

The Plausible Link between Vaccines and Autism has not been Debunked

In 2001 the Institute of Medicine (IOM) stated that an association between mercury exposure and neurodevelopmental disorders including autism, attention deficit hyperactivity disorder (ADHD) and speech or language delay was biologically plausible [1 p3]. However the IOM rejected this theory in 2004 because it was considered that further studies were needed to prove a causal link. Here is the IOM statement that describes why the theory was rejected:

The body of evidence favoured rejection of a causal relationship between thimerosal-containing vaccines and autism and that the hypothesis generated to date, concerning the biological mechanism for such causality, are theoretical only. The committee also stated that the benefits of vaccination are proven and the hypothesis of susceptible populations is presently speculative and that widespread rejection of vaccines would lead to increases in incidences of serious infectious diseases [1 p3].

In other words, the studies that investigated this link did not prove the causal theory so the IOM rejected the theory. It was rejected even though Congressman Burton informed the US Congressional Hearing into Thimerosal in 2003 that many of the epidemiological studies conducted or funded by the CDC to investigate the link were claimed to be of poor design, under-powered and fatally flawed [2]. A theory of causation should not be rejected if scientific studies with universally accepted criteria have not been done.

Recently there has been discussion of a US Center for Disease Control and Prevention (CDC) cover up of the link between MMR vaccines and autism. This occurred after the revelation that a CDC whistleblower assisted in manipulating the data in a 2004 study of a relationship between MMR vaccine and autism [3]. By omitting some of the data it was possible to hide the fact that there was a 236% higher rate of autism in vaccinated African-American boys than unvaccinated boys. This manipulated study was published in the journal *Pediatrics*. Dr. William Thompson has issued this claim through his lawyers Morgan Verkamp LLC. In

addition, he has reportedly apologised to Dr. Andrew Wakefield for the unjust damage this study caused to his career [4].

This information is currently being investigated by US Congressman Bill Posey. A cover up of safety data by government regulators is facilitated by the conflicting interests that these boards are protecting [5] [6] [7]. The role of the US and Australian government regulators of medicines/vaccines includes sponsoring vaccine research, approving vaccines for the market and *monitoring the safety of these products in the population*. This means they are responsible for protecting the interests of both consumers and industry: two stakeholders with opposing interests. These government regulators are 100% funded by industry and therefore it is not possible for these boards to fulfil their regulatory role objectively. This is because they are required to monitor the safety of the very products they have approved for the market. In addition, many members of government vaccine advisory boards have personal conflicts of interest including financial ties to pharmaceutical companies [5] [6].

In June 2014 an article was published by a group of researchers at Sydney University who carried out a systematic international review of studies investigating the plausible link between autism and childhood vaccinations. This meta-analysis included a review of 10 epidemiological studies and was published in the medical journal *Vaccine* (June 2014) [8]. The study was described as a comprehensive review of all the evidence and it concluded that childhood vaccines are not associated with causing autism or autism spectrum disorders (ASD). However, the study 'selected' 10 articles to review and there are many aspects of the design of the studies and the meta-analysis that throw these conclusions into question.

This study, like the CDC's own review of childhood vaccines, does not include the many independent studies (>165) that have found Thimerosal, an organic mercury-based compound to be harmful to humans [9]. Many studies have linked mercury as a cause of the following conditions: acrodynia, poisoning, allergic reaction, malformations, autoimmune reactions, developmental delay, tics, speech delay, language delay, attention deficit disorder and autism. Yet the researchers at Sydney University claim that their systematic review of studies shows that the components of vaccines are not a cause of autism.

The issue of conflicts of interest arises in scientific research because it is observed that industry funded studies are more likely to find positive results for the sponsor of the study and that these results are more likely to be published [6] [10]. Governments are using epidemiological studies funded and co-authored by researchers involved with industry to debunk the plausible causal link between vaccines and autism. Information about the flaws in the study designs used to debunk the autism link is presented in the peer-reviewed article by Hooker et al (2014) titled 'Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe' [9].

This information was not reported in the Australian mainstream media which results in selective information being used in mainstream debates. This lack of exposure of scientific information in the media has been approved by the Australian Communication and Media Authority (ACMA) on the basis that presenting this information would provide 'false balance' to the vaccination debate (ACMA) [11]. On the rare occasion that a negative story about vaccines is reported in the mainstream media, the ACMA accepts that it should be presented to the public with the opinion of the journalist [11]. The flaws in autism research were described in a press release in the *Digital Journal* in June 2013. This article was titled 'CDC's Vaccine Safety Research is Exposed as Flawed and Falsified in Peer-Reviewed Scientific Journal: Substantial Scientific Evidence Exists that Vaccine Ingredient is a Developmental Neurotoxin' [12] but Australian mainstream journalists did not report on this information.

Conclusions made from epidemiological studies are dependent upon the inclusion and exclusion criteria chosen by the researchers. The choice of parameters influences the statistical data that is produced and this is fundamental to the outcomes of the study. Studies that are funded by pharmaceutical companies often employ company researchers to design the studies and choose the study parameters. In this way industry is able to influence the outcome of the study and this underscores the need for independent assessment of the study design.

A *comprehensive* review of the causal link between vaccines and autism needs to include all

types of scientific evidence, including animal studies, clinical evidence and the ecological evidence of children's health at the population level, and not just selective epidemiological studies of population cohorts. Biological and clinical evidence is suggesting a causal link between vaccines and autism therefore independent empirical studies of vaccinated and unvaccinated animals/children are required to prove or disprove this causal link. These types of empirical studies have never been used by governments to dismiss the link between vaccines and autism [13].

There has been a significant increase in autism over the same period as the increased use of vaccines in Australia in the 1990's [14]. Yet the media and lobby groups describe researchers who investigate the risks of vaccination as '*anti-vaxers*'. This derogatory label is being used to dismiss the scientific arguments presented by people who are questioning the safety of the ever-expanding vaccination schedule. The majority of people questioning vaccination today are educated parents who have researched vaccines and have not found evidence to support the government's claims about safety and efficacy. Parents would like to debate the use of an increasing number of vaccines in children. Labelling this group as *anti-vaccination* is a way of ignoring the scientific evidence of the risks and it is hindering informed debate on this important health issue. Independent research assessing the risks of vaccines is not synonymous with anti-vaccination and it shouldn't be labelled as such.

The risks of vaccines must be properly assessed in order to promote the best health outcomes in populations. Like all medical interventions it is necessary to understand the risks and benefits of a procedure before it is implemented in the population. The *Good Practice Guidelines* for Medical Practitioners in Australia are also hindering the freedom of doctors to speak openly about the risks of vaccines. Doctors are required to promote vaccination to patients because it is an accepted medical practice in western medicine [15]. This requirement is linked to the registration of medical practitioners. Consequently, they can lose their livelihood if they speak about the risks of vaccines. This was recently demonstrated when chiropractors were ordered to remove all '*anti-vaccination*' material from their waiting rooms [16]. The conflicts of interest in the Australian regulatory board for vaccines and for representatives on vaccine advisory boards for policy are areas possible industry bias that are not transparent to the public.

Researchers (and government advisors) need to examine *all* the evidence that suggests a causal link for a disease and not select just 10 epidemiological studies to draw conclusions. Evidence of the safety of the combined schedule of vaccines should be obtained from controlled clinical trials in animals before they are recommended in humans; these studies have never been done. The small scale study of the health effects of hepatitis B vaccine on children demonstrated there was a 3 fold increased risk of autism in children who were given the hepatitis B vaccine at birth [17].

Conclusion

The promotion of vaccination on the fear of disease is not a foundation for evidence-based medicine. Until researchers can prove that the increase in autism, asthma, allergies, anaphylaxis, speech delay, ADHD, neurological damage and other chronic illness in children is not being caused by the increased use of vaccines then health is put at risk when fear of infectious diseases is used by the media to promote vaccines to the public. The public is entitled to be openly informed about the risks of vaccines and to participate in discussions about the number of vaccines recommended for children in the government's public health policy.

Judy Wilyman MSc (Population Health)

PhD Candidate

References:

1. Food and Drug Administration (FDA). Vaccines, Blood and Biologics. Thimerosal in Vaccines. US Department of Health and Human Services.
<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228> (accessed March 2013)
2. Burton D. 2003. Mercury in Medicine Report, US Congressional Record; Findings and Recommendations, Safe Exposure Standard as Reported in Executive Summary. 20th May www.aapsonline.org/vaccines/mercinmed.pdf (accessed June 2013).
3. Press Release, 2014, Confirming the manipulation of data in a 2004 CDC Study into Autism <http://www.morganverkamp.com/august-27-2014-press-release-statement->

- [of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/](#)
4. Whistleblower apologises to Dr. Andrew Wakefield for his part in manipulating the data <http://truthbarrier.com/2014/09/02/breaking-news-cdc-whistleblower-text-messages-to-andy-wakefield-study-would-have-supported-his-scientific-opinion/>
 5. Conflicts of Interest in the CDC
http://www.lawyersandsettlements.com/articles/drugs-medical/CDC_Big_Pharma-00285.html#.VBKzfvmswwC
 6. Goldacre B. 2012. *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*. London: Fourth Estate.
 7. Baxter K. 2010. Structural Barriers to Reform of the Australian Health and public hospital system. Australian Centre for Health Research (ACHR). Canberra: TFG International Pty Ltd. January.
 8. Taylor LE, Swerdfeger AL, Eslick GD, 2014, Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies, *Vaccine*, Vol 32 June; 29; pp3623-3629
<http://www.sciencedirect.com/science/article/pii/S0264410X14006367>
 9. Hooker B, Kern J, Geier D, Haley B, Sykes L, King P, Geier M, 2014, Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe, *Biomed Research International*, Vol 2014, Article ID 247218, 8 pages.
 10. Stamatikis E, Weiler R, Ioannidis J. 2013. Undue industry influences that distort healthcare research, strategy, expenditure and practice: a review. *European Journal of Clinical Investigation*. 43: 5(May): pp469-475.
 11. Australian Communications and Media Authority (ACMA), 2013, Investigation Report 2976 – Media Watch Broadcast on ABC October 1st 2012.
 12. Watchung NJ, 2014, CDC's Vaccine Safety Research is Exposed as Flawed and Falsified in Peer-Reviewed Scientific Journal: Substantial Scientific Evidence Exists that Vaccine Ingredient is a Developmental Neurotoxin, *Digital Journal*, PR Newswire, June 13 <http://www.digitaljournal.com/pr/1985793>
 13. Posey B. 2012. Posey Questions CDC on Autism Research. Hearing of the House Government Reform and Oversight Committee.
https://www.youtube.com/watch?v=uNWTOMei_6A
 14. Australian Institute of Health and Welfare (AIHW). 2005. Child health, development and wellbeing. Australian Government:
 - a) Selected Chronic Diseases among Australia's Children. Bulletin 29. September 2005.

- b) Chronic Diseases and Associated Risk Factors.
 - c) A Picture of Australia's Children. May. 2005 (accessed March 2006).
15. Medical Board of Australia (MBA). 2010. Good Medical Practice: A Code of Conduct for Doctors in Australia. <http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx> (accessed October 2013).
 16. Smith P. 2013. Chiro ordered to ditch anti-vax message. *Australian Doctor*. 9th August
 17. Gallagher CM and Goodman CS. 2010. Hepatitis B vaccination of male neonates and autism diagnosis, NHIS 1997-2002. *Journal of Toxicology and Environmental Health*. 73: 24: pp1665-77.