are reported." The Vaccine Safety Datalink (VSD) can, in principle, according to the Institute of Medicine (IOM, 2013) [6], be used to compare outcomes of vaccines and unvaccinated children. Based on the IOM's recommendation, in 2016, the CDC published a white paper (CDC, 2016 [7]; Glanz et al., 2016 [8]) on studying the safety of their recommended pediatric vaccine schedule. Unfortunately, to date, no studies have been published comparing a diversity of outcomes of vaccinated and unvaccinated children using the VSD.

There are serious limitations inherent to long-term vaccine safety studies as currently implemented. Post-licensure studies on vaccine safety typically employ an "N vs. $N + 1$" design of analysis, meaning they compare fully vaccinated children with fully vaccinated children missing only one vaccine. Despite reports of increases in vaccine cessation, virtually none of the post licensure-vaccine safety studies have included comparisons to groups completely unexposed to vaccines.

A few independent (non-CDC) studies do exist that have compared outcomes between vaccinated and unvaccinated children. A small survey study of 415 families with homeschooled children by Mawson et al., 2017 [9] that compared vaccinated with completely unvaccinated children reported increased risk of many diagnoses among the vaccinated children including (condition, fold-increase): allergic rhinitis (30.1), learning disabilities (5.2), attention deficit hyperactivity disorder (ADHD) (4.2), autism (4.2), neurodevelopmental disorders (3.7), eczema (2.9), and chronic illness (2.4). The increased risk of neurodevelopmental disorders appeared to be higher in cases of preterm births. A study from Germany (Schmitz et al., 2011) [10] reported no increases in adverse outcomes other than atopy.

A limitation of both of these studies is that they relied on parental surveys, and both had a small unexposed group. A further limitation in the German study [10] is that they also defined a child as unexposed to vaccines even if they received vaccination for varicella, rotavirus, pneumococcal, meningococcal, influenza, and/or others; the study, therefore, is not "vaccinated vs. unvaccinated". Studies of Diphtheria, Pertussis, and Tetanus (DTP) vaccine that had an unexposed group found an increased risk of mortality (Mogensen et al., 2017) [11] and asthma (McDonald et al., 2008) [12] in the vaccine exposed group. Gallagher and Goodman, 2008 [13] reported increased ASD in a hepatitis B vaccine-exposed group. Studies funded by the pharmaceutical industry or conducted by the CDC typically tend to find no harm associated with vaccination, while studies conducted without pharmaceutical industry funding have often found harm.

Hooker and Miller 2020 [14] recently found an increase in odds ratio (OR) in developmental delay (OR 2.18), asthma (OR 4.49), and ear infection (OR 2.13) in vaccinated children compared to unvaccinated children in a study using data from three practices. In the current study, we assess the total outcomes of patients ranging in age from 2 months to 10.4 years of all children in a pediatric practice that have not been vaccinated compared to those who have been variably vaccinated based on medical records using a novel measure, the Relative Incidence of Office Visit (RIOV), and compare results from that measure to results obtained using odds ratios of incidence of diagnoses.

2. Materials and Methods

2.1. Data Source and Provenance

A detailed proposal for a retrospective study was submitted to an Institutional Review Board (IRB), and was approved (Pro00031853 letter dated 7 May 2019). The data source for this study was all billing and medical records of Integrative Pediatrics, a private pediatric practice located in Portland, Oregon. Data collected from True North Data (Mill Creek, WA, USA) were de-identified by trained and honest brokers with the Institute for Pure and Applied Knowledge (IPAK) affiliation

who were certified to de-identify patient data as required under the Health Insurance Portability and Accountability Act (HIPAA), thus ensuring that the data analysts never saw identified data. Outcomes were represented by International Classification of Diseases (ICD) codes (See Supplementary Materials Table S1). Coded data were matched back to the identified medical and billing record to provide a data parity check by our honest brokers team.

2.2. Inclusion/Exclusion Criteria

All patients that were born into the practice between 1 June 2008 and 27 January 2019, with a first visit before 60 days of life and a last visit after 60 days. All inclusion/exclusion criteria applied are outlined in Figure 1.

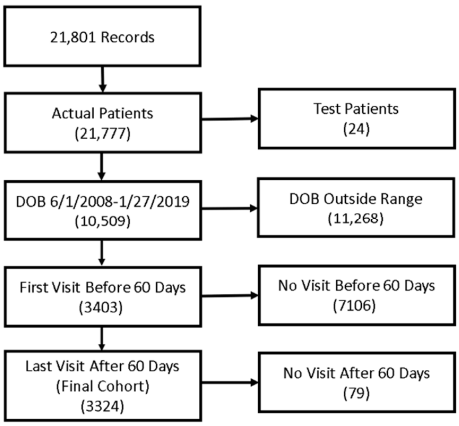

Figure 1. Inclusion criteria diagram.

2.3. Study Population

The inclusion/exclusion criteria lead to 3324 patients, of which 2763 were variably vaccinated, having received 1 to 40 vaccines (Figure 1).

2.4. Demographics

The study population had similar proportions of males and females (Table 1). Nearly all patients had been breastfed in both the vaccinated (96.6%) and the unvaccinated (98%) conditions. Among the vaccinated, 25.16% had a family history of autoimmunity, whereas among the unvaccinated, 31% had the same characteristic. Functionally, this also likely reflects the net effects of decisions between the patient/doctor dyad in determining risk of long-term poor outcomes sometimes associated with vaccination.

Table 1. Demographic variables in the analyzed data set.

Category	Unvaccinated (N = 561)	Vaccinated (N = 2763)	χ^2	*p*
Male (N,%)	279 (49.7%)	1432 (51.8%)	0.819	0.365
Female (N,%)	282 (50.3%)	1331 (48.2%)		
Breastfed (N,%)	550 (98%)	2670 (96.6%)	3.037	0.081
			T-test	
FHA (any)	174 (31%)	695 (25.16%)	28.239	<0.00001
Mean DOC	741	1525	17.69	<0.00001
DOC matched	741	741 (N = 561)	0	1.0
Mean BW (kg) unmatched	3.3	3.28	0.509	0.305

DOC = "Days of Care" = (day of age at last record − day of age at first record); FHA = family history of autoimmunity (at least one condition); Mean BW = average body weight (day 1). The "**T-test**" is in bold in the table because it is a column subheader.

2.5. Variation in Vaccination

The study population has a great diversity in vaccination uptake (Figure 2), reflecting the combined outcome of the patient/physician dyad considering vaccine risk information leading to informed consent on the part of the patients in the practice.

Given the potential of a cohort effect leading to time-based trends in vaccination and to protect against health-care seeking behavior, we calculated for each patient the number of days of care (DOC) as the number of days between the last and first office visits. Importantly, DOC is the range from first to last recorded visits for each patient and is not expected to be influenced overall by healthcare seeking behavior. Among the vaccinated, the mean DOC was 1525 days; among the unvaccinated, the mean DOC was 741 days. This reflects age of patient, not healthcare seeking behavior (prior to matching, unvaccinated: min age, 2 months, mean age 2 years 1 month, and max age 10 years 1 month; vaccinated: min age 2 months, mean age 4 years 3 months, and max age 10 years 6 months; after DOC matching, average age in the vaccinated was also 2 years 1 month). The difference in DOC between the vaccinated and unvaccinated groups was highly significant prior to DOC matching (Student's t, $p < 0.0001$). The patient populations did not differ in mean predicted birthweight (unvaccinated 3.3 kg; vaccinated 3.28 kg, $p = 0.61$ (Student's t)).

From this analysis, only DOC could be a potential confounding variable, potentially collinear with patient age, given full consideration by a matched analysis (see below).

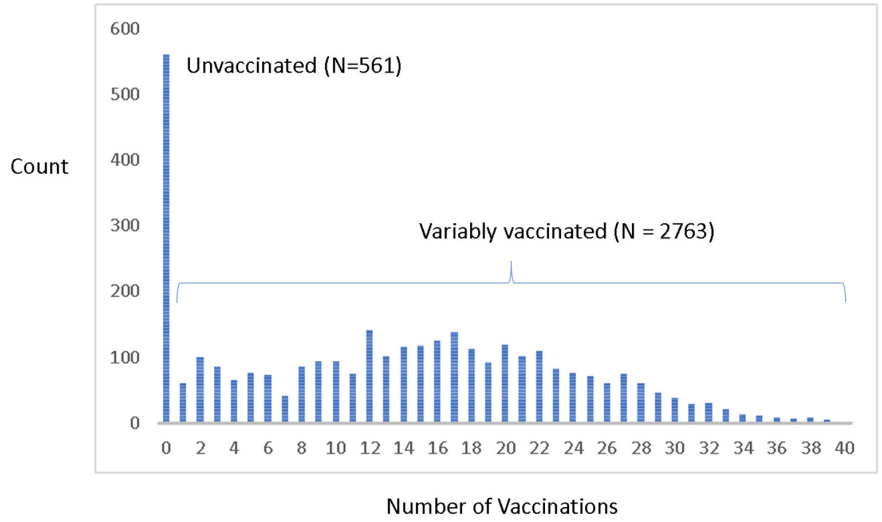

Figure 2. Distribution of vaccination across the patient cohort.

2.6. Analysis 1. Relative Incidence of Average Billed Visitation Rates in Percentile Vaccinating vs. Unvaccinated (Aka "Whole Cohort" Analysis: Unblocked and Unmatched)

2.6.1. Relative Incidence of Office Visit (RIOV)

Typical retrospective analyses of association of outcomes and vaccine exposure rely on the incidence of conditions, which is the percentage of a group with a particular diagnosis of interest. This is the equivalent of "at least one billed office visit", which is a specific form of "at least n office visits" related to a diagnosis. Use of incidence-only is therefore an arbitrary decision on data representation. We generalized the approach by considering the incidence of office visits over each patients' record related to a diagnosis. First, patients were ranked by the number of vaccines accepted. For controls, the average incidence of billed visitations per conditions was calculated within percentiles ranging from the 5th (least vaccinated) to the 90th percentile of vaccination acceptance (Figure 3). For the study outcomes, data were represented as quartiles.

Average incidence of office visit ratio (RIOV) plots for the vaccinated (OV_V) and unvaccinated (OV_{UV}) groups were used to provide assurance of the robustness of the results in the study design and design of analysis. In some cases, the percentile groups in the non-vaccinating end of the immunization axis had zero patients; in those cases, the value of the least vaccinating percentile was used as the denominator for the relative incidence to avoid division by zero. In contrast therefore to "most vaccinated" ("MV") to "unvaccinated" ("UV"), such analyses were therefore "most vaccinated" vs. "least vaccinated" ("LV") patients. This modification had to be applied to the billed diagnoses of "developmental speech delay" and "pain". The *y*-axis in the graphical representation of the data in the percentile analysis is the average incidence of related visitations per condition at a given percentile of vaccination/the average incidence of the related visitations per condition in the unvaccinated (OV_V/OV_{UV}). Incidence ratios were calculated as a ratio of average incidence per patient in each percentile compared to the un- or least-vaccinated group (the latter to avoid division by zero, e.g., ADHD); they are equivalent to an expression of relative risk of diagnosis for each study outcome.

2.6.2. Natural Positive and Negative "Controls"

It is well known that "fever" is a side effect of vaccination. In this analysis, we therefore used incidence of "fever" as positive controls on trends in the data. Similarly, "Well Child" visits can be considered a type of negative control given that they were regularly scheduled events and that they set a comparator value of RIOV for other outcomes (Figure 3).

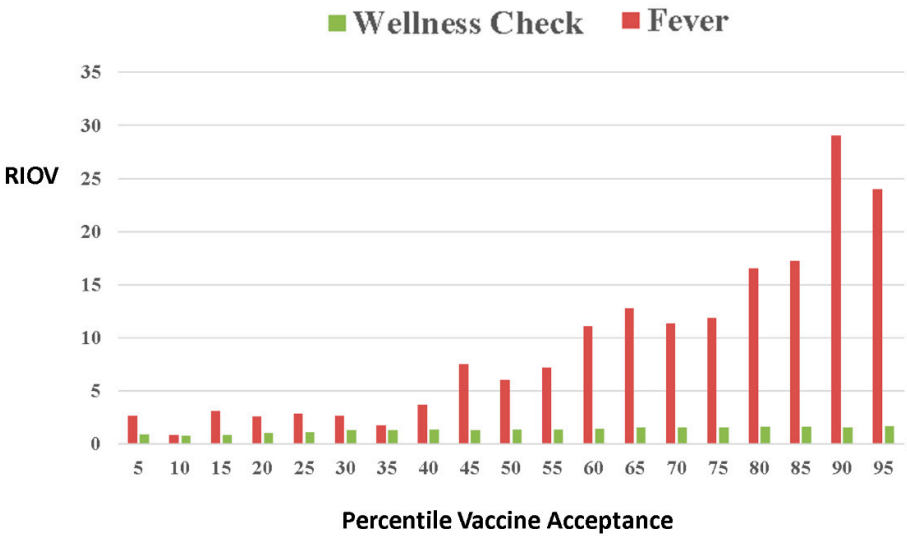

Figure 3. Relative Incidence of Office Visit (RIOV) percentile vaccinated vs. unvaccinated design of analysis: power decreases from left to right; thus, a stable trend (increase or decrease) becomes noteworthy. The data shown are for the Relative Incidence of Office Visits (RIOVs) to average incidence ratio of billed office visits related to fever in the vaccinated compared to the unvaccinated (OV_V/OV_{UV}) conditions and for "Well Child" visit on the right. For all the clinical conditions studied, RIOV reflects the total number of billed office visits per condition per group, reflecting the total disease burden on the group and the population that it represents.

2.7. Analysis 2. Odds Ratio Analysis of Incidence of Diagnoses

For comparison to the RIOV method, the same data were also analyzed using a classical odds ratio of incidence of diagnoses using the rates of diagnosis of each condition in the vaccinated and unvaccinated groups using 95% confidence interval testing. Odds ratios per each ith diagnosis were calculated as the standard ratio of the rate of exposure in those with the diagnosis ($p_{1,i}$) to the rate of exposure in those without diagnosis ($p_{2,i}$), i.e.,

$$OR_i = \frac{p_{1,i} \Big/ (1 - p_{1,i})}{p_{2,i} \Big/ (1 - p_{2,i})} \quad (1)$$

Relative risk ratios for each of the ith conditions with n_{1i} vaccinated in D_1 diagnosed and n_{2i} vaccinated among D_2 without diagnosis was calculated as

$$RR_i = \frac{n_{1,i} \Big/ (D_{1,i})}{n_{2,i} \Big/ (D_{2,i})} \quad (2)$$

Z-tests of proportion were conducted to provide *p*-values. Effect size was estimated with absolute risk difference (ARD), calculated as (vaccinated diagnosis rate − unvaccinated diagnosis rate).

2.8. Analysis 3. Days-of-Care (DOC)-Matched Vaccinated vs. Unvaccinated RIOV Analysis

Because this is an observational retrospective study, a potential limitation of the time-agnostic analysis is that more recent and younger patients' parents in the practice have opted to vaccinate less frequently and, being younger, have fewer office visits. Thus, fewer diagnoses may be expected to be related to lower exposures due to the combined effects of age (less time) and vaccine choice behaviors. Given this shift occurring in vaccination choices over time, it is possible that a false signal may be embedded due to temporal population-wide shifts due to unmeasured factors, such as cultural shifts in attitudes toward vaccination unrelated to personal outcomes or specific risk. Therefore, an additional analysis was conducted to assess the signal in Days-of-Care (DOC)-matched groups. For each unvaccinated patient, a patient with identical or closest DOC values was selected (without bias) from among the more numerous vaccinated patients. RIOV analysis was conducted on the resulting two groups.

2.9. Analysis 4. DOC-Matched OR on Incidence of Diagnoses. Vaccinated vs. Unvaccinated

As a comparison to analysis 3, odds ratios of incidence using diagnoses were calculated on the same data resulting from the matching of patients for DOC.

2.10. Analysis 5. Cumulative Office Visit Risk (COV Relative Risk)

To provide another view on the data considering the dimension of time, we calculated for all vaccinated patients and separately for the unvaccinated the number of diagnoses of all of the conditions studied at each day of life considering the vaccinated patients born into the practice (N = 2763) compared to the unvaccinated patients (N = 561). We also then calculated the cumulative office visits per each day of life. It is important to note that, in these analyses, a patient can have office visits related to the same diagnosis multiple times. These two representations of the data provide a clear graphical representation of the comparison of the vaccinated and unvaccinated and seem to also provide some insight into the typical timing of onset of a study outcome. Cumulative incidence of risk of office visit (RIOV) would be the cumulative numbers divided by the number of patients per group and would thus also reflect age-specific cumulative probabilities (risk of diagnosis-related office visit). Due to the imbalance in study design, the COV curve for the unvaccinated are expressed as the adjusted number

of office visits expected if the study had been balanced with equal numbers to make the two curves directly comparable in scale when expressed as numbers of office visits (multiplier factor 4.9).

2.11. Analysis 6. Family History Blocked RIOV Analysis

Data on family history of autoimmune disorders or autism were used to block patients into those who had a family history on record (FH+) and those who did not (FH−; blocked design). Average RIOV ratios were calculated to determine whether increased vaccination was associated with increased relative incidence of office visitations in both clinical groups (similar to analysis 1), given family history (FH+ and FH−). The results are not otherwise matched or blocked.

2.12. Analysis 7. RIOV vs. OR Incidence of Diagnoses Power Simulation Comparison

A comparison of the power of the test statistics RIOV and OR on incidence is provided to demonstrate the relative power of RIOV to detect differences and associations compared to odds ratio of diagnoses. Poisson variables drawn from distinct theoretical populations were analyzed using both RIOV (full values of x_i) and OR on incidence ($x_i > 0$). For the simulation, 1000 measurement sets $X = \{x_1, x_2, x_3 \ldots x_n\}$ drawn from a Poisson distribution of 400,000 random values were used to simulate two groups (each of size N = 400) for each Poisson λ value ranging from 1 to 1.1 (step 0.01). The null data ($\lambda = 1$) were used to represent the unvaccinated with no effect.

We simulated an increased effect of vaccines on office visits by increasing λ from 1.01 to 1.1 (step 0.01), with 400,000 values at each level of λ. Increased levels of λ represent increased numbers of office visits due to negative effects of vaccines. The data were analyzed using OR of incidence counting each individual value of $x_i > 0$ as a positive diagnosis and again using RIOV, leaving the generated values of x_i in both simulated groups intact.

2.13. Analysis 8. Gender Blocks

We blocked the cohort data into gender blocks (males and females). RIOV analysis was conducted on the vaccinated vs. unvaccinated in both gender blocks.

2.14. Analysis 9. Age (Youngest Third and Oldest Third) Blocks

One of the honest brokers ranked the patients by date of birth and sent a set of age-ranked identifiers to the analyst (J.L.-W.). The data were blocked into the youngest 1/3 and the oldest 1/3. RIOV analysis was conducted on the vaccinated vs. unvaccinated in both age blocks.

2.15. Analysis 10

We compiled and presented the number of diagnoses for infections targeted by vaccines (considering the CDC pediatric schedule) in the vaccinated and unvaccinated groups in the full cohort. We evaluated each vaccine targeted infection individually and analyzed the association between vaccination status and overall occurrence of vaccine-targeted infections using vaccine-targeted diagnoses. We studied the incidence of vaccine-targeted diagnoses in the vaccinated and unvaccinated groups using the χ^2 test.

3. Results

The overall full-cohort RIOV analysis of the vaccinated (N = 561) vs. unvaccinated (N = 2763) groups are presented in Table 2. There were no cases of ADHD in the unvaccinated group.

Table 2. RIOV and test of proportions of office visits per condition for the fully vaccinated (N1 = 2763) vs. (never) unvaccinated (N2 = 561) groups comparison: these results are not adjusted for days of care. CI = confidence interval.

Condition	Vaxxed	Unvaxxed	RIOV	95% CI	Z	*p*
Fever	759	17	9.065	8.801	12.476	<0.0001
"Well Child" Visits	32,826	4987	1.336	1.149	6.540	<0.0001
Ear Pain	269	16	3.414	3.232	5.310	<0.0001
Otitis media	3105	216	2.919	2.518	23.441	<0.0001
Conjunctivitis	1018	87	2.376	1.935	9.783	<0.0001
Eye Disorders (Other)	277	31	1.814	1.586	3.350	0.0008
Asthma	336	13	5.248	5.065	6.693	<0.0001
Allergic Rhinitis	405	12	6.853	6.662	8.158	<0.0001
Sinusitis	107	5	4.345	4.240	3.566	0.00036
Breathing Issues	621	44	2.866	2.561	7.898	<0.0001
Anemia	979	36	5.522	5.181	13.603	<0.0001
Eczema	512	23	4.520	4.281	8.479	<0.0001
Urticaria	174	17	2.078	1.908	3.027	0.00244
Dermatitis	742	105	1.435	0.992	4.034	<0.0001
Behavioral Issues	343	17	4.097	3.900	6.087	<0.0001
Gastroenteritis	688	30	4.656	4.374	6.543	<0.0001
Weight/Eating Disorders	1115	90	2.515	2.056	10.264	<0.0001
Seizure	43	8	1.091	0.985	0.229	0.8181

RIOVs were calculated using the number of patients as the sample size in each group (Vaxxed and Unvaxxed) with the exception of well-child visits and otitis media visits, both of which were greater in number than the number of patients.

3.1. Analysis 1 Results, Unmatched and Unblocked

RIOV analysis views across deciles provide a graphical view on the trends in the data (e.g., Figure 3). Recalling that the data are represented as the average incidence of billed office visits for patients in each percentile of the vaccine acceptance/unvaccinated groups, the statistic is the incidence of office visits in each percentile relative to the non-vaccinating portion of the population, but it is not relative risk of diagnosis. Results for outcomes were presented by study outcome cluster in quartiles for clarity.

Examination of the unmatched, unblocked results shows widespread increased RIOV among outcomes with all but seizures, and the developmental delay outcomes were significant. Those results are consistent with low power due to low overall incidence in the cohort. These results are not adjusted for days of care.

R1.1. Group A: Autoimmune Respiratory Illnesses. Large increases in office visits were found among the vaccinated group in this group of respiratory illnesses. Our quartile representation shows consistent increases in the incidence of office visits for allergy, allergic rhinitis, asthma, sinusitis, and breathing issues with increased vaccine acceptance compared to the unvaccinated group (Figure 4A). In the most vaccinated quartile compared to unvaccinated comparison, the relative risks (and lower CI) of office visits related to these conditions were estimated for asthma (16.01), allergic rhinitis (20.64), sinusitis (11.32), and breathing issues (6.52); all were highly significant in univariate analysis ($p < 0.0001$).

R1.2. Group B: Attention Deficit/Hyperactive Disorder and Behavioral Issues. Because there were no cases of ADHD in the unvaccinated group, the quartile analysis uses a comparison to the least vaccinated decile to avoid division by zero. Large increases were found in office visits among the vaccinated compared to the unvaccinated groups in outcomes in this group as well. The quartile representation shows large increases in ADHD and moderately large increases in behavioral issues (Figure 4B). Both of these conditions had highly significant relative incidences of office visit (ADHD, RIOV = 53.74; behavioral issues, 10.28) ($p < 0.00001$).

R1.3 Group C: Ear Pain, Otitis media, and Eye Disorders. Issues with the ear showed a range of increases with vaccine acceptance over the quartiles; in the last quartile, the differences were all

significant (ear pain (RIOV = 10.37), otitis media (RIOV = 7.03), and eye disorders (5.53) (Figure 4C) ($p < 0.00001$).

R1.4. Group D: Autoimmune Conditions of the Skin and Blood. Skin reactions commonly observed and sometimes attributed to vaccination showed consistent, moderate increases in RIOV in the last quartile of eczema (2.315), urticaria (4.81), and dermatitis (2.72) (Figure 4D); $p < 0.0001$.

R1.5. Group E: Gastroenteritis, Weight/Eating Disorders, and Seizure. The RIOV of both gastroenteritis and weight/disorders increased over the quartiles with increased vaccine uptake, as did seizure (Figure 4E).

R1.6. Group F: speech, language, social, and learning delays showed variable but nonsignificant response over the axis of vaccination. Autism was only significant at the third quartile (Figure 4F).

Sensitivity analysis for multiple hypothesis testing in the full cohort data did not change the outcome of analyses for most comparisons. Specifically, an increase of the critical value of Z on the test of proportions from 9.98 to 18 resulted in no loss of significance except for seizure; when increased to 19, dermatitis and behavioral issues lost significance.

Associations were found comparing the most vaccinated quartile for most of the outcomes (Table 3) with the exception of developmental delays and autism spectrum disorders (Figure 4). Following the same analysis protocol for all other conditions, the rate of autism was found to be higher at the third quartile of vaccine uptake compared to unvaccinated (Figure 4F). This is expected given that families with children with autism may be inclined to opt out of the vaccination program, potentially reflecting a signal of informed choice by families excluding them from the higher vaccinated quartile.

Table 3. RIOV analysis of outcomes of the vaccinated vs. unvaccinated groups, matched for Days of Care (DOC) matched comparison (N1 = 561 and N2 = 561).

					Test of Proportions	
Condition	**Vaxxed**	**Unvaxxed**	**RIOV**	**95% CI**	**Z**	**P(Z)**
Fever	78	17	4.596	4.412	6.547	<0.00001
"Well Child" Visit	5204	4989	1.045	1.041	2.156	0.0307
Ear Pain	18	16	1.127	1.022	0.354	0.726
Otitis media	355	216	1.646	1.001	8.312	<0.00001
Conjunctivitis	113	87	1.301	1.023	2.042	0.04136
Eye Disorders—Other	38	31	1.228	1.076	0.877	0.3788
Asthma	20	13	1.541	1.437	1.317	0.186
Allergic Rhinitis	21	12	1.753	1.649	1.600	0.1096
Sinusitis	6	5	1.202	1.143	0.306	0.756
Breathing Issues	75	44	1.708	1.502	3.015	0.00252
Anemia	130	36	3.618	3.361	7.912	<0.00001
Eczema	64	23	2.788	2.613	4.581	<0.00001
Urticaria	14	17	0.825	0.925	−0.541	0.5892
Dermatitis	86	105	0.821	1.090	−1.459	0.1443
Behavioral Issues	54	17	3.182	3.026	4.452	<0.00001
Gastroenteritis	89	30	2.972	2.763	5.728	<0.00001
Weight/Eating Disorders	147	92	1.601	1.288	4.023	<0.00001
Seizure	10	8	0.798	0.067	0.874	0.6312
Respiratory Infection	703	382	2.682	1.134	51.85	<0.00001

The calculation of Z for "Well Child" visits compared the proportion of number of office visits per group to the total number of days of care (length of time in practice; per group: vaccinated = 416,101, unvaccinated 416,056) in this DOC-matched analysis.

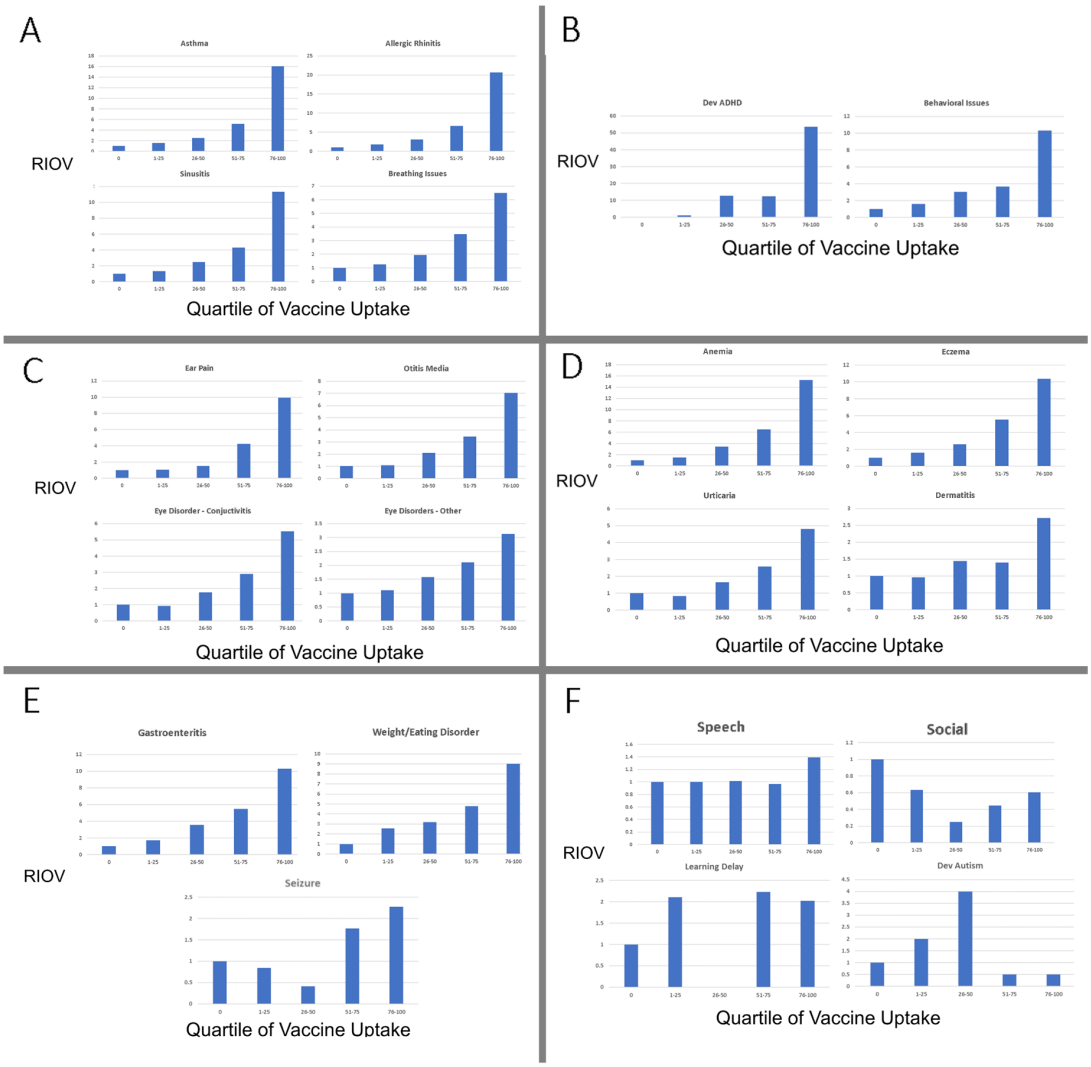

Figure 4. RIOV axis of vaccination percentile vaccine uptake analysis: incidence of study outcome-related office visits relative to that found in the 2763 variably vaccinated compared to the 561 unvaccinated groups for each percentile of vaccine uptake on the *x*-axis. (**A**) Autoimmune respiratory illnesses; (**B**) attention deficit/hyperactive disorder and behavioral issues; (**C**) ear pain, otitis media, and eye disorders; (**D**) autoimmune conditions of the skin and blood; (**E**) gastroenteritis, weight/eating disorders, and seizure; and (**F**) development delays in speech, learning, and social interactions and autism spectrum disorder.

3.2. Analysis 2 Results. Odds Ratio on Incidence of Diagnoses

When the data are represented as the number of patients in each group who had at least one record of an office visit related to a given condition, the signals remain (Table 4). Incidence of diagnoses of each condition was compared between the 561 unvaccinated and the 2763 vaccinated individuals. This result is similar overall to the RIOV analysis; we present the odds ratio, relative risk, lower than 95% of each, along with the absolute risk difference (vaccinated − unvaccinated) in Table 4. Among all of the outcomes, allergic rhinitis and anemia had the highest OR; anemia, weight/eating disorders, and respiratory infection showed the highest absolute risk difference (ARD; all increased in the vaccinated).

Table 4. Incidence of diagnoses of conditions in the vaccinated vs. unvaccinated groups in the population under study.

Outcome	OR	RR	Relevant 95% CI	ARD *	Significant
Fever	9.57	8.08	5.35/7.45	0.15	+/+
Ear Pain	4.11	3.87	2.22/3.40	0.06	+/+
Otitis media	3.11	2.2	2.49/2.11	0.12	+/+
Otitis externa	3.832	3.756	1.395/3.000	0.02	+/+
Conjunctivitis	2.67	2.21	2.04/2.08	0.15	+/+
Eye Disorders (Other)	1.9	1.82	1.24/1.61	0.04	+/+
Ear Disorders	2.359	2.32	1.08/1.86	0.02	+/+
Asthma	3.496	3.361	1.77/2.87	0.04	+/+
Allergic Rhinitis	6.479	5.595	3.31/5.31	0.08	+/+
Sinusitis	3.529	3.451	1.42/2.79	0.02	+/+
Breathing Issues	2.46	2.238	1.74/2.04	0.08	+/+
Anemia	6.334	4.482	4.68/4.6	0.21	+/+
Eczema	4.763	4.301	2.86/3.89	0.09	+/+
Urticaria	2.258	2.183	1.29/1.87	0.03	+/+
Dermatitis	1.591	1.482	1.22/1.37	0.06	+/+
Behavioral Issues	3.13	1.8	1.80/2.60	0.05	+/+
Gastroenteritis	4.479	3.587	2.98/3.56	0.13	+/+
Weight/Eating Disorders	3.146	2.489	2.41/2.35	0.183	+/+
Allergy—Food	2.24	2.23	0.52/1.47	0.004	−/+
Pain	2.569	2.236	1.759/2.147	0.0754	+/+
Respiratory Infection	1.716	1.365	1.351/1.255	0.131	+/+

* ARD = absolute risk difference, calculated as (vaccinated diagnosis rate − unvaccinated diagnosis rate). Odds ratios and relative risk ratios were calculated as described in the Methods section (Equations (1) and (2), respectively). The +, − symbols represent the significance of the OR and RR statistics for each condition for the relevant (upper or lower) 95% CI.

3.3. Analysis 3 Results. Days of Care (DOC) Matched Vaccinated vs. Unvaccinated RIOV Analysis

Due to the likelihood of confounding on DOC, DOC-matched results inform on the robustness of associations. DOC matching also led to matching by age; the average rank of age in both the vaccinated and unvaccinated groups was nearly identical (Student's t, $p = 0.919$). Average age at last office visit was also not significantly different (Student's t, $p = 0.95$). The average age of first office visit differed only by 2 days (6 days vs. 8 days, Student's t, $p < 0.001$).

3.4. Analysis 4 Results. DOC-Matched Incidence

In the analysis of days-of-care-matched data represented as incidence, many of the conditions for which associations were found in the RIOV analysis were found to be undetectable by OR and Relative Risk analysis (Table 5). This included ear pain, eye disorders, ear disorders, asthma, allergic rhinitis, sinusitis, and urticaria (Table 5). Otitis externa, anemia, and respiratory virus infection had the highest absolute risk differences.

While RIOV is reduced in the DOC-matched analysis, the significance of an increased proportion of cases in the vaccinated individuals compared to unvaccinated individuals remains for most outcomes. Risk of seizure was significant for confidence interval testing in this matched analysis but not for Z-test ($p = 0.6321$). Some comparisons had too few counts in the DOC-matched analysis to be reliable (e.g., food allergy had 1 case in the vaccinated group and 2 in the unvaccinated group).

Table 5. Analysis 4: DOC-matched incidence analysis.

Outcome	OR	RR	95% CI	ARD	Significance
Fever	3.88	3.66	2.02/2.75	0.057	+,+
Ear Pain	1.559	1.57	0.723/0.966	0.01	−,−
Otitis media	1.551	1.4	1.17/1.22	0.078	+,+
Otitis externa	2.01	1.996	0.602	1	+,+
Conjunctivitis	1.323	1.273	0.942/1.05	0.033	−,+
Eye Disorders—Other	1.25	1.24	0.729/0.879	0.011	−,−
Ear Disorders	1.29	1.28	0.476/0.671	0.003	−,−
Asthma	1.224	1.22	0.503/0.679	0.003	−,−
Allergic Rhinitis	1.452	1.44	0.615/0.842	0.007	−,−
Sinusitis	1.2	1.2	0.364/0.540	0.008	−,−
Breathing Issues	1.614	1.549	1.504/1.217	0.037	+,+
Anemia	3.216	2.865	2.098/2.368	0.103	+,+
Eczema	2.822	2.682	1.57/2.01	0.047	+,+
Urticaria	1	1	0.471/0.595	0	−,−
Dermatitis	0.884	0.898	1.27/1.13	−0.012	+,+
Behavioral Issues	2.13	2.067	1.11/1.45	0.0266	+,+
Gastroenteritis	2.785	2.572	1.74/2.054	0.073	+,+
Weight/Eating Disorders	1.915	1.721	1.386/1.47	0.089	+,+
Allergy—Food	0.498	0.499	5.51/3.53	−0.001	−,−
Seizure	1.756	1.746	0.511/0.836	0.0053	−,−
Infection—Respiratory	1.716	1.365	1.351/1.255	0.131	+,+
Pain	1.274	1.255	0.783/0.927	0.014	−,−

The symbols "+, – " denote the significance of the relevant (upper or lower) 95% CI analysis for OR and RR.

3.5. Analysis 5 Results. Cumulative Office Visits

The visual impact of the cumulative office visit plots is striking; more so than other plots, the time element (day of life) provides an index by which to compare the accumulation of human pain and suffering from potential vaccine side effects (Figure 5). These results are worth studying closely and noticing the variation among the cumulative office visits per condition and the stark differences between the rates of billed office visits in the most and unvaccinated patients born into the practice.

False discovery sensitivity analysis performed by increasing of the critical of value of Z (test of proportions) from 9.98 to 18 caused a loss of significance for ear and eye conditions only. All other conditions were robustly significant to $Z_{crit} < 19.2$ (behavioral issues). The remainder of the conditions retained significance well beyond $Z_{crit} = 24$.

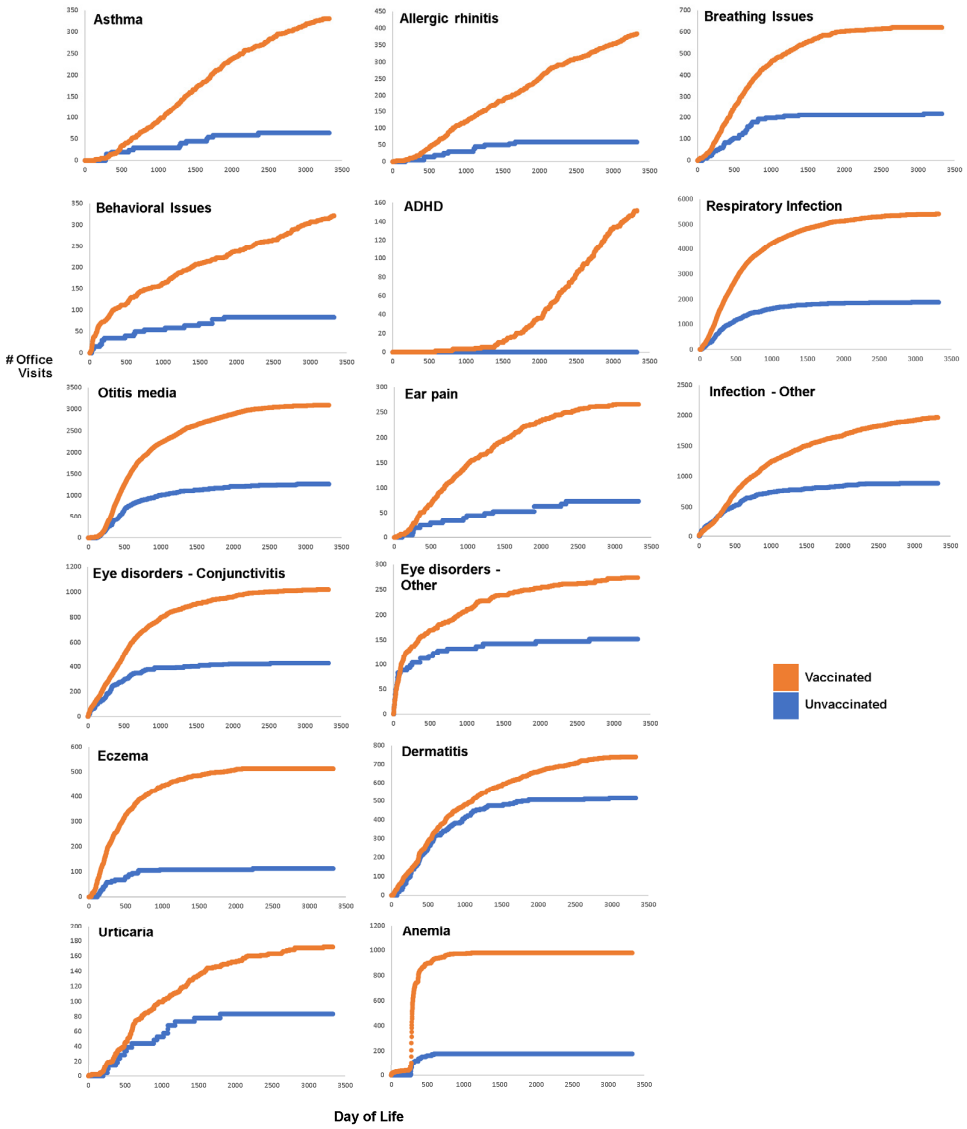

Figure 5. Analysis 5. Cumulative office visits in the vaccinated (orange) vs. unvaccinated (blue) patients born into the practice: the clarity of the age-specific differences in the health fates of individuals who are vaccinated (2763) compared to the 561 unvaccinated in patients born into the practice over ten years is most strikingly clear in this comparison of the cumulative numbers of diagnoses in the two patient groups. The number of office visits for the unvaccinated is adjusted by a sample size multiplier factor (4.9) to the expected value as if the number of unvaccinated in the study was the same as the number of vaccinated.

3.6. Analysis 6 Results. Family History-Blocked RIOV Analysis

The relative incidence of visitation per condition for patients with family history of autoimmune conditions and those patients with no record of family history of autoimmune conditions indicate variation among conditions in the likelihood of family history playing a role, either biologically or by influencing patient choice, in the association of vaccine uptake and outcome (Table 6). Within the pattern (Score FH+ >> Score FH−), family history of autoimmunity itself is consistent with a biological risk factor of the outcome. This was the pattern for fever, sinusitis, and potentially anemia. Within the pattern (Score FH+ << Score FH−), this is consistent with the signal of vaccine choice, implying that further vaccine uptake may have increased the risk of the condition in the unvaccinated. This was

the case in otitis externa, asthma, allergic rhinitis, and dermatitis. In this analysis: FH + N1 = 175 vaccinated, N2 = 88 unvaccinated; FH−, N1 = 385 vaccinated, and N2 = 186 unvaccinated.

Table 6. RIOV score blocked by family history and implication for co-factor status.

Condition	FH+	FH−	Pattern *	Consistent w/Risk Cofactor? **
Fever	21.826	3.818	+,+	yes
"Well Child" Visit	2.690	1.009	+,−	yes
Ear Pain	10.500	13.427	+,+	no
Otitis externa	0.988	9.242	−,+	yes
Otitis media	30.500	21.715	+,+	maybe
Conjunctivitis	19.266	13.443	+,+	maybe
Other Eye Disorder	2.343	3.902	+,+	maybe
Asthma	8.143	19.030	+,+	yes
Allergic Rhinitis	18.382	54.339	+,+	yes
Sinusitis	27.316	8.282	+,+	yes
Breathing Issues	9.524	10.188	+,+	no
Anemia	29.302	20.027	+,+	maybe
Eczema	17.292	13.718	+,+	maybe
Urticaria	4.135	4.404	+,+	no
Dermatitis	1.470	4.922	−,+	yes
Sezure	0.989	0.634	−,−	no
Respiratory Infection	4.556	5.396	+,+	no

* +,+ CI testing significant in both comparisons, +,− significant under FH+ block but not FH- block, etc. ** Yes = FH is a likely co-risk factor for outcome. Numerators (N1 and N2) for both groups were adjusted in fever and "Well Child" visits by a factor of 20; Otitis externa, anemia, and Otitis externa (factor of 2) and Otitis media (factor of 3). This does not change the RIOV score but allows the Z-test score to estimated.

3.7. Analysis 7 Results. Power Simulation

The resulting 1000 comparison sets at each value of λ (N1 = 400 λ = 1.0 vs. N2 = 400 $\lambda = 1.x$ for each $\{x = 0.01, 0.02, 0.03 \ldots 0.50\}$ were analyzed twice, first as an odds ratio of "diagnosis" ("0" = no diagnosis vs. ">0" = diagnoses). The second analysis conducted was a ratio of relative incidence of office visits, with each groups' sum of values within each comparison group representing the total number of office visits being compared.

The simulations were not intended to precisely model the data from the current study; instead, it is intended to demonstrate the principle that the loss of information caused by using the incidence of health condition rather than the more sensitive measure of the number of office visits results in a loss of power to detect adverse events.

Over the range studied, the average increase in power achieved from the analysis using RIOV compared to the odds ratio of diagnoses was doubled over that of odds ratio on incidence of diagnoses (133%) (Figure 6). RIOV was more powerful compared to OR on rates of diagnosis over the simulated range. Our results demonstrate that drug and vaccine safety studies should employ RIOV rather than OR on rates of diagnosis of health conditions that might be attributable to the treatment, therapy, or vaccine.

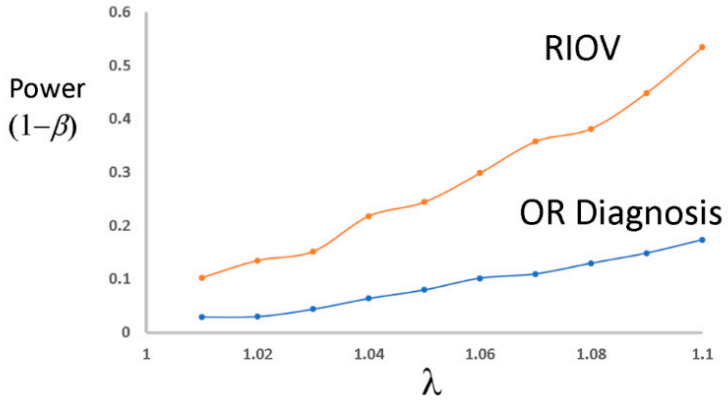

Figure 6. Simulated demonstration of increased power of RIOV (number of office visits) relative to the power of odds ratio of incidence of diagnoses (at least one office visit).

3.8. Analysis 8. Gender Blocks

In the gender block analysis, the following conditions were significant in both the male and female ROIV comparisons: fever, "Well Child" visits, ear pain, otitis media, conjunctivitis, eye disorders (other), asthma, sinusitis, breathing issues, anemia, eczema, behavioral, gastroenteritis, and weight/eating disorder. The developmental delays were largely underpowered for robust analysis due to low overall rates in the practice, but two conditions were significantly lower in the vaccinated females (autism) and males (social development). These results, provided as a table with RIOV values and exact *p*-values of Z in Supplementary Materials Table S2, were not DOC- or age-matched.

3.9. Analysis 9 Age Blocks: Oldest Third and Young Third Blocked Analysis

The following conditions were significantly increased ($p < 0.05$) in the vaccinated group in both age blocks: fever, otitis media, conjunctivitis, sinusitis, breathing issues, anemia, gastroenteritis, and weight/eating disorder. The following conditions were significantly increased in the vaccinated group in the younger (more recent) age block only: asthma and allergic rhinitis. The following conditions were significantly increased in the older age block only: "Well Child" visit and eczema. None of the developmental delay categories were significantly increased in either the older or younger age blocks, likely due to low power. Social delay was significantly increased in the unvaccinated older age block. Two health outcomes, pain and respiratory infection, were increased in the unvaccinated group under the older block but were not significantly different in the younger block. These results, requested by a peer reviewer, demonstrate robustness of many associations to blocking by age and by gender and are provided as tables in Supplementary Materials Table S3 (including RIOV values and exact *p*-values of Z).

3.10. Analysis 10 Results—Vaccine-Targeted Diagnoses

There was a total of 41 vaccine-targeted diagnoses in patients born into the practice, mostly (by far) in varicella (29) and less so in pertussis (10). Overall, the groups show differences in vaccine-targeted diagnoses (Table 7; $\chi^2 = 0.292$, $p = 0.588$). The rates of any diagnosis were vaccinated, 7/2647 (0.00264) and unvaccinated, 34/561 (0.0499). The odds ratio of having a diagnosis of any vaccine-targeted infection (Dx_V/Dx_{UV}) was 0.054 (0.114), *Z*-score, 7.155, $p < 0.0001$. Relative risk of any vaccine-targeted diagnosis was 0.053 (0.119), $Z = 7.117$, $p < 0.0001$, number needed to treat (NNT) = 21.15 (17.72 to 26.225 (benefit)).

Table 7. Incidence of vaccine-targeted diagnoses in the study cohort.

Vaccine Targeted Diagnosis	Vaccinated	Unvaccinated	Deaths
Diphtheria	0	0	0
Hepatitis A	0	0	0
Hepatitis B	0	0	0
HiB *	0	0	0
Measles	0	0	0
Meningococcus	0	0	0
Mumps	0	0	0
Pertussis	1	9	0
Pneumococcal	0	0	0
Rotavirus	0	2	0
Rubella	0	0	0
Tetanus	0	0	0
Varicella	6	23	0
Total **	7	34	0

* Haemophilus influenzae type B; ** Overall for all $\chi^2 = 99.51$. $p < 0.00001$.

The overall probability (risk) of a vaccine-targeted diagnosis in the unvaccinated, however, was only 0.0123, among 13 conditions. It is important to note that zero deaths have been attributed to any vaccine-targeted diagnosis in this practice over the study period.

4. Discussion

The analysis of total outcomes related to vaccine and drug exposures is rarely conducted. It is made complex due to factors such as changes in trends in vaccine or drug acceptance, and the very signal sought—indication of adverse events from vaccines—can be changed by decisions made to avoid vaccine injury by those at risk. We have shown that the outcome of observational studies is sensitive to the choice of test of association and have presented a test (RIOV) more powerful than odds ratios on incidence (Figure 6).

Matching on DOC provides protection against healthcare-seeking behavior because each patient in the vaccinated group is matched to a person in the unvaccinated group with nearly identical length of records in the practice. This also led to matching on age, adding protection against incidental temporal confounds in changes over time in vaccination trends or schedules: both the vaccinated and unvaccinated matched samples are representative of the entire age range of the study cohort. Most of the differences in ratios persist comparing the full cohort analysis when the data were matched for DOC (Analysis 2; Table 3). All RIOV were >1, indicating increased risk of office visit for a specific outcome, except seizure, urticaria, and dermatitis. The change in direction of seizure likely points to "cessation of vaccination signal" following initial events. The difference between the vaccinated and unvaccinated groups was no longer significant for dermatitis following matching for DOC.

The variation in vaccination was the outcome of the final decisions on the part of the patients after consulting with their physicians in the practice. This adherence to the tenets of informed consent, as required by federal regulations for both medical practice and for post-market surveillance studies, is also a key element built into "The Vaccine Friendly Plan" (VFP), developed in a manner to space aluminum-containing vaccines out and to avoid aluminum-containing vaccines (ACVs) whenever a non-ACV is available. The net effects of these changes on aluminum accumulation in children is described in [15]. Children on the CDC schedule would have on average received more vaccines in total; considering the most vaccinated of the VFP compared to the CDC schedule reveals that CDC-scheduled children receive 14 more vaccines by age 2 compared to those most vaccinated on the VFP; by age 5 years, children receive 4 more vaccines (CDC 6, VFP 2), and by ten years, children receive six more vaccines under the CDC schedule compared to the VFP (CDC + 8, VFP, +2). This represents a

total of 24 additional vaccines those on the CDC schedule would have received in 2019 compared to the most vaccinated individuals in this retrospective study. Children on the CDC schedule also would have received more instances of more than one ACV per visit and a larger number of ACVs.

We have found higher rates of office visits and diagnoses of common chronic ailments in the most vaccinated children in the practice compared to children who are completely unvaccinated. The data clearly show different odds of developing many of these adverse health conditions. We have demonstrated in many ways that most of the statistical associations found tend to be robust to age in cohort (days of care), vaccination range, and family history. The first of these is the contrast in the increase in fever cf. "Well Child" visit (Figure 3). The second is robustness of the results to adjustment to days of care provided and of course robustness to the age-matched design as well.

Vaccination appears to have had the largest impact on anemia and respiratory virus infection on the number of office visits in the vaccinated compared to the unvaccinated groups. Due to a small number of cases and corresponding low power, neurodevelopmental conditions and seizures are not well studied using the data available. Autism, at a study-wide rate of 8 per 1000, is far lower than the national rate (18.5–21 per 1000). Speech, learning, and social delays were found to have different full-cohort practice-wide incidences of 0.023, 0.003. and 0.009, respectively. Future studies with less restrictive inclusion criteria that also avoid temporal confounding by matched DOC may help us better characterize these populations in the practice.

Our family history of autoimmune conditions analysis points to numerous conditions likely carrying a genetic risk of vaccine-related adverse health effects. This, however, is only one study from data from a single practice, so any absence of a pattern consistent with a genetic risk of adverse health effects should not be taken as evidence of absence of a role of genetic risk. Larger studies able to estimate the interaction term between family history and vaccine exposure should be undertaken.

Previous studies such as the Mawson study (2017) [9] reported high odds ratios for allergic rhinitis (30.1), learning disabilities (5.2), ADHD (4.2), autism (4.2), neurodevelopmental disorders (3.7), eczema (2.9), and chronic illness (2.4) but were limited because they were based on survey data. While not necessarily fatal to a study, the highly charged nature of the vaccine risk research brings a special concern over survey respondents who might, for the sake of advocacy, seek or unintentionally emphasize their unvaccinated child's lack of diagnoses or amplify their vaccinated child's larger number of diagnoses. Recall bias is a potential factor in this setting, and therefore, our results go a long way to validate those on the Mawson (2017) [9] study. The age range in that study was also restricted to 6- to 12-year-olds, precluding the comparison of the cumulative rates from day 1 of life. Survey studies in the future should obtain HIPAA permissions to access at least a portion of patients' medical records to at least estimate the accuracy of responses compared to medical records from a sample. Despite limitations of survey studies, our results validate many of these results.

Numerous studies conducted in the past have found an association of vaccination with adverse health effects. Numerous studies reporting an association of individual vaccines with adverse study outcomes are too numerous to cite here; many more such studies are reviewed online [16]. For example, a prior study reported a vaccination association with asthma and allergy (e.g., Hurwitz and Morgenstern, 2000) [17].

Concerned over healthy user bias (HUB), i.e., healthier individuals accepting more vaccines leading to differences in study outcome are alleviated in this practice, the physicians and patients overtly came to a joint decision on whether to vaccinate on a patient-by-patient and vaccine-by-vaccine basis. As originally described, if "healthy user bias" was the explanation problem, we would see more illness in the unvaccinated; we found the opposite. We do see the potential signal of informed avoidance of vaccine injury with informed consent and without coercion potentially weakening associations of vaccine injury. This type of effect has historically been interpreted as a form of healthy user bias, but it can be equally interpreted as the signal of avoidance of vaccine injury due to informed consent. Our design of analysis allows the detection of some potential instances (e.g., autism, in which

some individuals at risk of adverse outcome who otherwise would have been in quartiles 3 and 4 stopped vaccinating).

Glanz et al., 2003 [18] found that parents who tended to not accept all vaccines or who delayed vaccines were 2 times more likely to report that they began thinking about vaccines before their child was born and were also 8 times more likely to report that they constantly reevaluate their vaccine decisions than parents who accepted all vaccines. Notably, the signal of change in vaccination behavior following adverse events via informed consent would appear to be detectable as a reduction in the overall incidence of adverse outcomes in the unvaccinated group and fewer office visits related to those outcomes. This opposing trend is the opposite of the expectation that physicians may be more likely to admit the unvaccinated for health issues than the vaccinated (described by [18]). Lifestyle differences between the vaccinated and unvaccinated groups in this practice cannot explain the large difference in outcomes, and if they do, then it would be objective to conclude that everyone should adopt the lifestyle followed by the unvaccinated if they want healthier children. That lifestyle choice includes, for many families, avoiding some or all vaccines, and thus, the lifestyle choice concern is inextricably linked to vaccine exposure.

Because we are considering the potential effects of cumulative vaccination, the potential problem of reverse temporal association with appropriately juxtaposed association is undefined in our study. The RIOV design of analysis makes the reverse temporal association irrelevant, as in the vaccinating population, the cumulative number of vaccinations over the course of a decade is the independent variable. For reverse temporal association concern to manifest, all or most of the diagnoses would have had to had occur prior to the first vaccine, which is extremely unlikely (and are not at all what our data show). Our accumulation diagrams make clear the general tendencies toward requiring medical attention for outcomes in vaccinated vs. unvaccinated segments of the patient population in a distinctly age-specific manner. We have focused on the cumulative effects of vaccines on overall health and therefore, this concern cannot logically apply to the study as it is designed.

4.1. Caveat on Applicability of Results (Generalizability)

Data from this single and unique practice provides a unique opportunity to examine variation in outcomes associated with variation in vaccination. A number of unique factors may limit the generalizability of these findings to other practices, including the fact that patients in the practice appear to be, on average, becoming healthier over time with less chronic illness and seem to have lower frequencies of certain health issues compared to national trends. Under the Vaccine Friendly Plan, parental choice leads to cessation of vaccination more frequently if certain health indications present following vaccination, leading, by observation, to a reduction in identifiable adverse health conditions. Therefore, our results may or may not generalize to other practices but could be expected to apply to practices that adopt the Vaccine Friendly Plan over the next ten years. Our results are likely conservative compared to practices that do not screen actively for patients who might experience further health complications due to vaccines. We conducted our analyses and present our results and interpretation with these caveats in mind.

We have been keenly aware of the brewing political controversies around vaccination studies, including the public's increased awareness of the dearth of long-term randomized prospective clinical studies that use inert placebos such as saline. Many studies have failed to detect the association of vaccines with adverse outcomes; however, they have mostly used correlative retrospective studies focused on odds ratios of mere incidence and have largely been agnostic to intrinsic methodological power. A white paper for conducting retrospective studies on vaccines [6,7] suggests adjusting/correcting for variables that correlate with vaccination status and/or outcomes. This is an incorrect and risky strategy; in a situation with highly collinear independent variables, adjusting for co-risk factors can remove variation in the model important to finding accurate interpretive context of the main variable of interest and prevents the development of risk models to avoid adverse vaccine outcomes. The CDC's white paper has fostered the widespread practice of selecting a subset of available

variables as confounders for adjusted analyses when the functional relationships among collinear variables are not well established, a feat that Vansteelandt et al., 2010 [19] consider "impossible". The protocol introduces serious risks of model misspecification due to adjusting for variables that correlate with outcomes and overadjustment of highly and sometimes multicollinear variables without formal model selection protocols and should be discontinued.

The use of objective criteria for model selection is rare, and the common practice of arbitrary selection of potential confounders could conflate signals when study outcome measures or measurements collinear with study outcome measures are treated as confounders. This increases the risk of overadjustment bias (See Schisterman et al., 2009 [20]). Not all potential confounders are in fact confounders; they may in fact represent a co-risk factor that could be used to predict risk of adverse events. "Adjusting" for risk factors of vaccine adverse events would undo signals expected to be functionally related to risk of vaccine toxicity; these include birthweight, gestational age, mother's income, and mother's age, all variables that are likely multicollinear and may well be important functional indicators of specific risk to vaccine adverse events. Repeated rounds of analysis of the same data set following observation of results to achieve a desired result (toward or away from statistical significance) without showing all the stages of analysis is now understood to increase the likelihood of bias and can be seen as "*p*-hacking" (George et al., 2016) [21] or "results-peeking". Such activities undertaken to achieve a desired result and failure to bring forward the full set of alternative or interim results should be discouraged by scientific journals publishing any type of observational research studies on any subdiscipline of research.

We recommend stratification and blocking with RIOV, which makes explicit the robustness of the association in different subpopulations. It also makes transparent the effect of subgroup sample size on power. Underpowered designs and methods should not yield presented hypothesis testing results (negative or positive) as definitive as they can have misleading and potentially disastrous effects on public health policies.

Given the massive abundance of electronic medical record data, the dearth of independent studies such as ours on vaccine safety is conspicuous. The value of any vaccination program must be seen as a product of the total net health effects of the individual vaccines in the program, and negative findings should provide an agency for a shift in their use, respect for patient choice, and regulation of their excipients and vaccine formulation.

It is little appreciated that the results of observational studies—including retrospective vaccine safety studies—can depend to a large degree on the statistical method(s) selected and the variables used to "adjust for" variation as found in an observational data set. We have introduced a new measure—RIOV—as a more powerful alternative to the commonly used odds ratios of incidence of diagnosis. We have shown OR on incidence of diagnosis to be, via our simulations (Analysis 7), a less powerful test than RIOV. OR on incidence is in fact a de facto lossy transform (binarization of a continuous variable office visits) of RIOV. Office visits carry more information than diagnoses; specifically, measures based on the number of office visits will carry information on severity in addition to the number of yes/no ever-diagnoses. Our days-of-care-matched incidence (diagnosis only) analysis appears to be the least powerful analysis when odds ratio using incidence is considered; reduced power of OR on incidence relative to RIOV analysis may explain the failure of many prior studies to detect an association between exposure to vaccines and adverse health effects. The realization that studies of the relative occurrence of office visits is a more powerful measure than incidence of diagnoses means that future vaccine studies can be made more capable of detecting real associations of adverse outcomes associated with vaccination.

Many families across the United States who are not vaccinating or who have stopped vaccinating their child or children or who choose to partially vaccinate often choose to opt out as a direct result of adverse health observations following vaccination, including health conditions that to date have not been attributed to vaccination based on epidemiological studies. Parents are almost universally told by their child's health care provider that the health issue was not due to the vaccine, in spite of growing

evidence in the scientific literature that supports both plausible mechanisms of action for chronic illnesses including epidemiological associations. It is now apparent that the commonly reported lack of association of adverse events may be due to the use of a test statistic with low intrinsic power and due to problems including model misspecification and overadjustment bias and that further research is needed to update guidelines and recommendations via additional studies.

We attribute the relative dearth of epidemiological findings similar to ours to a number of factors, including the use of incidence of diagnoses, which is clearly likely to be (on first principles) a less sensitive measure of differences in vaccine-induced disease burden. Importantly, RIOV is a readily accessible measure that likely has a higher power to detect associations than ratios of incidence or odds ratio. The underreporting of adverse events to VAERS is also a factor precluding the detection of adverse events that can be attributed to vaccines. According to the US CDC (CDC, 2020) [22] and the US Department of Health and Human Services (HHS) [23], healthcare providers should report to VAERS (a) any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations and (b) an adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine. Also, the CDC reports that healthcare providers are strongly encouraged to report to VAERS (a) any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event and (b) vaccine administration errors. Finally, the CDC reports that vaccine manufacturers are required to report to VAERS all adverse events that come to their attention; they are also required to pass on such reports to the Food and Drug Administration.

Regardless of such recommended reporting, the inquiry by Harvard Pilgrim (Ross et al., 2011) [5] on underreporting found that vaccine adverse events are underreported to VAERS by a factor of 100. If doctors are not reporting events because they believe they are not attributable to vaccines and VAERS is the primary resource by which new adverse events are detected, heretofore, undetected adverse events are not discovered. Families experiencing vaccine-induced chronic illnesses not yet recognized by science as adverse outcomes to vaccination are going to object strenuously to mandatory vaccination policies, and science will lag behind the public awareness of vaccine-induced human pain and suffering. This lag is currently undermining trust in public health vaccine policies, government regulating and licensing agencies, vaccine makers, and proponents of vaccination—including most of mainstream media in the US—who insist all vaccines are universally "safe and effective."

This study, and others, indicates that the correct path forward should include the enforceable requirement of all physicians to report all adverse health events recorded in medical records over an extended period to capture those adverse events that are latent, whether they are already recognized by the HHS or not, so as to empower users of the VAERS system to be better able to detect adverse outcomes associated with vaccination. Mandatory adoption of an ESP-VAERS-like adverse event detection system embedded in electronic medical record systems in practices and clinics would be beneficial toward a full understanding of vaccine-related morbidity and mortality in our populations and could lead to a significant increase in overall health. This study also provides information on diagnosed infections targeted by pediatric vaccines.

4.2. Strengths and Limitations

Factors such as sample size limitations, likely due to changes in vaccine acceptance following initial adverse events, limit our ability to robustly test hypotheses of association for some outcomes, especially in neurodevelopmental disorders and vaccination and seizures. If a link does exist, the absence of clear associations is likely due the small number of patients in the practice with neurodevelopmental disorders and seizures, which, ironically, may be due in part to the respect for patient preference, leading to informed choices by families at potential risk.

A related potential limitation includes that, because the data used were from billed diagnoses (in the case of outcomes) or billed vaccination, there may be some occurrences that were missed if insurance did not cover those events for a given patient (e.g., ASD diagnosed via a family

counselor/psychologist/psychiatrist). Similarly, diagnoses of developmental delay outside of the office may have not made it into the medical record for some patients. However, given that part of our data representation of such diagnoses was a per-patient count of reports of such diagnoses, the effects of these possible sampling limitations is likely mostly restricted to neurodevelopmental delays, and such an effect is more likely in outcomes related to data for a limited number of diagnoses than on vaccination data.

A criticism of association studies that detect negative health effects of vaccines is that some unknown, unmeasured confounder, or set of confounders might offer an alternative explanation. An example is the concern that our results may be explicable by other, unmeasured, healthier lifestyle choices made by families who also do not vaccinate. This seems highly unlikely given the relationships between increased adverse outcomes and vaccine acceptance, and lifestyle choices do not seem to be plausible explanations for many of the outcomes we have measured, although exposures to environmental substances such as cigarette smoke and acetaminophen (paracetamol), and malnutrition, which are known to impact negatively the immune system and development, cannot be ruled out as additive or multiplicative risk factors to vaccine adverse reactions and to the examined outcomes. The positive control outcome "fever" (Figure 3) points to a pattern expected following vaccination with no known or suspected relationship to lifestyle choices. However, if it were so, it would appear that our collective priority as a medical community should not be the pursuit of complete vaccination across the population but instead studies on what those other lifestyle choices might include and massive recommendations toward improving the lifestyle choices across the population.

Our study also has numerous strengths: the sample is fully representative of the practice population, and our design protocol had robust data provenance (parity checking) and rigorous data analysis. We avoided overadjustment bias and used a more powerful test to detect adverse events, demonstrated the robustness of the results to analysis assumptions, and have been careful to avoid overdrawn conclusions.

5. Conclusions

We could detect no widespread negative health effects in the unvaccinated other than the rare but significant vaccine-targeted diagnosis. We can conclude that the unvaccinated children in this practice are not, overall, less healthy than the vaccinated and that indeed the vaccinated children appear to be significantly less healthy than the unvaccinated.

We concur with Mawson et al., 2017 [9], who reported: "Further research involving larger, independent samples is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children's health."

We also concur with Hooker and Miller 2020 [14], who wrote: "Further study is necessary to understand the full spectrum of health effects associated with childhood vaccination".

Other pediatric practices with variably vaccinating populations should be studied using a methodology similar to ours to attempt to refute or validate our findings and those of Mawson et al., 2017 [9], Hooker and Miller 2020 [14], and the numerous studies that have reported adverse health following vaccination. We are particularly interested in further study of the relationship between specific vaccines and combination of vaccines on specific outcomes as well as the relationship between the uptake of specific types of vaccines—inactivated, live virus, and aluminum-adjuvanted—with specific outcomes. Larger studies using electronic medical records from major medical institutions should be undertaken by research teams with no financial interest in the outcome of the studies (e.g., revenue from vaccination and from treatment of vaccine-related adverse outcomes).

Unintended and nonspecific consequences of vaccination, such as increased risk of chronic health conditions from vaccine exposures, must also be examined to determine if for any vaccine-targeted infection alternative methods of infection-avoidance or effective treatments that reduce disease sequela are available and preferable to vaccination in various circumstances, as has been reported by Cowling

et al., 2012 [24] and by Wolff (Wolff, 2020) [25]. Our findings are consistent with the concern that vaccination may increase respiratory virus infection risk, clearly a grave concern in the age of COVID-19.

Our finding of a robust signal of anemia deserves follow up: aluminum is known to bind to transferrin [26] and, in so doing, may interfere with the proper deposition of iron in the bones of children. Iron deficiency can also contribute to febrile seizures, a known side effect of some vaccines. Our society should work to identify safer vaccine schedules and safer adjuvants [27–35] and to reduce autoimmunity risk by removing unsafe epitopes—peptide sequences from pathogens or human cell line remnants in vaccines that match human proteins in sequence or structure from any tissue [36]—would seem expeditious, kind, and wise.

Future studies should now focus on the relative incidence of billed office visits, now that it has been shown to be a more sensitive and powerful measure of outcomes with a larger dynamic range than binary yes/no incidence of diagnoses.

Supplementary Materials: The following are available online at http://www.mdpi.com/1660-4601/17/22/8674/s1: 'Table S1: ICD code mapping'; Table S2: 'LW and Thomas Supplemental S2 Gender Block Results 2.8.xlsx'; Table S3: 'LW and Thomas Supplemental S3 Age Blocks R2.9.xlsx'.

Author Contributions: P.T. directed the care of the patients in the study; P.T. conceived of the study concept; both J.L.-W. and P.T. designed the study; J.L.-W. designed the analysis strategy, and J.L.-W. conceived of and executed the data analysis including the power simulations and drafted the first manuscript; two anonymous honest brokers de-identified the data and provided a data parity check; all technical errors in the execution of analysis, if any, are the sole responsibility of J.L.-W. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest: J.L.W. has, in the past, been but is no longer a compensated expert witness in cases in the US National Vaccine Injury Compensation Program. P.T. receives income in the form of royalties from the sale of his book, and he receives income from the sale and administration of vaccines in his practice. P.T. is the owner of Integrative Pediatrics, the population for this study, and is the author of the book "The Vaccine-Friendly Plan: Dr. Paul's Safe and Effective Approach to Immunity and Health—from Pregnancy Through Your Child's Teen Years" by Balantine Books 2016.

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Exhibit C

9 FLU VACCINE FACTS

Are Mandates Science-Based?

PHYSICIANS FOR INFORMED CONSENT
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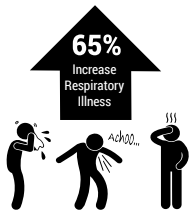
1. THERE IS A 65% INCREASED RISK OF NON-FLU RESPIRATORY ILLNESS IN POPULATIONS THAT GET THE FLU VACCINE.

Although some studies suggest positive effects of the flu vaccine on the incidence of illness caused by flu viruses, that benefit is potentially outweighed by the negative effects of the flu vaccine on the incidence of non-flu respiratory illness.[1] To address the concern among patients that the flu vaccine causes illness (i.e., acute respiratory illness), the Centers for Disease Control and Prevention (CDC) funded a three-year study,[2] published in *Vaccine*, to analyze the risk of illness after flu vaccination compared to the risk of illness in unvaccinated individuals.

The study, which included healthy subjects, found a 65% increased risk of non-flu acute respiratory illness within 14 days of receiving the flu vaccine. The authors state, "Patients' experiences of illness after vaccination may be validated by these results." The most common non-flu pathogens found were rhinovirus, enterovirus, respiratory syncytial virus, and coronaviruses.

This is important because although flu vaccines target three or four strains of flu virus,[3] over 200 different viruses cause illnesses that produce the same symptoms—fever, headache, aches, pains, cough, and runny nose—as influenza,[4] and more than 85% of acute respiratory illnesses do not involve the flu.[5]



There is a 65% increased risk of non-flu respiratory illness in populations that get the flu vaccine. The most common non-flu pathogens are rhinovirus, enterovirus, respiratory syncytial virus, and coronaviruses.[2]

2. THE FLU VACCINE DOESN'T REDUCE DEMAND ON HOSPITALS.

The National Institute of Health (NIH) funded a study[6] to measure the effect of seasonal influenza vaccination on hospitalization among the elderly. The study analyzed 170 million episodes of medical care and found that "no evidence indicated that vaccination reduced hospitalizations."

In addition, a 2018 Cochrane review[7] of 52 clinical trials assessing the effectiveness of influenza vaccines did not find a significant difference in hospitalizations between vaccinated and unvaccinated adults. Instead, the reviewers found "low-certainty evidence that hospitalization rates and time off work may be comparable between vaccinated and unvaccinated adults."

Furthermore, the Mayo Clinic conducted a case-control study[8] to analyze the effectiveness of the trivalent inactivated influenza vaccine (TIV) in preventing flu hospitalization in children 6 months to 18 years old. The study evaluated the risk of hospitalization in both vaccinated and unvaccinated children over an eight-year period. The authors state: "TIV is not effective in preventing laboratory-confirmed influenza-related hospitalization in children." Instead, "[W]e found a threefold increased risk of hospitalization in subjects who did get the TIV vaccine."

A review of 52 clinical trials assessing the effectiveness of influenza vaccines did not find a significant difference in hospitalizations between vaccinated and unvaccinated adults.[7]

3. THE FLU VACCINE DOESN'T PREVENT THE SPREAD OF THE FLU.

Households are thought to play a major role in community spread of influenza, and there has been a long history of analyzing family households to study the incidence and transmission of respiratory illnesses of all severities. As such, the CDC funded a study[9] of 1,441 participants, both vaccinated and unvaccinated, in 328 households. The study evaluated the flu vaccine's ability to prevent community-acquired influenza (household index cases) and influenza acquired in people with confirmed household exposure to the flu (secondary cases). Transmission risks were determined and characterized.

In conclusion, the authors state: "There was no evidence that vaccination prevented household transmission once influenza was introduced."[9,10]

Furthermore, a systematic review[5] of 50 influenza vaccine studies conducted for the Cochrane Library states: "Influenza vaccines have a modest effect in reducing influenza symptoms and working days lost. There is no evidence that they affect complications, such as pneumonia, or transmission."

Exhibit C

4. THE FLU VACCINE FAILS TO PREVENT THE FLU ABOUT 65% OF THE TIME.

The CDC conducts studies to assess the effects of flu vaccination each flu season to help determine if flu vaccines are working as intended.[11] As circulating flu viruses are constantly changing (primarily due to antigenic drift mutations),[12] flu vaccines are reformulated regularly based on a "best guess" of which viruses might circulate during the coming flu season.[3] The CDC states: "CDC monitors vaccine effectiveness annually through the Influenza Vaccine Effectiveness (VE) Network, a collaboration with participating institutions in five geographic locations… [A]nnual estimates of vaccine effectiveness give a real-world look at how well the vaccine protects against influenza caused by circulating viruses each season."[13]

Data from the CDC's Influenza VE Network indicate a 65% vaccine failure rate between 2014 and 2018 (Fig. 1).[11]

5. REPEAT DOSES OF THE FLU VACCINE MAY INCREASE THE RISK OF FLU VACCINE FAILURE.

Studies have observed that influenza vaccines have low effectiveness in individuals who are vaccinated in two consecutive years.[9] A review of 17 influenza vaccine studies published in *Expert Review of Vaccines* states, "The effects of repeated annual vaccination on individual long-term protection, population immunity, and virus evolution remain largely unknown."[14]

6. DEATH FROM INFLUENZA IS RARE IN CHILDREN.

Before the widespread use of the influenza vaccine in children, between 2000 and 2003, each year kids age 18 and younger had about 1 in 1.26 million or 0.00008% chance of dying from the flu.[15] In a 2004 report, the CDC stated, "Deaths from influenza are uncommon among children with and without high-risk conditions."[16]

7. THE FLU VACCINE DOESN'T REDUCE DEATHS FROM PNEUMONIA AND FLU.

The National Vaccine Program Office, a division of the U.S. Department of Health and Human Services (HHS), funded a study[17] to examine flu mortality over the period of 33 years (1968–2001). The study found no decrease in flu mortality associated with the widespread use of the influenza vaccine. The authors state: "We could not correlate increasing vaccination coverage after 1980 with declining mortality rates in any age group… [W]e conclude that observational studies substantially overestimate vaccination benefit."

Furthermore, the National Institute of Health (NIH) funded a study[6] to measure the effect of seasonal influenza vaccination on mortality among the elderly. The study analyzed 7.6 million deaths and found "a sharp increase in influenza vaccination rates at age 65 years with no matching decrease in hospitalization or mortality rates."

8. PATIENTS DON'T BENEFIT FROM THE VACCINATION OF HEALTHCARE WORKERS.

A review[18] of more than 30 influenza vaccine studies conducted for the Cochrane Library states, "Our review findings have not identified conclusive evidence of benefit of HCW [healthcare workers] vaccination programs on specific outcomes of laboratory-proven influenza, its complications (lower respiratory tract infection, hospitalization or death due to lower respiratory tract illness), or all cause mortality in people over the age of 60." The authors conclude, "This review does not provide reasonable evidence to support the vaccination of healthcare workers to prevent influenza." In addition, "There is little evidence to justify medical care and public health practitioners mandating influenza vaccination for healthcare workers."

9. FLU VACCINE MANDATES ARE NOT SCIENCE-BASED.

A Cochrane Vaccines Field analysis[19] evaluated studies measuring the benefits of flu vaccination. The analysis, published in the *BMJ*, concludes: "The large gap between policy and what the data tell us (when rigorously assembled and evaluated) is surprising… Evidence from systematic reviews shows that inactivated vaccines have little or no effect on the effects measured... Reasons for the current gap between policy and evidence are unclear, but given the huge resources involved, a re-evaluation should be urgently undertaken."

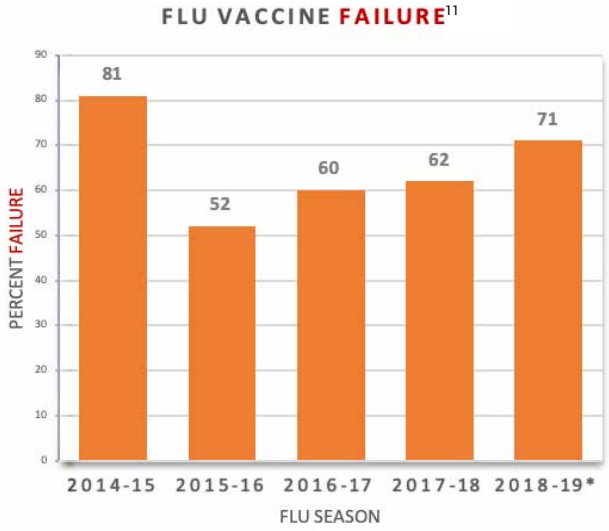


Figure 1: Centers for Disease Control and Prevention (CDC) data from the U.S. Flu VE Network indicate that the flu vaccine has failed to prevent the flu about 65% of the time.

All references are available at: physiciansforinformedconsent.org/flu-vaccine.

These statements are intended for informational purposes only and should not be construed as personal medical advice.

Exhibit C

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*Estimates presented to the Advisory Committee on Immunization Practices on June 27, 2019

Exhibit C

Exhibit D

MEASLES

What Parents Need to Know

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1. WHAT IS MEASLES?

Measles is a self-limiting childhood viral infection.

- Measles symptoms include a prodromal (initial) phase of cough, runny nose, eye irritation and fever, followed by a generalized rash on days 4–10 of the illness.[1]
- Measles is contagious during the prodromal phase and for 3-4 days after rash onset.[1]
- Most measles cases are benign and not reported to public health departments.[2]
- Before the measles mass vaccination program was introduced, nearly everyone contracted measles and obtained lifetime immunity by age 15.[1]
- In rare situations, measles can cause brain damage and death.[3,4]

Centers for Disease Control and Prevention (CDC) publishes measles case-fatality rates based on reported cases. However, nearly 90% of measles cases are benign and not reported to the CDC.[2] Calculating case-fatality rates based on reported cases (that constitute only 10% of all cases) results in a case-fatality rate that is 10 times higher than what it actually is in the general population. Data analysis herein is based on total measles cases (both reported and unreported).

2. WHAT ARE THE RISKS?

In the modern era, it is rare to suffer permanent disability or death from measles in the United States. Between 1900 and 1963, the mortality rate of measles dropped from 13.3 per 100,000 to 0.2 per 100,000 in the population, due to advancements in living conditions, nutrition, and health care—a 98% decline (Fig. 1).[2,5] Malnutrition, especially vitamin A deficiency, is a primary cause of about 90,000 measles deaths annually in underdeveloped nations.[6] In the U.S. and other developed countries, 75–92% of hospitalized measles cases are low in vitamin A.[7,8]

Research studies and national tracking of measles have documented the following:

- 1 in 10,000 or 0.01% of measles cases are fatal.[3]
- 3 to 3.5 in 10,000 or 0.03–0.035% of measles cases result in seizure.[9]
- 1 in 20,000 or 0.005% of measles cases result in measles encephalitis.[4]
- 1 in 80,000 or 0.00125% of cases result in permanent disability from measles encephalitis.[4]
- 7 in 1,000 or 0.7% of cases are hospitalized.[10]
- 6 to 22 in 1,000,000 or 0.0006–0.0022% of cases result in subacute sclerosing panencephalitis (SSPE).[11]

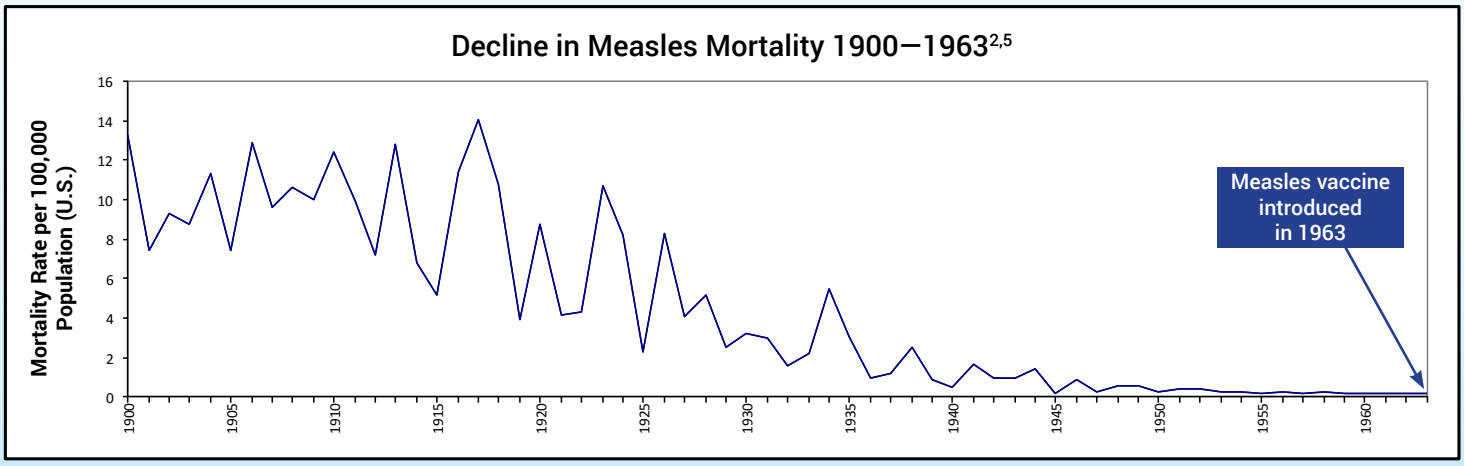

Figure 1: Measles death declined 98% from 1900 to 1963, before the measles vaccine was introduced.

Exhibit D

3. WHAT TREATMENTS ARE AVAILABLE FOR MEASLES?

Since measles resolves on its own in almost all cases, usually only rest and hydration are necessary. When treatment is recommended, options include the following:

- High-dose vitamin A[12]
- Immune globulin (available for immunocompromised patients, such as those on chemotherapy)[13]
- The antiviral medication, ribavirin[14-16]

Vitamin A

The World Health Organization (WHO) recommends that serious measles cases be treated with high-dose vitamin A, 50,000–200,000 IU, orally on two consecutive days.[13]

4. ARE THERE ANY BENEFITS FROM GETTING MEASLES?

There are studies that suggest a link between naturally acquired measles infection and a reduced risk of Hodgkin's and non-Hodgkin's lymphomas, as well as a reduced risk of atopic diseases such as hay fever, eczema and asthma.[17-21] In addition, measles infections are associated with a lower risk of mortality from cardiovascular disease in adulthood.[22] Moreover, infants born to mothers who have had naturally acquired measles are protected from measles via maternal immunity longer than infants born to vaccinated mothers.[23]

5. WHAT ABOUT THE VACCINE FOR MEASLES?

The measles vaccine was introduced in the U.S. in 1963 and is now only available as a component of the measles, mumps, and rubella (MMR) vaccine. It has significantly reduced the number of reported measles cases; however, immunity from the vaccine wanes so that by age 15, about 60% of vaccinated children are susceptible to subclinical infection with measles virus, and by age 24–26, a projected 33% of vaccinated adults are susceptible to clinical infection.[24] The manufacturer's package insert contains information about vaccine ingredients, adverse reactions, and vaccine evaluations. For example, "M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility."[11] Furthermore, the risk of permanent injury and death from the MMR vaccine has not been proven to be less than that of measles (Fig. 2).[25]

Measles Mortality vs. Leading Causes of Death in Children Under Age 10 (per 100,000 Population)[26,27]

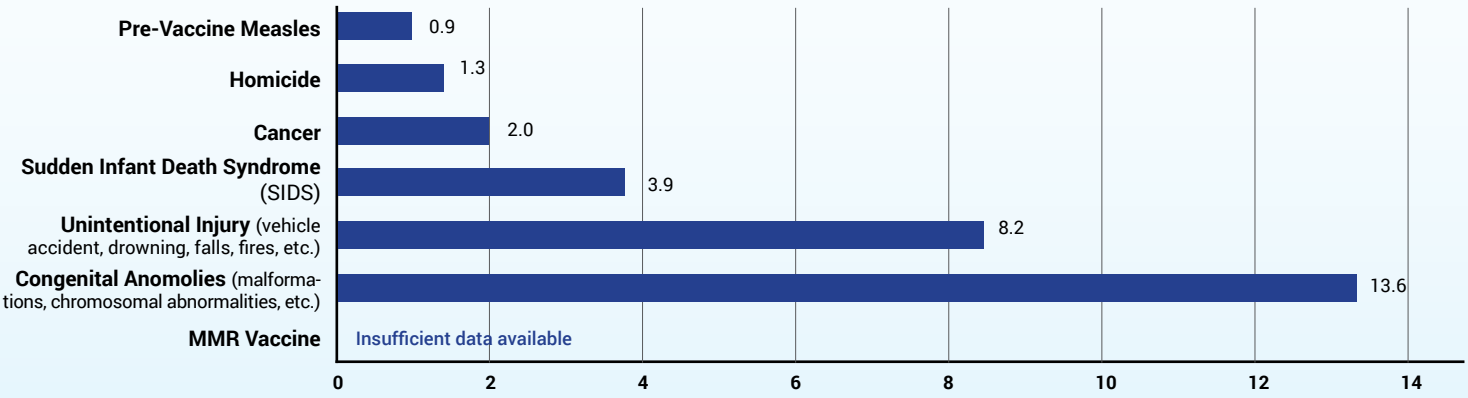

Figure 2: This graph shows the measles death rate before the vaccine was introduced, when measles was a common childhood viral infection, and compares it to the leading causes of death in children under age 10 today. Hence, in the pre-vaccine era, the measles death rate per 100,000 was 0.9 for children under age 10. In 2015, the death rate per 100,000 for homicide was 1.3, followed by cancer (2.0), SIDS (3.9), unintentional injury (8.2), and congenital anomalies (13.6). The rate of death or permanent injury from the MMR vaccine is unknown because the research studies available are not able to measure it with sufficient accuracy.[25]

All references and the Measles Vaccine Risk Statement (VRS) are available at physiciansforinformedconsent.org/measles.

These statements are intended for informational purposes only and should not be construed as personal medical advice.

Exhibit D

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Exhibit D

MMR VACCINE (Measles, Mumps, and Rubella)

Is It Safer Than Measles?

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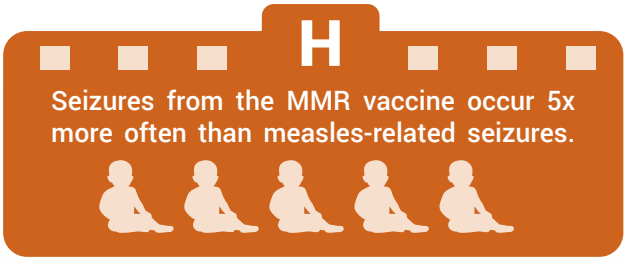
1. WHAT ARE SIDE EFFECTS OF THE MMR VACCINE?

Common side effects of the MMR vaccine include fever, mild rash, and swelling of glands in the cheeks or neck.[1] A more serious side effect is seizure, which occurs in about 1 in 640 children vaccinated with MMR[2]—about five times more often than seizure from measles infection.[3]



The World Health Organization (WHO) states that serious allergic reactions to the vaccine occur in about 1 in 100,000 doses.[4] However, other severe side effects include deafness, long-term seizures, coma, lowered consciousness, permanent brain damage, and death.[1] While the Centers for Disease Control and Prevention (CDC) states that these side effects are rare, the precise numbers are unknown.[1] Additionally, the manufacturer's package insert states, "M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility."[5]

2. HOW ARE RISKS OF VACCINE SIDE EFFECTS MEASURED?

Methods to measure vaccine risks include surveillance systems, clinical studies, and epidemiological studies.

3. HOW ACCURATE IS SURVEILLANCE OF ADVERSE EVENTS FROM THE MMR VACCINE?

The government tracks reported cases of vaccine side effects through the Vaccine Adverse Event Reporting System (VAERS). Approximately 40 cases of death and permanent injury from the MMR vaccine are reported to VAERS annually.[6] However, VAERS is a passive reporting system—authorities do not actively search for cases and do not actively remind doctors and the public to report cases. These limitations can lead to significant underreporting.[7] The CDC states, "VAERS receives reports for only a small fraction of actual adverse events."[8] Indeed, as few as 1% of serious side effects from medical products are reported to passive surveillance systems,[9] and as few as 1.6% of MMR-related seizures are reported to VAERS.[10] In addition, VAERS reports are not proof that a side effect occurred, as the system is not designed to thoroughly investigate all cases.[11] As a result, VAERS does not provide an accurate count of MMR vaccine side effects.

4. HOW ACCURATE ARE CLINICAL TRIALS OF THE MMR VACCINE?

The CDC states, "Prelicensure trials are relatively small—usually limited to a few thousand subjects—and usually last no longer than a few years. Prelicensure trials usually do not have the ability to detect rare adverse events or adverse events with delayed onset."[7] Since measles is fatal in about 1 in 10,000 cases and results in permanent injury in about 1 in 80,000 cases,[3] a few thousand subjects in clinical trials are not enough to prove that the MMR vaccine causes less death and permanent injury than measles (Fig. 1). In addition, the lack of adequate clinical trials of the MMR vaccine resulted in the manufacturer's package insert data to be reliant on passive surveillance for rates of MMR-related neurological adverse reactions, permanent disability, and death.[5]

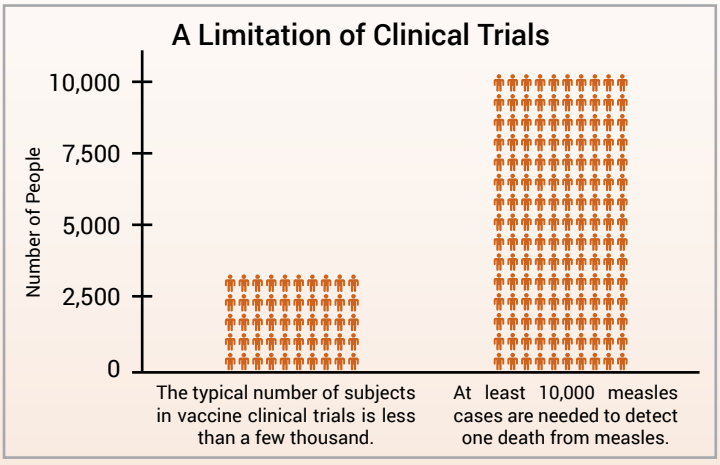


Figure 1: There are not enough subjects in clinical trials to prove that the MMR vaccine poses less risk than measles.

Exhibit D

5. HOW ACCURATE ARE EPIDEMIOLOGICAL STUDIES OF THE MMR VACCINE?

Epidemiological studies are hindered by the effects of chance and possible confounders—additional factors that could conceivably affect the groups being studied. For example, there is a well-known 2002 Danish study published in the *New England Journal of Medicine* involving about 537,000 children that looked for an association between the MMR vaccine and certain adverse events.[12] The raw data in the study was adjusted, in an attempt to account for potential confounders, and the study found no association between the MMR vaccine and the adverse events. However, because there is no evidence that the estimated confounders used to adjust the raw data were actually confounders, the study did not rule out the possibility that the MMR vaccine increases the risk of an adverse event that leads to permanent injury by up to 77%. Consequently, the study did not rule out the possibility that such adverse events might occur up to four times more often than death from measles: 1 in 2,400 compared to 1 in 10,000 (Fig. 2 and Table 1). The range of possibilities found in the study, between the adjusted data and the raw data, makes the result inconclusive; even large epidemiological studies are not accurate enough to prove that the MMR vaccine causes less death or permanent injury than measles.

6. IS THE MMR VACCINE SAFER THAN MEASLES?

It has not been proven that the MMR vaccine is safer than measles. The vaccine package insert raises questions about safety testing for cancer, genetic mutations, and impaired fertility. Although VAERS tracks some adverse events, it is too inaccurate to measure against the risk of measles. Clinical trials do not have the ability to detect less common adverse reactions, and epidemiological studies are limited by the effects of chance and possible confounders. Safety studies of the MMR vaccine are particularly lacking in statistical power. A review of more than 60 MMR vaccine studies conducted for the Cochrane Library states, "The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."[13] Because permanent sequalae (aftereffects) from measles, especially in individuals with normal levels of vitamin A, are so rare,[3] the level of accuracy of the research studies available is insufficient to prove that the vaccine causes less death or permanent injury than measles.

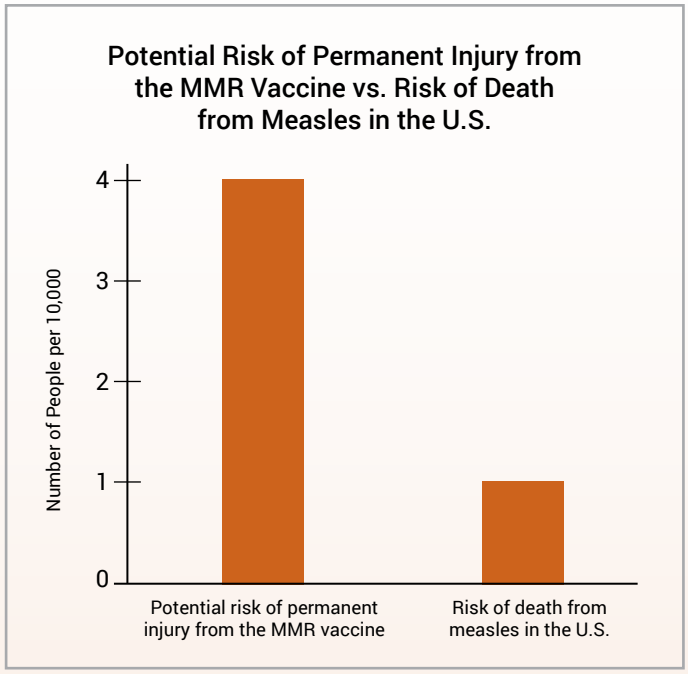


Figure 2: A 2002 Danish study did not rule out the possibility that the MMR vaccine can cause an adverse event leading to permanent injury four times more often than measles can be fatal.

Table 1: Statistical Analysis of an Epidemiological Study with Over Half a Million Children

RR = Relative risk
(risk in group vaccinated with MMR) ÷
(risk in group not vaccinated with MMR)

CI = Confidence interval
(possible range of RR due to effects of chance)

Adjusted RR reported in study
= 0.92 (95% CI, 0.68 to 1.24)

Unaltered RR recorded in study
(263/1,647,504) ÷ (53/482,360)
= 1.45 (95% CI, 1.21 to 1.77)

Potential RR = 1.77
(potential 77% greater risk than unvaccinated group risk)

Unvaccinated group risk recorded in study
= 53 in 97,000

77% of 53 in 97,000
= 1 in 2,400 additional risk in group vaccinated with MMR

All references and the Measles Disease Information Statement (DIS) are available at physiciansforinformedconsent.org/measles.

Exhibit D

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Exhibit D