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Evidence Showing Childhood Vaccinations Are Causing Autism and Other Intellectual Disabilities

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Abstract

The association between vaccines and neurodevelopmental disorders has been referred to by the recently re-elected US President Donald Trump and his new Secretary of Health and Human Services, Robert F Kennedy Jr. The question is re-opened in this issue of the *IJVTPR* challenging the claim by the US Centers for Disease Control and Prevention (CDC) that "vaccines do not cause autism". This paper reviews preclinical, and clinical data, and outlines genetic susceptibilities to toxicants known to be causally associated with intellectual disabilities. Based on the pertinent scientific literature, and my own clinical experience as an MD, the positive association of autism with vaccines is getting more and more difficult to deny. The Bradford Hill criteria, which require temporal connection, significant magnitude of injury, consistency of similar cases across groups, systematic elimination of other possible causes, evidence of dose dependence, and the existence of a plausible theoretical explanation to demonstrate a true causal relationship, are all met. According to the CDC the prevalence of autism was about 1 in 150 children in 2000 and by 2020 it had risen to 1 in 36. Given the alarmingly rapid increase in autism and neurodevelopmental disorders, policymakers, health authorities, and parents should take seriously the message from the independent scientific community about the dangers of vaccines.

Keywords: *adjuvants, autism, Bradford Hill criteria, causality, childhood vaccines, clinical trials, surveillance, unreliable safety data,*

Introduction

The risk assessment for any new medicinal product usually begins with the evaluation of animal and *in vitro* data. Extrapolating from animal data to humans is challenging, but animal models play an important role in helping to predict vaccine potential for harm to the general public as well as the financial risks to drug and vaccine manufacturers (Kiros et al. 2012, Golding et al. 2018). However, according to the Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule (2013), the safety data for the commonly used

childhood vaccinations come almost exclusively from surveillance after the products are already on the market, or from clinical trials involving human beings, and not from animal models, or *in vitro* studies of the components in the products. For example, the first safety check in a Phase I trial for the multivalent diphtheria and tetanus toxoid, acellular pertussis, inactivated poliovirus, and hemophilus influenza type B conjugate adsorbed (DTaP-IPV + Hib) vaccine, has been conducted using South Korean human infants (Kang et al. 2016) and adults in India (Sharma et al. 2023). The Summary of Product Information for this multivalent vaccine claims in section 5.3:

> Non-clinical data reveal no special hazard for humans based on conventional studies (EMA 2020).

Such a statement is typical in the product information sheets and merely reflects what is assumed rather than anything experimentally known. It also repeats what is supposedly believed about all vaccines according to the CDC (2024). Consequently, safety data for pediatric vaccines come mainly from clinical trials and surveillance of human recipients after those products have been approved for distribution to the public. However, neither of these sources of information about vaccines — not the clinical trials and not the after-market surveillance — can be considered reliable for several reasons. Furthermore, a closer look at official mortality statistics and the history of the development of vaccines against feared diseases (e.g., smallpox) draws into question the common mainstream claim that vaccines save "millions of lives every year" and so forth (Oller & Oller 2010, see especially chapter 7; also Shaw 2021; and Robert F. Kennedy, Jr. 2021).

Numerous historical as well as current medical findings from animal and human studies point to a causal connection between childhood vaccinations and developmental disorders, contrary to what medical professionals and clinicians are taught and contrary to what the pharmaceutically controlled mainstream press encourages parents to believe as described in this review.

VACCINE MANUFACTURERS HAVE OBTAINED GOVERNMENT PROTECTION

Ever since 1986 when the US first passed the National Childhood Vaccine Injury Act (NCVIA), the vaccine manufacturers have been protected from lawsuits originating from private individuals (Oller et al. 2010, p. 639). More recently, however, the PREP Act — Public Readiness and Emergency Preparedness Act, authorized in 2020 and amended 12 times by 2024 — has greatly expanded the protection from liability for the manufacturers, promoters, and clinicians administering vaccines. Here is an excerpt from the most recent version of that Act as of the time of this writing:

> The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims:
>
> - of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions
> - determined by the Secretary to constitute a present, or credible risk of a future public health emergency

- to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures

A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations (ASPR 2020-2024).

Children with neurodevelopmental disabilities on the autism spectrum tend to be in the most affected group. In their almost encyclopedic volume about communication disorders first published in 2010, Oller et al. but now on ResearchGate 2025, noted the following on p. 222:

> The CDC estimates that about 50% of the cases diagnosed in 2000 and 2002 were also "cognitively impaired" with significant "Intellectual Disability or Mental Retardation" (retrieved February 27, 2009 at http://www.cdc.gov/ncbddd/autism/documents/AutismCommunityReport.pdf [a document no longer available from the CDC], p. 20). Also, it is worth noting that all of the DSM manuals [*Diagnostic and Statistical Manual of Mental Disorders*, 4th Edition, Text Revision (DSM-IV-TR) from 1980 – when autism was first officially recognized as a category of mental disorders – forward, all of the manuals have indicated that about two-thirds of the cases are severe. The 1994 manual describes the whole autism spectrum (alias the PDDs) as involving "severe and pervasive impairment . . . distinctly deviant relative to the individual's developmental level or mental age" (1994, p. 65). It says that only in "about one-third of cases, some degree of partial independence is possible" (1994, p. 69).

It should also be kept in mind, as Oller and colleagues argue, if the cases of autism are typically severe in more than 50% of the individuals impacted by it, the idea that doctors and parents have just gotten a lot better at detecting cases seems spurious. It is almost impossible not to notice individuals on the autism spectrum who are either nonverbal altogether or who have characteristic marks such as toe-walking, hand-flapping, screeching, and the like, as most severe cases do. Together with the literature on genetic susceptibility, the empirical evidence, I believe, satisfies all the Bradford Hill criteria (Fedak et al., 2015) supporting the growing public awareness that childhood vaccines definitively do increase the risk of autism, intellectual disabilities, and chronic disorders of all sorts (Garner 2021, 2022). According to Garner's statistically well-powered national survey, children who avoided all the post-birth vaccines as well as the Vitamin K shot (loaded with thimerosal in most cases) and also were not impacted by any vaccines urged upon their mothers prior to their birth, also had no cases at all of the autism diagnosis. Hence, the Bradford Hill criterion of absence of the cause (vaccines) being perfectly correlated with absence of the effect of interest (autism) is fulfilled by Garner's research.

"Safety and Efficacy" Have Not Been Demonstrated

Regarding clinical trials, placebo-controlled studies are considered acceptable only in certain situations, such as when developing a locally affordable vaccine (Rid et al. 2014). This means that in most clinical trials, the control group receives another vaccine against the same or a different disease. Such trials are powerless to show anything other than a possible difference in the number of adverse events between the vaccines given to the control group and those given to the treatment group. Such studies only show whether one of the products is more harmful than the other. They cannot show

either product to be safe, and they cannot demonstrate whether the vaccine can prevent any targeted disease. If the compared products are about equally harmful, the CDC reports, nonetheless, that both are "safe". If both are merely assumed to be about equally effective or ineffective, the CDC reports that both are "effective".

At best one of the products, the newer treatment vaccine, or the control product being regarded as a "placebo" (possibly containing adjuvants, preservatives, and/or other toxic excipients), may actually turn out to be less harmful than the other, but the comparison is typically set up to systematically avoid contrasting any vaccine against a genuine harmless placebo such as a plain appropriate saline solution. Only a comparison with an appropriate saline control would provide a reliable assessment of the safety of a vaccine, or of its distinct components, but such studies are considered ethically problematic. According to the CDC and manufacturers of vaccines, all of them are "safe and effective", "have saved millions of lives", and "prevented needless suffering", and, therefore, no human beings should ever be deprived, even temporarily, of these benefits (Rid et al. 2014, Greenwood 2014).

In cases where something close to a genuine placebo is used in clinical trials with human recipients, the "placebo", in most instances is not a biologically neutral pure saline solution. Rather it is a reactogenic aluminum-containing product as noted by the Informed Consent Action Network (ICAN 2023) with respect to pediatric vaccines licensed by the US Food and Drug Administration (FDA), and as Tomljenovic and McHenry (2024) have shown to be the case with the pre-licensing clinical trials of the Gardasil HPV vaccine. Comparative studies with a true saline control are entirely missing from the records. The comparison of two reactogenic agents, however, such as an adjuvant-containing "placebo" and an active vaccine, has no scientific validity as a study of "safety" of any particular vaccine under investigation. An adjuvant-containing "placebo" can be as toxic and as harmful, or nearly as harmful, as the vaccine, as shown in a study in which sheep were inoculated with the vaccine, an aluminum control, or a saline solution (Asín et al. 2020). Both of the non-placebo groups showed dramatic evidence of harm in contrast with the sheep that only received injections containing phosphate-buffered saline solution. Their findings are not surprising if we take into consideration what Asín and colleagues (2018) already knew about aluminum toxicity in sheep and about aluminum toxicity in general (Shaw & Tomljenovic 2013; Martinez, Escobar, et al. 2017; Martinez, Piagette, et al. 2017; Davidson & Winey, 2021), and, especially, in humans (Igbokwe et al. 2019).

Additionally, the correspondence with health authorities (Anonymous, 2023) has revealed that the Bradford Hill criteria, which are traditionally used to ferret out true causal relationships between medical treatments, toxic exposures, injuries, and the like (regardless whether the outcomes are judged to be favorable or adverse) are less frequently brought to bear, it seems, than they used to be (Fedak et al. 2015). With respect to adverse events associated with vaccines, the most worrying outcome of the abandonment, or at least diminishing application of the Bradford Hill criteria, is that there remains no clear limit on the number of reported serious adverse reactions, vaccine injuries, even deaths, that will lead to the withdrawal of the marketing authorization for what is known to be an injurious and even lethal product. In practice, this means that, despite the number of serious adverse events (including deaths) that may be associated with a vaccine — consider the recent experience with the COVID-19 products (Dowd et al. 2024; Robert F. Kennedy, Jr. 2024;

Mead, Seneff, Rose, et al. 2024; Mead, Seneff, Wolfinger, et al. 2024) — the health authorities seem to promote the idea that all marketed vaccines remain both "safe and effective" just as long as the remarkably lax and inefficient pharmacovigilance practices now in place, ones that protect vaccine manufacturers far more than consumers (Oller et al. 2010; Shaw 2021; Pelech & Shaw 2024), continue to be followed.

Preclinical Safety of Vaccines Is Largely Based on Studies of Adjuvants

None of the vaccines currently used have undergone the standard preclinical animal and other studies of genotoxicity, fertility, mutagenicity, teratogenicity, and carcinogenicity (Kiros et al. 2012, Golding et al. 2018, Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule 2013, EMA 2020) that are required of other pharmaceutical products in general. The appallingly inadequate supervision of the manufacture of vaccines in general has come to the attention of the general public during the COVID-19 crisis (Gutschi 2022; Speicher, Rose, & Gutschi 2023), which still appears not to be completely gone. Instead, the preclinical safety data tend to refer to "conventional" studies (Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule 2013) which presume and proclaim the "safety and efficacy" of the vaccines, the adjuvants added to them, and multivalent combinations of them without ever conducting the necessary trials comparing the toxic products not against each other but against a genuine placebo consisting of a pure saline solution.

It is claimed without adequate testing that the doses of adjuvants used in vaccines are too diluted to cause any harm at the supposedly minuscule dose levels in the vaccines (Geier & Geier 2004). That claim is presumed true in spite of evidence that the toxicants in the vaccines, for instance, the adjuvants consisting of aluminum salts are known to be harmful to humans (Facciolà et al. 2022). More importantly, the studies relied on by the CDC and FDA to license and promote the vaccines, do not compare multivalent vaccines and multiple combinations of them against any genuine placebo administration (Jablonowski & Hooker 2024).

Due to the lack of adequate preclinical studies, ones that are sufficiently powered as Lyons-Weiler (2025) argues in this issue of the *IJVTPR*, this review focuses on what is known about two of the best-known and highly controversial vaccine toxicants. Specifically, I focus attention on the mercury-based preservative known as thimerosal in the US, and as thiomersal in the UK, and as known by both terms throughout the world. Also, I look at the aluminum salts used as adjuvants (helpers to jump-start the human immune defenses) that are also placed in many of the vaccines. As Haley (2005) showed years ago, a negligible dose of either of those toxicants — either thimerosal or an aluminum adjuvant — might not cause a noticeable adverse reaction whereas the interacting combination of the two can act synergistically killing more than 60% of the neuronal cells exposed *in vitro* over a 25 hour time frame.

Both thimerosal, the preservative, and the aluminum compounds used as adjuvants, such as aluminum hydroxide, are still common ingredients in vaccines. All of them stimulate the body's defenses to up to something comparable to a high-level military alert — they almost immediately cause the mobilization of the body's defences on account of what is medically describable as an attack by a foreign agency. From the viewpoint of vaccine manufacturers, getting that sort of reaction from the body of the vaccine recipient, is desirable because, according to them, such a

reaction means more resources in the recipient will be activated and devoted to the production of antibodies against whatever disease agents are targeted in the vaccine.

Thimerosal is a mercury-based anti-microbial preservative. Despite concerns raised in epidemiological studies (Geier & Geier 2004; Hurley et al. 2010; Geier et al. 2014) and in other empirical contexts (Bernard et al. 2002; Holmes et al. 2003; Geier & Geier 2007; Kern et al. 2013; Sharpe et al. 2013; Robert F. Kennedy, Jr. 2014) — many of them suggesting that thimerosal is causally linked to autism — health authorities have not deemed it necessary to ban thimerosal from all vaccines (Gołoś & Lutyńska 2015). For instance, thimerosal is still used in multidose vials of flu vaccine even though those vaccines are recommended for use with pregnant women (concerning which see the research findings of Garner 2021, 2022 revealing harmful effects of that practice) and mercury is definitely known to cross the placental barrier to impact unborn children during an exceedingly vulnerable period of their development (Yang et al. 1997; Kozikowska et al. 2013; Findik et al. 2016).

Failed Searches Do Not Carry the Same Weight as Successful Ones

Although the mainstream medical journals continue to promote the idea that failed searches for causal relations are just as informative as successful ones — often arguing that failed searches merit consideration and publication about equally alongside successful searches — mathematical measurement theory and reflective thought show that such claims by medical editors are false. Finding something you are searching for puts an end to any claims to the effect that what is sought does not even exist. Failing to find something searched for proves very little. Once gold was discovered in California, no one would be apt to pay attention to claims that many attempts to find gold out there had failed. Once the sound barrier was broken by the first test pilot, the theory that it could not be broken was abandoned. Proving a null hypothesis, such as the claim by the CDC that "vaccines don't cause autism", no matter how many failed searches are carried out by the CDC, is an argument worthy only of ridicule.

Just one replicable study showing that some vaccine, vaccine combination, or some component in vaccines, or combination of components in vaccines, have caused autism is sufficient to overturn all prior studies claiming to prove the null hypothesis that vaccines cannot and do not cause autism. Proponents of vaccines may argue that they never cause neurological diseases and disorders, but the nation-wide survey conducted by Joy Garner and also her paper published in this journal (2021, 2022) together show that all those claims are patently false. To claim that many researchers have looked and looked and have not found a causal relation, therefore none exists, is preposterous from a logico-mathematical perspective. Importantly, it should also be kept in mind that any prophylactic vaccine given to healthy people should not pose serious health risks; whenever in doubt, toxicologists use certain factors obtained from "no-observed-effect level" or "no-observed-adverse-effect-level" animal and *in vitro* studies to calculate what is the safe dose-level of any chemical they might administer to humans (National Research Council (US) Committee on Risk Assessment of Hazardous Air Pollutants 1994).

Mathematical reasoning can prove certain general propositions, both positive ones and negative ones, but failed empirical searches cannot possibly justify the universal acceptance of any perfectly general (universal) proposition. Empirical studies can rule out general claims just as Garner's study shows that Offit's claim that "vaccines do not cause autism" is false, but Paul Offit could cite ten

thousand failed searches for the relationship he claims can never be found because it does not exist, and his argument would still be ridiculous and would be overturned by Garner's one study. All his failed searches, moreover, no matter how numerous they might become would be refuted by a single successful search. That being said, studies claiming to have found no association between vaccines and autism such as those by Hviid et al. (2003), and by Parker et al. (2004) are comparable to claims prior to 1995 that the Bose-Einstein condensation would never be produced experimentally, or that the Bell test for the theory of quantum entanglement would never be carried out, but such claims are false. As noted by Hooker et al. (2014) empirical studies claiming to support, much less to prove, the null hypothesis as boldly claimed by Paul Offit, and as endorsed by the CDC, are methodologically biased and hopelessly under-powered to show what they claim to demonstrate (also see the paper by Lyons-Weiler in this issue of the *IJVTPR*).

Perhaps to try to appear reasonable, when in fact much of their work is not reasonable, due to the potential increased risk of autism associated with thimerosal exposure, authorities have suggested either using the smallest possible dose, or replacing thimerosal with an aluminum salt (Clements et al. 2001; van't Vee 2001; WHO 2004; Mahboubi et al. 2012). Unfortunately, after thimerosal was supposedly replaced in 1997, 2000, and 2001, depending on the authority consulted according to investigative reporting by Sharyl Attkisson (2025), with an aluminum adjuvant in many vaccines, the risk of autism and neurodevelopmental disorders nonetheless continued to increase (Tomljenovic & Shaw 2011, Mold et al 2018, Exley & Clarkson 2020, Boretti 2021). Attkisson claims that the government just lied:

> Thimerosal was not removed from all vaccines, or "all vaccines given to children", at any point since 1997, 1999, 2001, or any other date that health authorities commonly claim (Attkisson 2025).

The notion that thimerosal was causing autism, but that aluminum salts would not do so, was a theory never actually tested. Given that thimerosal was not removed from the vaccines, it is apparently the case that those vaccines, and their components in combination, whatever they may actually be, are causally related to the observed continuing increase in autism diagnoses during the years when the authorities were lying about removing thimerosal.

Mercury in General and Thimerosal (ethylmercury) in Particular

Mercury (Hg) is an inorganic metal well known for its hazardous consequences to human health. It is especially damaging to the kidneys and the central nervous system. Mercury in any form does not do the environment any good either as it tends to accumulate, especially from dental laboratories, in rivers, lakes, and the oceans of the world (Wu et al. 2024). As a toxic and highly active chemical, mercury interacts with a range of substances resulting in the formation of different organic mercury compounds including methylmercury and ethyl mercury (Wu et al. 2024). Thimerosal (or thiomerosal), the trade names for the organomercurial compound (sodium ethyl-mercury Hg-thiosalisylate) containing 49.55% Hg by weight (Geier et al. 2014) is the preservative in many vaccines that has been suspected of causing neurological disorders for more than two decades. It breaks down to ethylmercury and thiosalicylate in the body (Barret 2005, Wu et al. 2024). Based on its pharmacokinetics, organic mercury has been considered to be more toxic than inorganic mercury, supposedly having low bioavailability via the oral route of introduction to the body. However, mercury can accumulate in the central nervous system and other tissues (Wu et al 2024), so it is not without the power to do harm.

The presumed safety of thimerosal has been based on the assumption that ethyl mercury (the thimerosal metabolite) has a similar toxicokinetic profile to methylmercury, but careful animal studies comparing the two toxicants, for instance, by Barret (2005), and by Dorea et al. (2013) plainly refute that argument. With two groups of newborn monkeys, one exposed to thimerosal and one to methylmercury, Barret (2005) found that even though total mercury concentrations were lower in the thimerosal group than in the methylmercury group, the proportion of inorganic mercury in the brain was much higher in the thimerosal group (21-86%) compared to the methylmercury group (6-10%). This means that findings from studies of methylmercury cannot be generalized to predict what will happen with thimerosal exposure. Additionally, inorganic mercury in the thimerosal group was found to persist in the brain much longer than organic mercury did in the methylmercury group. Thimerosal had an estimated half-life in the brains of recipients of more than six months. These findings tend to demolish the claims that because methylmercury tends to be excreted and not to cross the blood brain barrier, the same cannot be supposed for the thimerosal in vaccines.

There is direct evidence from a mouse study suggesting that thimerosal has adverse effects on newborns (Li et al. 2014). This study showed that high doses of thimerosal, 20 times higher than those in newborn humans up to 4 months of age, can cause long-lasting dysregulation including neurodevelopmental disorders, synaptic dysfunctions, and endocrine dysfunctions, all of which are potential explanatory descriptions of autistic behaviors observed in thimerosal exposed mice. In a critical review summarizing clinical, epidemiological, and biochemical studies on thimerosal toxicity, Geier and colleagues (2015) concluded that thimerosal exposure is associated with a host of adverse outcomes, including fetal and infant deaths, congenital malformations, and developmental disorders, even at the doses currently administered in vaccines. It is also important to keep in mind that the cumulative impact of the toxins in vaccines can only increase as the number of injections demanded by the CDC and health regulators continues to increase.

In spite of all this scientific evidence the CDC still claims on today's date (March 26, 2025), at the CDC's website concerning thimerosal at this URL: https://www.cdc.gov/vaccine-safety/about/thimerosal.html:

> Thimerosal use in medical products has a record of being very safe. Data from many studies show no evidence of harm caused by the low doses of thimerosal in vaccines.

Then, on the same date, clicking on the link labeled "Autism and Vaccines" at this URL: https://www.cdc.gov/vaccine-safety/about/autism.html we find the following statement claiming a null hypothesis:

> . . . vaccines do not cause ASD [autism spectrum disorders] . . .

A little farther down the same site claims:

> Research shows that thimerosal does not cause ASD.

After an advisory note at the same website for the CDC on the same date that tells readers to "keep reading" we find the following statement:

> Additional studies and a more recent rigorous review by the Institute of Medicine have found that MMR vaccine does not increase the risk of autism.

Then, after yet another recommendation for the reader to keep going, the CDC offers the assurance that the CDC together with the Food and Drug Administration (FDA), are monitoring vaccine safety, so the public can rest assured, as claimed at this URL: https://www.cdc.gov/vaccine-safety-systems/about/cdc-monitoring-program.html

> CDC and FDA monitor vaccine safety using different systems that work together . . .

Aluminum

Shoenfeld and Agmon-Levin have described in 2011 autoimmune/inflammatory syndrome induced by adjuvants (ASIA), known also as "Shoenfeld syndrome". It consists of a group of immune-mediated disorders following exposure to adjuvant agents such as those containing aluminium. The ASIA syndrome manifests itself in various medical conditions: vaccination-induced autoimmune disorders, siliconosis, Gulf War Syndrome, macrophagic myofascitis with chronic fatigue syndrome, sick-building syndrome (Caldarelli et al. 2024) and possibly also small fiber neuropathy related to the development of dysautonomia (Tervaert et al. 2023).

The role of aluminum adjuvants in vaccines has been vigorously debated (Tomljenovic & Shaw 2011, 2012; Principi & Esposito 2018; Crépeaux et al. 2020; Goullé & Grangeot-Keros 2020). Researchers have called for independent, rigorous and honest science to resolve questions related to, among other things, the toxicokinetics of different forms of aluminum (Crépeaux et al. 2020). This controversy is complicated by the apparent lack of appropriate preclinical toxicity studies (Tomljenovic & Shaw 2012). Opponents have dismissed realistic concerns about vaccine injuries as "myths" and "misinformation", reminding their readers that the World Health Organization (WHO) named "vaccine hesitancy" as one of the top ten global health challenges in 2019 (Geoghegan et al. 2020). However, a few recently published animal studies suggest that aluminum adjuvants and aluminum from other sources constitute a clear health risk to humans. Intraperitoneal administration of aluminum-based adjuvants to mice has been shown to cause dose-dependent systemic adverse effects including hypothermic reactions, apathy, stooped posture, and infiltration of neutrophil and eosinophil granulocytes into the peritoneal cavity (Freiberger et al. 2018). Sheep inoculated repeatedly with an aluminum-containing adjuvant vaccine or aluminum were found to have different cognitive and social behavior compared to sheep vaccinated with saline; aggressive interactions, stereotypies, excitability, and compulsive eating increased in comparison to the saline-exposed group (Asín et al. 2020).

There is also direct evidence from humans on the possible role of aluminum in autism and other neurodegenerative diseases. Mold and coworkers (2018) have measured aluminum from brain tissues of five donors with autism. They found that aluminum levels in each lobe (i.e., occipital, frontal, temporal, and parietal) of all five individuals (aged 15–50) at a mean of 2.3–3.82 μg/g dry weight of tissue which is the highest value for aluminum in the human brain ever found up to the date of their study. The clinical relevance of this finding has been supported by a study in which the aluminum content of 191 brain tissue samples from 20 donors without neurodegenerative diseases was consistently low, with more than 80% of the tissues having aluminum content below 1.0 μg/g tissue dry weight (Exley & Clarkson 2020). High aluminum concentrations have also been measured in

brain tissues of donors with familial Alzheimer's disease and multiple sclerosis, with measured aluminum concentrations exceeding 10 μg/g dry weight of tissue in both diseases (Mirza et al. 2017, Mold et al. 2018).

Safety Surveillance Ignoring Bradford Hill's Criteria Misses Health Risks

In the decade from 2000 up to 2010, when the author was personally involved in assessing the causality of voluntarily reported adverse reactions at the Finnish Medicines Agency (now Fimea), the Bradford Hill criteria were applied. A causal relationship was considered confirmed if: 1) there was a temporal association between the adverse symptom and vaccination, 2) a reasonable biological explanation for the appearance of the symptom was known, 3) there was evidence that the vaccine had caused similar symptoms earlier, and 4) if no other plausible explanation could be found for the observed symptom (Anonymous 2023). The more serious the suspected adverse reaction, the more important it was to examine the relevant literature to see if there was any plausible biological explanation for the reported event. More recently, however, the criteria for assessing the causal basis of observed symptoms have been modified (Gallagher et al. 2011). Nowadays, verification of a biological explanation is no longer considered as important in the assessment of causality. This was made clear by the European Medicines Agency (EMA) they were asked about suspected causal factors for any give safety signal:

> When a safety signal requires further investigation, EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), gets involved to carry out a full assessment; new data may be brought to bear, and other bodies may be consulted. These data include clinical trial results, epidemiological studies monitoring the safety of the vaccine, toxicological investigations, and any other relevant information. Plausible biological mechanisms are also considered. However, please note that an investigation into such mechanisms is not a requirement to establish potential causality and consider further regulatory action, such as an update of the medicine's product information, or any other action to minimize or manage the risks (Anonymous 2023).

Lessons from the Tobacco industry

An important lesson has been learned from the tobacco industry. The association between smoking, lung cancer, and multiple other disease conditions was evident from epidemiological studies long before it was taken seriously by regulatory agencies (Weston et al. 2003) and it provides a good example showing how investigating the molecular damage directly attributable to smoking could induce lung cancer. The resolution of the long-standing denial and obfuscation by the tobacco industry of the causal relationship between smoking and disease outcomes in smokers is instructive. The vested interests defended cigarette smoking for decades before the government agencies ended up confirming the causal association of tobacco use, particularly of cigarette smoking, and a multitude of diseases including lung cancer, gastrointestinal diseases, and so forth. Among the dramatic empirical demonstrations that cigarette smoking is causally associated with lung cancer and other disease conditions in smokers is the systematic evidence of the numerous beneficial health effects that occur when people quit smoking Sanchez at al. 2024).

Nowadays, health authorities assure healthcare professionals and the public that vaccines are "safe and effective" thanks to their "careful safety monitoring systems" that reveal and respond appropriately to what they call "potential safety signals". In the cases of serious adverse events

following, for example, the COVID-19 injections — events including many cases of fatal myocarditis, neurological consequences, hematological problems, autoimmune disorders, reactivated cancers, and miscarriages and birth defects — all of them tended to be brushed aside with the claim the such events are "very rare", that the benefits of the vaccine outweigh the risks, and the government agencies are continuing "active monitoring" and "transparent" follow-ups (Yaamika et al. 2023). However, studies of reported adverse events regarded as "potential safety signals" (Teófilo et al. 2023) are not followed up with appropriate further investigation applying the Bradford Hill criteria for the assessment of causation and many serious adverse reactions are either dismissed as "rare", or may remain altogether undiscovered (Bellavite et al. 2024).

The unhappy outcome for the general public is that there is no reliable safety data for vaccines (Garner 2021). The frequency of adverse events cannot be determined from spontaneous voluntary reports, which may not even be applied in post-marketing surveillance, and which cannot exist prior to clinical trials. Voluntary post-marketing reports have been estimated to reveal only 5%–10% of all adverse reactions (Desai 2022), or even less in the empirical studies by Lazarus et al. completed in 2010 concluding that "fewer than 1% of vaccine adverse events are reported".

This means that well over 90% of the actually occurring adverse reactions are unreported, and the few that are reported are *not routinely assessed applying the Bradford Hill criteria to try to determine what is actually causing them*. Furthermore, as I have already noted, clinical trials of vaccines are not conducted comparing the active ingredients in the vaccine against a true placebo such as an appropriate saline solution in a control group. Also, as Lyons-Weiler argues in this issue of the *IJVTPR*, studies cited and relied upon by the CDC and the FDA, claiming that there is no causal association between vaccines and childhood neurological disorders, are typically under-powered statistically. In other words, they could not detect a causal relation even if they were effectively sitting on top of it. As a result, such under-powered and inappropriately designed studies, ones aiming to prove a null hypothesis, are of no value in safety assessments except possibly to mislead the public into accepting the often-repeated claims that vaccines are "safe and effective" and that any "adverse reactions" are actually "very rare". Recently introduced COVID-19 vaccine trials have included an inert placebo group, but the follow-up period has been too short for any realistic safety evaluation (WHO Ad Hoc Expert Group on the Next Steps for COVID-19 Vaccine Evaluation 2021).

Published clinical data on the suspected link between vaccines and autism are conflicting; there are studies supporting a positive association (Delong 2011; Gallagher & Goodman 2010; Mawson et al. 2017; Hooker & Miller 2020; Mawson & Jacob 2025) and the opposite (Taylor et al. 2014; Uno et al. 2015; Mohammed et al. 2022). Some have argued that the association of vaccines with autism is just an imaginary invention of misguided people:

> Myths that vaccines or mercury are associated with autism have been amplified by misguided scientists; frustrated, but effective parent groups, and politicians (Davidson 2017).

Studies claiming a negative outcome for any causal link of vaccines to autism, in other words, a failed search, have been criticized for biased, inappropriate and statistically underpowered designs (Hooker et al. 2014; Turville & Golden 2015; Lyons-Weiler et al. 2021). Hooker and coworkers (2014) found numerous methodological issues and even evidence of malfeasance in six studies

purporting to show that thimerosal in vaccines is safe. Taylor's (2014) meta-analysis has been criticized because it compares autism incidence only between different groups of children who received different (but about equally harmful) vaccines, and not between vaccinated children and fully unvaccinated children (Turville & Golden 2015). Such weaknesses appear in the case-control study by Uno and colleagues (2015) and the systemic review by Mohammed and colleagues (2022) each of which used failed searches for a link between vaccines and autism to claim having justified acceptance of the null hypothesis that no such link exists. For instance, Mohammed et al. concluded:

> According to our review, there is no link between the development of ASD and immunization (2022, in their Conclusions).

Similarly, Uno et al. concluded:

> No convincing evidence was found in this study that MMR vaccination and increasing thimerosal dose were associated with an increased risk of ASD onset (2015, in their Abstract).

It is exceedingly difficult, in fact, it is virtually impossible according to Garner's research (2021, 2022) given the nearly complete global vaccination coverage (GBD 2025), to find completely unvaccinated children in order to have a sufficiently powered control group for the kind of comparison that is needed. It is also noteworthy that a reanalysis of CDC data on autism incidence and time of first MMR vaccination did show a significantly increased risk of earlier vaccination among African American males in individuals who had no prior intellectual disability (Hooker 2018). Accordingly, Lyons-Weiler, Fujito, and Pajer (2021) criticized the 2018 study titled "Prenatal tetanus, diphtheria, acellular pertussis vaccination and autism spectrum disorder" by Becerra-Culqui, et al. because they made arbitrary data adjustments that excluded genetically susceptible individuals and they ignored important prenatal infections, prior medical injuries, and other confounding factors.

Clinical data linking autism to childhood vaccinations may be controversial in the eyes of people with huge financial vested interests in the vaccine manufacturing and marketing industry, but epidemiological studies, clinical experience and adverse events suggest a clear dose-dependent association between the number of injections, their temporal proximity to each other, and the number of toxicants and targeted disease agents to which recipients were exposed. Using regression analysis and controlling for family income and ethnicity, Delong (2011) found that the higher the proportion of children who received recommended vaccinations by the age of two, the higher the rate of autism, speech or language impairment in each US state between 2001 and 2007. Similarly, Mawson and Jacob (2025) found that children who had had only one vaccination visit were 1.7 times more likely to be diagnosed with autism than unvaccinated children. Moreover, when the unvaccinated were compared to children who had at least 11 "well-baby" (vaccine) visits with their pediatrician or doctor, the children keeping up with all those visits to the doctor's office were 4.4 times more likely to be diagnosed with autism. Also, based on the parental recall of prior visits to the doctor's office, the early development of most of the children who had at least 11 "well-baby" visits was normal until sometime between the ages of one and three. That's when the symptoms preceding the diagnosis of autism, or some other developmental disorder, began to appear along with the increasing number of vaccinations. My own clinical observations are consistent with the

findings reported in the recently published review by Jablonowski and Hooker (2024). In their study of a total of

> 1,542,076 vaccine combinations administered to infants (less than 1 year of age at time of vaccination) between July 1st, 1991 and May 31st, 2011 . . . . [it was found that combining a] greater number of vaccines yields an exponentially greater number of disease diagnoses [and] that adverse events increase with exposure to increased combinations of infant vaccines (pp. 1103, 1110).

Genetic Susceptibilities May Help Explain Autism Spectrum Disorders

According to the 2025, 5th edition of the *Diagnostic and Statistical Manual*, produced and maintained by the American Psychiatric Association, autism spectrum disorder, or just plain autism, is a "neurodevelopmental disorder" somewhat vaguely and loosely "characterized by repetitive, restricted, and inflexible patterns of behavior, interests, and activities, as well as difficulties in social interaction and social communication". Among practitioners like myself, it is regarded as a heterogeneous collection of symptoms which occur in varying degrees of severity (Oller & Rascón, 1999; Global Burden of Disease Study 2021, Havdahl et al. 2021). The etiology is believed to involve injuries from environmental factors, such as toxins and electromagnetic forces (Perkel 2017; Jagetia 2022; Deruelle 2023), all of which may interact synergistically (see research by Haley 2005), and may be impacted by inherited as well as *de novo* genetic variants (Rossignol et al. 2014; Carter & Blizard 2016; Rylaarsdam & Guemez-Gamboa 2019), such as are being produced by gene editing therapies leading up to the mRNA technologies deployed in response to COVID-19 which seem to be further modifying the human genome (Zhang et al. 2021; Domazet-Lošo 2022; Aldén et al. 2022). Fragile-X (and its genetically modified mouse model) has been considered a genetic variant of autism (Dölen & Bear 2009), but rather than causing autism, genetic syndromes such as Fragile-X, and Down Syndrome, are believed only to increase the risk of a comorbid diagnosis (Kaufmann at el. 2017, Spinazzi et al. 2023). On the other hand, although hundreds of risk genes have been linked to autism, they are thought by some researchers to account for only 10-20% of the extant cases (Rylaarsdam Guemez-Gamboa 2019; Havdahl et al. 2021). Furthermore, we know from clinical experience that certain genetic variants associated with developmental disorders in general, and autism in particular, being as it is a somewhat vague diagnostic category based on symptoms, have highly variable phenotypes (Lötjönen et al. 2025).

A plausible theoretical explanation for strong and long-standing doubts about a true causal link between childhood vaccines and autism comes from studies of genetic risk variants and impaired detoxification pathways. As early as 2007, it was suggested that genetic polymorphism in individuals with the autism diagnosis, or on the autism spectrum, could adversely impact sulfur metabolism, methylation, detoxification, dopamine signaling, and the formation of neuronal networks (Deth et al. 2008). Later studies seemed to confirm the "redox/methylation hypothesis of autism" in which oxidative stress, initiated by environmental factors in genetically vulnerable individuals, leads to impaired methylation leading to neurological deficits caused by reduction in the capacity for synchronizing neural networks (Rossignol et al. 2014, Carter & Blizard 2016, Rodriguez-Gomez et al. 2021). It is worth noting that environmental pollutants (Lewis 2020), especially glyphosate, a broad-spectrum herbicide (Seneff et al. 2024), are likely culprits in increasing the risks associated with childhood vaccinations. However, given that the oral bioavailability of e.g., aluminum is less

than 1% compared to the approximately 100% bioavailability of intravenously or intramuscularly injected aluminum (Yokel & McNamara 2001), exposure to aluminum compounds in vaccines is probably much more apt to be causing disorders than exposure to aluminum in food or other environmental sources.

Conclusions

The debate about vaccines causing autism has been clouded by powerful the financial interests of stakeholders in vaccine manufacturing and marketing. Nevertheless, a causal relationship between vaccines and the autism diagnosis is confirmed by the following facts, which incidentally, fulfill all the Bradford Hill criteria confirming the inference that such a causal relation actually exists:

(1) Based on numerous preclinical, animal and clinical studies, vaccine components such as the preservative thimerosal and the aluminum compounds used as adjuvants in vaccines are known toxicants damaging cells, particularly neurons, in animals and humans, but they are especially hazardous to newborns and in the early years of child growth and development.
(2) There are no well-designed, statistically sufficiently powered studies to justify the "safe and effective" claims of vaccine manufacturers and their promoters at the CDC and FDA; specifically, controlled clinical trials using biologically neutral saline as a control have never been conducted, and surveillance based on voluntary post-market reporting of adverse events attributable to vaccines and their components is inadequate with fewer than 10% of actually occurring adverse reactions ever being reported.
(3) Health authorities are not testing valid indicators of harm, which are downplayed as "safety signals" — when they are actually indicators of severe harm to some percentage of recipients and of lesser harm to all recipients — by applying the Bradford Hill criteria to assess causality, and the agencies supposedly protecting the general public are not imposing reasonable limits on the number of serious adverse events that will be allowed before the watch-dog agencies suspend the marketing authorization of the offending product.
(4) Epidemiological studies concluding there is no causal relationship between vaccines and chronic disease conditions such as autism, are (a) logically mistaken, (b) experimentally flawed, and (c) are plagued by a dearth of unvaccinated individuals with which the needed comparisons might be made: (a) there is no way that any number of experimentally failed searches can prove that there is no causal relation between vaccines and autism; (b) many of the designs used in preclinical studies have completely avoided the necessary comparison of recipients of a vaccine challenge with controls who received a harmless saline placebo, and other studies have been statistically underpowered to such a degree as to be insensitive to any causal relation even if one was present and could be easily detected by a better designed study.
(5) The global increase in vaccinations not only correlates with the increase in autism and intellectual disabilities in vaccinated individuals, but it does so in a dose dependent manner such that symptoms increase with increasing exposures to vaccinations.
(6) Most children who develop autism between the ages of 1 and 3 were healthy at birth and thus fulfill the Bradford Hill criterion of temporal proximity.
(7) Genetic susceptibility because of an impaired detoxification pathway provides a plausible theoretical explanation for the causal relationship. In summary, therefore, in light of the

relevant scientific literature, the Bradford Hill criteria are met, suggesting that vaccines do play a significant causal role in producing autism and intellectual disabilities.

Finally, given the significant burden this patient group poses to their families and to society at large, it seems that specialized medical care units should be established to address the numerous challenges faced by patients on the autism spectrum, by their families and by medical professionals trying to help them (Bjelogrlic-Laakso et al. 2014).

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