

Shortcomings in the Latest MMR Vaccination and Autism Study: A Healthcare Administrator's Response

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Abstract

While the autism rate continues to climb among school age children and younger, regulatory agencies continue to fumble the critical responsibility of proper testing of vaccines for safety. The problems are numerous. Here we look at conflicts of interest between corporate players and regulatory agencies as a source of the continuing inability to provide safety studies that are backed by science. As long as the autism crisis continues, the science is not "settled", as claimed by so many corporate entities.

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1. Background

- 1 On 4 March 2019, NPR released an article titled A Large Study Provides More Evidence that MMR Vaccines Don't Cause Autism. The study is touted as "one of the largest ever of the MMR vaccine." Rob Stein, author of the NPR piece, shares email correspondence from the primary author of the study, epidemiologist Anders Hviid of the Staten Serum Institute in Copenhagen, Denmark. According to Stein, Hviid states frankly, "MMR does not cause autism." Stein also notes from Hviid: "Parents should not avoid vaccinating their children for fear of autism."
- 2 [1] The study was published in the *Annals of Internal Medicine* in March 2019. Hviid wrote:
- 3
- 4
- 5 We found no support for the hypothesis of increased risk for autism after MMR vaccination in a nationwide

unselected population of Danish children; no support for the hypothesis of MMR vaccination triggering autism in susceptible subgroups characterized by environmental and familial risk factors; and no support for a clustering of autism cases in specific time periods after MMR vaccination. [2]

Hviid is confident in his assertions and explains clearly enough how the researchers came to their conclusions. Questions nevertheless remain. Hviid says that Andrew Wakefield's conclusions in the retracted Ileal-lymphoid-nodular hyperplasia, non specific colitis, and pervasive development disorder in children have not been replicated, and that "observational studies have not been able to identify an increased risk for autism after MMR vaccination," then cites a 2014 meta-analysis of ten observational studies (among several other studies) that failed to replicate any of Dr. Wakefield's findings and subsequently demonstrated no link between the MMR vaccine and autism. [3]

2. The Thompson Case

Close examination of the second point of reference, Dr. Taylor's et. al. 2014 study *Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies*, reveals that the 17th piece cited in Dr. Taylor's work is William Thompson's 2004 *Age at first measles-mumps-rubella vaccination in children with autism and school matched control subjects: a population based study in metropolitan Atlanta*. Dr. Hooker's conclusions drawn from his discussions with Dr. Thompson shed a different light on that meta-analysis.[4] The public deserves to know what happened with the omitted data and why the matter seemed to just go away. The following is a quotation of Dr. Thompson's admission:

I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal *Pediatrics*. The omitted data suggested that African American

males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed. I want to be absolutely clear that I believe vaccines have saved and continue to save countless lives. I would never suggest that any parent avoid vaccinating children of any race. Vaccines prevent serious diseases, and the risks associated with their administration are vastly outweighed by their individual and societal benefits [5]

Opposing views presented on the matter include the interpretation of the CDC[6], and Dr. Hooker's take can be found here. [7] Transcripts of the phone calls between Dr. Hooker and Dr. Thompson are also available. [8]

3. Corporate Connections

Concerns about the financial backing of the study also exist: Financial support was provided by the Novo Nordisk Foundation and the Danish Ministry of Health. Novo Nordisk is a massive multinational pharmaceutical company in Denmark with a market capitalization that is greater than \$49B USD. According to last year's annual report they anticipate an effective 2019 tax rate of 20-22%. [9] The government of Denmark receives significant tax revenue in an arrangement like this. Therefore, both the Danish Ministry of Health and Novo Nordisk have a vested interest in a study that will not produce any negative outcomes. A study that demonstrated an association between vaccination and autism would obviously decrease demand for the MMR vaccine, thereby causing a negative financial impact for Novo Nordisk. This decrease in revenue leads naturally to less tax revenue for the government of Denmark. This does not mean that an inaccurate study result is guaranteed, but I believe there is a positive correlation between the degree of conflict of interest and the possibility that the performance of the study will be less than sat-

isfactory. On top of this, Dr. Christine Laine, the editor-in-chief of the *Annals of Internal Medicine*, reported that her husband has stock options and holdings with a company called Targeted Diagnostics and Therapeutics in the Disclosures portion of the study. TD&T is a biotechnology company located in West Chester, Pennsylvania that performs research and development in in-vitro diagnostics and imaging agents. Interestingly, they also perform R&D in receptor-based therapeutics and cancer vaccines. Unfortunately, the Bloomberg snapshot redirects to www.tdtinc.com, which does not seem to be in service at the time of this writing.[10]

4. Connections at the Publisher

The editor-in-chief of the *Annals of Internal Medicine* has a personal financial interest in the continued promulgation of vaccination. Dr. Jaya K. Rao, a Deputy Editor of the *Annals of Internal Medicine*, has stock holdings/ options in Pfizer and Eli Lilly. Pfizer is a publicly traded company and is one of the largest pharmaceutical companies in the United States, having manufactured virtually all sorts of pharmaceutical products, including vaccines, for years. Eli Lilly is also a major American pharmaceutical company and is probably most well known for being the first company to develop Jonas Salk's polio vaccine in large quantities. A deputy editor of the *Annals of Internal Medicine* has a personal financial interest in the continued promulgation of vaccination. Dr. Catharine Stack, a Deputy Editor for Statistics at the *Annals of Internal Medicine*, reported holdings in Pfizer, Johnson & Johnson, and Colgate-Palmolive. Johnson and Johnson is an American pharmaceutical company who is probably most famous for Bandaids™ and baby powder but has recently decided to press into vaccine research and development [11], and of course Pfizer is a major vaccine manufacturer. The Deputy Editor for Statistics at the *Annals of Internal Medicine* has a personal financial interest in the continued promulgation of vaccination. Christina Wee, a deputy editor of the *Annals of Internal Medicine*, discloses that she is employed with Beth Israel Deaconess Medical Center. The nature of her relationship with

the Medical Center is apparently a conflict of interest. The remaining four editors claim no conflicts of interest. Both the authors of the study and at least three of the individuals who choose what is printed in the *Annals of Internal Medicine* have substantial financial ties to vaccine manufacturers. It is unseemly and distressing to see such direct conflicts of interest in those who hold positions that traditionally were safeguards of objectivity in science. Conflicts of interest like these have the possibility to create pressure to prioritize financial incentives over the discovery process. We should take seriously reviews of the information from researchers not financially backed by the pharmaceutical industry.

5. Industry Legal Troubles

It is also hard to overlook the legal troubles endured by the pharmaceutical industry in general, and Merck in particular. Before it was taboo to speak of these things, *Huffington Post Canada* published Lawrence Solomon's 2014 update about Merck's whistleblower suit. [12] Reuters covered the suit in 2015 when Merck was accused of not answering questions regarding the current efficacy of the vaccine, preferring to only provide data from a half century ago.[13] Now Merck's position seems less secure than ever: their licensing of the vaccine may be threatened. Documents revealed via FOIA request demonstrated the FDA knowingly licensed the MMR vaccine for use in the United States following clinical trials with small numbers of enrollees and only a six week adverse reaction tracking period ¹.

6. Neglect of Adverse Events

The study nevertheless resulted in a large number of participants with new upper respiratory infections and gastrointestinal problems. In at least one study group this exceeded 50% of participants – adverse events were not taken into consideration during the

¹ Unfortunately, this is one of the longest tracking periods I have ever seen. The DT Toxoids Adsorbed vaccine, first approved in the United States in 1997, was approved after clinical safety trials that monitored for adverse reactions for 24 hours. <https://www.fda.gov/media/75962/download>

safety profile, and no person in the control group received an inert placebo.[14] As a healthcare administrator with a vested interest in public health, especially from a financial and operational perspective, I find it inconceivable that this product would be forced upon anyone, especially children. Nevertheless, several states are attempting to remove philosophical and medical exemptions to vaccination, removing a parent's right to choose whether or not they want to trust the claims of Merck. Dr. Brian Hooker also identifies several shortcomings in Hviid's study. He alleges that:

- several thousand autistic children are not represented in the study when they should be.
- many of the children were too young to receive an autism diagnosis in the first place
- two different MMR vaccines were used in the study
- there is no accounting for the change in the Danish vaccination schedule which occurred in 2008, at which time the age of the second MMR vaccine was reduced from 12 to 4, which is younger than the average age of an autism diagnosis.[15]

7. The Missing Autistic Children

Dr. James Lyons-Weiler identifies issues also. The rate of autism amongst study participants is just over half of the rate of autism in Denmark, echoing Dr. Hooker's allegation of missing children as well. An ASD rate of 0.9-1% amongst a population with an autism rate of 1.65% is probably not representative of the population at large. He argues that cumulative vaccine exposure is a better indicator of developing autism than one vaccine. [16] An analogy would be that a study on the effects of a 12th shot of bourbon on a group of college kids who have already had 11 shots in order to determine whether or not that 12th shot carried with it an increased propensity toward intoxication might not find any influence of the 12th drink. Lyons-Weiler also reports that association studies do not test causality. In other words, this

study answers the question with the wrong type of study.

8. Autism is an Environmentally acquired disorder

Lyons-Weiler is not content to complain that epidemiology is an insufficient tool for assessing vaccine risk and then leave it alone. He posits an alternative. He argues that autism should be viewed as an acquired cellular detoxification deficiency syndrome. His theory, called the ER Hyperstress theory, hold that autism is a form of toxicant-induced loss of tolerance of toxins, and he argues that vaccine adjuvants play a significant role in this process. [17] Whether he is correct or not remains to be seen. It is difficult to understand how Dr. Hviid and colleagues can ignore the scientific studies that led Dr. Lyons-Weiler to this theory of autism. Perhaps Dr. Hviid is not aware of that literature. One could expect scientists interested in the causes of autism to be up-to-date on the literature. If Lyons-Weiler's theory is wrong, Hviid should demonstrate why. Or someone else should. But to simply repeat older literature while ignoring very recent (and possibly paradigm shifting) research is not responsible. ASD is not going anywhere. Massachusetts schools are serving four times as many children with ASD as they did a mere 15 years ago. [18] One in 35 four-year-olds in New Jersey have autism, a rise of 43% over the last four years. [19] Epidemiology studies designed to show that Dr. Wakefield was wrong have done nothing to drive rates down or even slow the ASD explosion.

9. The Study Patients Deserve

This leads to the conclusion that it is time for a true, vaccinated versus unvaccinated study. This stone remains unturned by the scientific establishment. Some have described such a study as unnecessary and unethical. These explanations are unconvincing. [20] There is certainly nothing unethical about the nature of a study like this. There are parents who are ready and willing to never vaccinate their children. There are parents who are ready and willing to

completely oblige their children to the CDC schedule. There are parents who will opt for a middle road. There are no shortages of parents or children necessary to fulfill all of the required components of the study. To argue that it is unethical to withhold vaccination from some children for the purpose of the study assumes knowledge of the outcome and thus begs the question. Knowing this to be the case, why not at least engage in a study? David Hawkes points to a vaccinated versus unvaccinated study that has been completed, referring to a review in Germany from 2003 to 2006. This study concluded that “the prevalence of allergic diseases and non-specific infections in children and adolescents was not found to depend on vaccination status.” The reader is left wondering why Hawkes uses this study to conclude that further research into autism is not necessary. Autism is not a communicable disease, and thus the citation of this study by Hawkes is non-sequitur. The authors of this study also have financial conflicts of interest. Dr. Schlaud was the lead investigator of an epidemiological study of deaths in children ages 2-24 months in 2004-2009, which was jointly funded by the Federal Ministry of Health, The Paul Ehrlich Institute, Sanofi Pasteur, and Glaxo Smith Kline. Dr. Poethko-Muller was responsible for coordinating the study. [21] It is time for a different group of scientists at the wheel, one with no financial ties to the pharmaceutical industry. There must be a study that compares the long-term health outcomes of completely unvaccinated children with their fully vaccinated (United States CDC schedule) counterparts. Undoubtedly this study should also include many children on the middle road. The internet is ripe with strawmen to knock over regarding this issue, but contrary to Dr. Christopher Johnson’s misgivings, calls to reject a study like this are disingenuous. No one is suggesting that an RCT take place and parents not know whether or not their children will be vaccinated. [22] I am simply asking for a review of the health outcomes of these populations sets. ² It is disingenuous to call for less scientific data. Are we afraid of what Science might discover?

²A few studies of this nature are in preliminary phases.

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