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Thimerosal and Neurodevelopment Disorders

The paper by Geier and Geier¹ is technically flawed. The most significant reasons are 1) failure to cite studies that find no relationship between thimerosal-containing vaccines and autistic spectrum disorder²⁻⁴; 2) failure to examine the Vaccine Adverse Event Reporting System (VAERS) database from 1990 onward, although these data are available; and 3) failure to provide a basis for the choice of children's age ranges examined in VAERS, accompanied by arbitrary choices of lag time to and dates of diagnosis.

The authors included "speech dis" [order] as a joint search term in VAERS among children aged ≤ 5 years, without further explanation. However, impaired social interaction is the hallmark of an autism diagnosis, whereas verbal and nonverbal communication problems are symptoms of autism. No explanation is provided for why autism cases in VAERS did not increase prior to 1998 even though thimerosal-containing vaccines were in use since the 1980s.¹

In 26 out of the total 777 autism cases reported in VAERS among children aged ≤ 5 years, the term "autism" was not related to and/or diagnosed in the patients. The authors either did not report or failed to recognize this.

Although autism symptoms may be indicated in the first months of life, the earliest diagnosis is not made until 18 months and is usually made around the age of three years.⁵⁻⁸ About 61% of reported autism cases in VAERS are for patients aged < 18 months. When only the cases of autism at ages ≥ 18 months ($n=290$) are plotted against their reporting date, "trends" similar to those reported by Geier and Geier appear—an increase after 1998 until 2002 and a decrease after 2002. In addition, there are an essentially unchanging number of cases reported from 1991 till 1998. Thus, the authors' assumptions about choice of age of children to include in the data analysis, lag time to diagnosis, and data selection are not supported.

Three years' data (1994, 1998, and 2002) stand out in the results reported by the authors. All three years can be related to external events that are unrelated to either an objective basis for diagnosis or a true causal relationship between thimerosal-containing vaccines and autistic spectrum disorder. These events may, however, clarify Geier and Geier's findings and are: the official broadening of the definition of autism diagnosis in 1994,⁹ Wakefield's publication of the first report on autism and measles, mumps, and rubella (MMR) vaccination in 1998¹⁰ (retracted in 2004¹¹), and the first claim being filed at the U.S. Court of Federal Claims for vaccine injuries resulting in autism spectrum disorder or a similar neurodevelopment disorder on July 3, 2002.^{1 2}

Hence, the paper by Geier and Geier is based on a subjective background, insufficient data analysis, questionable search criteria, and arbitrary date and data selection.

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In Reply: The studies referenced by Schure^{2 4} contain no actual new data from epidemiological, clinical, molecular, animal model, or other studies, but rather they review previous articles, all of which were published prior to the publication of an ever increasing body of new evidence supporting a causal relationship between thimerosal-containing vaccines and neurodevelopment disorders (NDs). Additionally, many of these studies contain opinions that have been shown to be suspect or untrue by subsequent publications. For example, Nelson and Bauman³ concluded that, in supposed contrast to mercury-poisoned brains, "...brains of autistic persons are commonly enlarged...[,] findings in the autistic forebrain have been unusually small, closely packed neurons...[,] and] [t]he most consistent finding in the neuropathology of autism is reduction in Purkinje cells...." Since the

publication of the Nelson and Bauman article in March 2003, Hornig et al.^{1,3} (as was referenced in our paper) have shown that administration of thimerosal to mice, mimicking the U.S. routine childhood immunization schedule of the 1990s (weight- and age-adjusted), observed autistic findings in a susceptible mouse strain that included increased brain size, densely packed neurons, and decreased numbers of Purkinje cells—providing scientific evidence of the *exact* neuro-anatomic findings in autism and *directly* contradicting Nelson and Bauman.

As Schure notes, we did not examine the VAERS database from 1990 onward. The reason is that it takes approximately 3 to 4 years from birth for a child to be diagnosed with an ND, according to the published literature we cited. Thus, data from the early 1990s would potentially include children born in the mid to late 1980s, while we were trying to assess trends in NDs in children born from the early 1990s through the early 2000s. Additionally, the choice of the period from 1994 onward was consistent with the public access data currently available from the California Department of Developmental Services (CDDS).

While Schure states that cases reported to VAERS “did not increase prior to 1998 even though thimerosal-containing vaccines were in use since the 1980s,” the California Department of Developmental Services (CDDS) reported that “beginning in the early 1980s California began to see an increasing and dramatic rise in the number of persons with [autism spectrum disorders].”¹⁴

Schure criticizes our search of the VAERS database for “speech dis” as a joint search term in VAERS among children aged ≤ 5 years, without further explanation. This description is not correct. Our analyses of the “speech dis” term involved a completely independent search of adverse event reports in the VAERS regardless of whether a particular report contained an autism outcome term. This analysis was done to assess the consistency of trends observed in VAERS with NDs other than autism. The results of our research emphatically showed consistent significant increases and subsequent decreases in NDs other than autism in the VAERS, as would be expected if these disorders are associated with mercury exposure.

With regard to VAERS reports of autism among children less than 18 months old, it is important to recognize that the age provided in the VAERS may reflect the time of initial onset of symptoms, not the age at diagnosis.

Schure notes the variability in the number of reports to VAERS. Our study shows that there is an overall, statistically significant upward trend during the first period examined, despite quarter-to-quarter increases and decreases in autism reports. Importantly, Schure attempts to use the power of hindsight to explain the results observed in three specific years. In contrast, in our original paper on this subject,¹⁵ published three years ago (i.e., prior to the accumulation of virtually all the data analyzed in the present study), we made a prospective prediction. Based upon our extensive examination of toxicokinetic data, epidemiological data, and literature review, we stated that there should be a downward trend in NDs after thimerosal was removed from childhood vaccines. Data from VAERS, CDDS, and the U.S. Department of Education all have shown this downward trend, precisely at the time that it should have occurred based on our hypothesis.

Also in 2003, the CDDS, noting that the rate of increase documented in its 1999 report had accelerated, predicted that autism “will most probably continue to be the fastest growing disability served by the regional center system.”¹⁴

Since the publication of our paper,¹ we have become aware of additional data from the State of Minnesota, showing the rise and subsequent fall of the rate of autism and other NDs in a pattern similar to that shown in the three databases on which we have reported. Additionally, the biological plausibility of our hypothesis continues to receive support from scientific and medical studies.

Critics such as Schure appear to oppose any data that contradict preconceived assumptions about the safety of vaccines, specifically the absence of a causal link between an increasing dose of thimerosal and an increasing incidence of NDs. It is time to face the truth, as distasteful as it is, that the rapid rise in mercury exposure from thimerosal in childhood vaccines and Rh₀(D) immune globulin caused a tragic epidemic of autism and related neurological disorders.

Methodologic Note:

This note is to clarify the method we employed to determine new cases of autism evaluated in our recent analysis of the CDDS database.¹ We employed the method defined by the CDDS’s own publication in 2003, which was used by the CDDS itself to substantiate that California had an autism epidemic.¹⁴

We actually used data that were contained in the CDDS’s own publication from the reporting quarter starting on January 24, 1994, through the reporting quarter ending on January 1, 2003,^{1,4} and we continued to use this method for our analysis of the online CDDS data.

The CDDS calculated the number of new cases of autism in each quarter by subtracting the total number of cases in the previous quarter from the total number in the quarter of interest. Note that once a patient officially enters into the CDDS program, he is entitled to benefits for life. This method of analysis does not adjust for potential increases or decreases in the number of persons with the diagnosis of autism owing to factors other than a new diagnosis, such as population migration or death. While such events occur, it is highly unlikely that their frequency is changing from year to year in a manner that would account for the observed trends. The figures are point-in-time counts, not measures of incidence or prevalence. There is, however, no reason to believe that there have been massive population shifts or changes in the birth and death rate that would invalidate these numbers as a measure of relative incidence or prevalence. The CDDS itself concluded that families immigrating into the state to receive services or a shift in the interpretation of diagnostic criteria could not account for the increasing prevalence through 2002.¹⁴

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¹³ Hornig M, Chian D, Lipkin WI. Neurotoxic effects of postnatal thimerosal are mouse strain dependent. *Mol Psychiatry* 2004;9:833-845.

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¹⁵ Geier MR, Geier DA. Thimerosal in childhood vaccines, neurodevelopment disorder, and heart disease in the United States. *J Am Phys Surg* 2003;9:6-11.

[Editor's note: Schure's statement concerning retraction of the Wakefield paper is misleading. Ten of the 13 coauthors, not including Wakefield, "retracted" an interpretation that the study did not make, i.e. that it had proved a link between MMR vaccine and autism, and cited concerns about an alleged undisclosed conflict of interest. They did not retract the discovery of unexpected intestinal inflammation in autistic children.]

Hospital Overcharging

In his editorial "Hospital Overcharging,"¹ Dr. Kenneth Christman points out that hospitals overcharge uninsured patients. These charges will also be assessed to patients with high-deductible insurance plans, and, consequently, many people may choose not to have high-deductible plans and health savings accounts (HSAs).

If hospitals reduce these charges, uninsured patients and those with high-deductible plans will pay less, and more people may choose to have HSAs. Although hospitals could be mandated to reduce charges, there are other policies that could be considered: establish incentives for hospitals to reduce charges, and reduce policies that may be keeping prices artificially high.

Incentives include threats of legal action and of adverse publicity. I think my hospital, a tax-exempt organization, would be more likely to respond to the threat of adverse publicity. There are organizations whose purpose is to help people reverse hospital overcharging. The best known is Consejo de Latinos Unidos (www.consejohelp.org), based in Los Angeles. Another method in this category is to mandate that hospitals publish their charges for uninsured patients, as Pennsylvania has done.

One policy that props up prices, at least for tax-exempt hospitals, is reporting the dollar value of charity services using the uninsured price. If hospitals were mandated to use the Medicaid or Medicare price, they could not use the high price for the uninsured to inflate their claims for charity care.

Intentionally or not, hospitals act in concert. When one hospital raises uninsured charges, the rest follow along. This also happens with executive pay. It is a vicious circle. If the charges are questioned, the hospital administrator can say, "That's what all the hospitals charge."

Another vicious circle is this: The higher the uninsured charges, the fewer will choose high-deductible health insurance. And the fewer who have high deductibles, the higher the uninsured charges can go. One way to break the circle is to recognize that if more people had high deductibles, prices would be forced down. If hospitals could only provide high-deductible insurance to their executives, and were not allowed to give them discounted services, thus exposing administrators to their own uninsured charges, my guess is that those charges would fall dramatically.

The charges to uninsured patients are important not only because of the effect on those patients but also on the popularity of high-deductible insurance and the success of free-market reforms. I hope that the Board of AAPS will investigate the factors leading to these high charges and promote policies that would reduce them.

Bradley Evans, M.D.
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The issue of hospital overcharging that Dr. Christman addressed¹ has bothered me for years as a stumbling block for acceptance of HSAs.

Recently my daughter and I both had minor outpatient procedures at a local hospital. I have insurance, but she, an independent adult college student, has none. The hospital discounted my fees by two-thirds, and my insurance paid most of the charge (after deductibles). My daughter was offered no discounts.

In effect, the hospital openly charges uninsured patients three times as much as they agree is a reasonable price for insured patients. How can HSAs survive that? And how can hospital administrators sleep at night with that on their conscience?

Gersh Lundberg, M.D.
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¹ Christman KC. Hospital overcharging. *J Am Phys Surg* 2006;11:6-7.

On P4P

Thanks for publishing Dr. Robert Gervais's article on pay for performance.¹ His article is much better than anything else I have read on this issue, and it should put the so-called medical leaders who are pushing these guidelines to shame if they had a sense of shame. I was a little disappointed that he did not cite the article that demonstrates that if physicians followed current "guidelines" for their chronic disease patients, there would be almost no time left for anyone to treat acute patients.² I think Dr. Gervais might agree that any P4P program will, considering the indebted state of our economy, quickly become a NP4NP (non-payment for non-performance) program. This would save the socialist supporters of the nanny state some money, which they possibly could use to arrest and prosecute more physicians.

Everest A. "Tad" Whited, M.D.
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¹ Gervais, RP. Payment for performance in perspective. *J Am Phys Surg* 2006;11:24-25.

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