Aluminum Adjuvants in Vaccines

What you should know about the safety science

Rodef Shalom 613

https://rodefshalom613.org
rodefshalom613@gmail.com

Aluminum Adjuvants in Vaccines **1**

Introduction 3

Key Points 3

How Aluminum Affects the Body 4

Aluminum disrupts body chemistry 4

Aluminum causes autoimmune diseases 4

Aluminum accumulates in the brain 5

Aluminum biopersistence causes macrophagic myofasciitis 6

Aluminum's history as a toxin; shown to cause epilepsy 6

Aluminum can provoke an allergic reaction 6

Aluminum and Mercury may be more toxic together 7

Government Agencies and Scientists Voice Concerns About Aluminum 7

Department of Health and Human Services - Workshop on Aluminum in Vaccines 7

The WHO: Aluminum is a neurotoxin 9

Weak studies are used to verify the safety of aluminum in vaccines 10

Addendum 11

The Political Economy of Autism 11

Please note that all bolded emphasis in the paper has been added by Rodef Shalom 613

Introduction

Aluminum (Al), as AAHS (amorphous aluminum hydroxyphosphate sulfate), aluminum hydroxide, or aluminum phosphate, is used as an adjuvant in a number of inactivated and subunit vaccines in order to provoke an immune response. While aluminum has no purpose in the human body and is a known toxin, there have been no studies to determine a safe level of aluminum, or of most other ingredients, in vaccines. Instead, the allowable amounts of aluminum that are sometimes used as a guideline for safety reviews, refer to allowable amounts of dietary aluminum. An infant (even one who is premature) is injected on day 1 with the Hepatitis B vaccine; a newborn of average birth weight will receive a 17-fold greater amount of aluminum than it would have had the amount been adjusted for body weight.[1]

Far from being a harmless adjuvant, aluminum poses serious health consequences for many vaccinees.

Key Points

- Aluminum adjuvants are promoted as safe and effective, yet:
    - Scientists have been aware of aluminum toxicity as early as 1921
    - The World Health Agency lists aluminum as a cause of neurodevelopmental disorders
- Aluminum is particularly dangerous for infants, the elderly, and those with impaired renal function
- Individuals involved in vaccine science, including vaccine manufacturers, do not fully understand metals or have knowledge of toxicological research
- Aluminum's mechanism of action is not well understood.
- Up to .85 mg of aluminum are allowed in each vaccine dose, per the FDA. Scientists do not know how this figure was arrived at.
- There have been no studies to determine a safe limit of injected aluminum
- Weak studies are used to justify the use of aluminum in vaccines and the vaccine schedule
- Aluminum deranges body chemistry. Aluminum:
    - Inhibits over 200 important biologically important functions
    - Interferes with the body's use of calcium, magnesium, Vitamin K, and hydrogen
    - Induces DNA damage
    - Interrupts bone formation resulting in spontaneous fractures
    - Can accumulate in the body when bypassing the gastrointestinal barrier (as with vaccines), resulting in aluminum overload
    - Negatively impacts the male reproductive system
- Aluminum has been found to cause severe and chronic illness including:
    - Encephalopathy (brain disease), dementia and impaired neurological development, osteopenia (low bone density), and osteomalacia (softening of bones to do impaired bone metabolism)
    - Macrophagic myofasciitis (MMF)
    - Allergy to aluminum
    - Aluminum induced bone disease
    - Many autoimmune/inflammatory diseases
    - Autism; aluminum is found in excessive amounts in the brains of autistic individuals
    - Epilepsy
- Concurrent exposure to both aluminum and mercury may have added dangers

[1] Reconsideration of the immunotherapeutic pediatric safe dose levels of aluminum, https://www.sciencedirect.com/science/article/pii/S0946672X17300950

How Aluminum Affects the Body

Aluminum disrupts body chemistry

Aluminum inhibits over 200 biologically important functions and is responsible for a variety of adverse effects in plants, animals, and humans. It is particularly dangerous for infants, the elderly and people with impaired renal function. It is **known to cause encephalopathy, dementia and impaired neurological development, osteopenia, and osteomalacia.**

Aluminum interacts with calcium, magnesium, Vitamin K and hydrogen. It slowly replaces Ca2+, Mg2+ and K+ from their exchange sites; aluminum that enters the cytoplasm affects the homeostasis of various ions, such as H+, K+, and Ca2+.

A**pproximately 70% of aluminium in the body is found in the skeletal system.**

Aluminum causes DNA damage.

"… **How Al induces DNA damage is not known**, although a likely mechanism is the induction of oxidative damage [25]. ... There is **evidence that Al induces chromosomal aberrations**, micronuclei and sister-chromatid exchanges in human lymphocytes.

Aluminum affects bone formation

"…When aluminium accumulates in bones, the process of bone formation is disrupted, and ... "aluminium-induced bone disease", develops, ending with spontaneous fractures [34]. ...

Aluminum can accumulate

"... **When the gastrointestinal barrier is bypassed ... aluminium has the potential to accumulate.** ...

Aluminum affects the male reproductive system

" Data reveals **the effect of Al on the mail [sic] reproductive system**. In particular mechanisms involving reactive oxygen species and oxidative damage have been highlighted as well as endocrine disruption, androgen receptor expression and libido decrease [98]."[2]

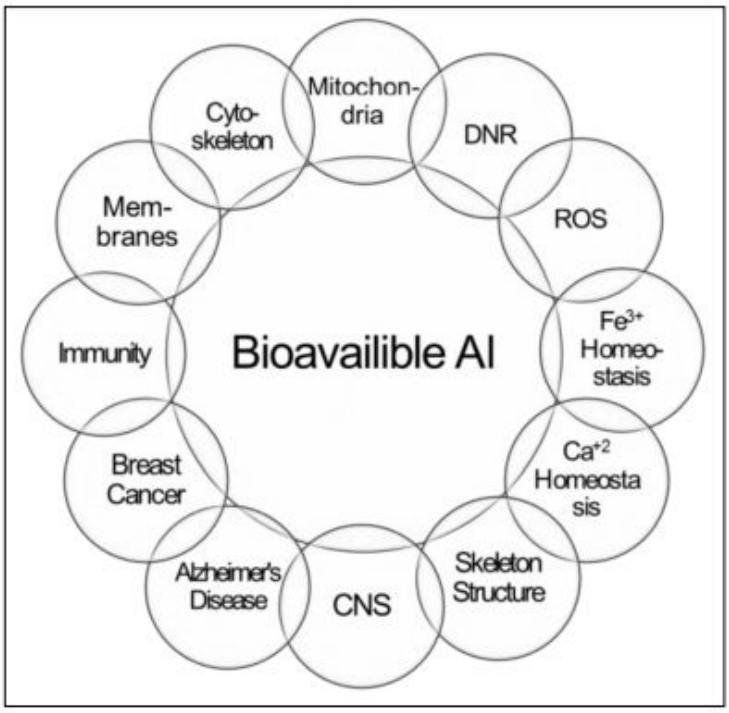


Fig. 3. Main cellular targets effected by aluminium and aluminium related diseases

Aluminum causes autoimmune diseases

Yehuda Shoenfeld, M.D., FRCP (Hon.) MaACR, M.D., is the founder of the Zabludowicz Center for Autoimmune Diseases at the Sheba Medical Center in Israel and the incumbent of the Laura Schwarz-Kipp Chair for Research of Autoimmune Diseases at Tel-Aviv University.[3]

[2] When chemistry meets biology: The case of aluminium - A review, https://bit.ly/370WYUu
[3] https://autoimmunity-network.com/page/Shoenfeld-CV and https://www.ifm.org/about/profile/yehuda-shoenfeld-md-frcp/

Shoenfeld has coined the acronym "ASIA" for **autoimmune/inflammatory syndrome induced by adjuvants** following his research which ultimately linked a number of conditions to aluminum adjuvants in vaccines. Along with 14 other researchers around the world, he published a medical textbook, Vaccines and Autoimmunity.[4]

> "We have published the criteria and classified it as we do usually with different autoimmune diseases, namely into major criteria and minor criteria. Major criteria include clinical manifestations such as severe fatigue, poor sleep, myalgia and arthralgia; the minor criteria include the presence of various autoantibodies and specific HLA [human leukocyte antigen] (e.g., DRB1). However, as I mentioned before, over the years many of these patients may go on to develop a more well-defined autoimmune disease. For instance, if they develop scleroderma or systemic sclerosis, they will suffer from tight skin, complications of the lungs, kidneys, and so forth."[5]

Aluminum accumulates in the brain

Christopher Exley, Professor in Bioinorganic Chemistry; Honorary Professor, UHI Millennium Institute at Keele University in the UK.

> "We have looked at what happens to the aluminum adjuvant when it's injected, and we have shown that certain types of cells come to the injection site and take up the aluminum inside them. These same cells are the ones we also see in the brain tissue in autism. So, for the first time, we have a link that, honestly, I had never expected to find between aluminum as an adjuvant in vaccines and that same aluminum potentially could be carried by those same cells across the blood-brain barrier into the brain tissue where it could deposit the aluminum and produce a disease, an encephalopathy. It could produce a more severe and disabling form of autism."[6]

> **"We recorded some of the highest values for brain aluminium content ever measured in healthy or diseased tissues in these male ASD donors** including values of 17.10, 18.57 and 22.11 µg/g dry wt. (Table 1). What discriminates these data from other analyses of brain aluminium in other diseases is the age of the ASD donors. Why, for example would a 15 year old boy have such a high content of aluminium in their brain tissues? There are no comparative data in the scientific literature, the closest being similarly high data for a 42 year old male with familial Alzheimer's disease (fAD)."[7]

> " ... an aluminium adjuvant in a vaccine is an acute exposure to aluminium at the vaccine injection site. However, the aluminium content of a single vaccine also represents a significant exposure to aluminium in an infant. For example, the injection of a single dose of Infanrix Hexa into an infant is equivalent to 164 times the daily dose of aluminium in breast milk feeding. Even allowing for an unrealistically high proportion of aluminium being retained in a granuloma at the vaccine injection site (say, for example 40% of the injected aluminium) the daily dose of aluminium in Infanrix Hexa is 100 times higher than an infant receives in breast-feeding. This is a high exposure to aluminium and inevitably results in aluminium being retained in an infant's tissues, including the infant brain. ... Infants, due to increased gastrointestinal absorption, reduced urinary excretion and a developing blood-brain-barrier, are uniquely vulnerable to aluminium. ..."[8]

[4] Vaccines and Autoimmunity, https://www.amazon.com/Vaccines-Autoimmunity-Yehuda-Shoenfeld/dp/1118663438
[5] Professor Yehuda Shoenfeld talks about ASIA, https://bit.ly/2XHHx0q
[6] Professor Christopher Exley - Aluminium, https://www.youtube.com/watch?time_continue=747&v=Ju4-lKwQ4ak
[7] Aluminium in brain tissue in autism, https://www.sciencedirect.com/science/article/pii/S0946672X17308763
[8] Infants are Uniquely Vulnerable to Aluminium in Vaccines, https://bit.ly/2UBl0jM

Aluminum biopersistence causes macrophagic myofasciitis

Aluminum adjuvants may remain in the body without being broken down or eliminated and can make their way into the brain.

> "...Concerns linked to the use of alum particles emerged following recognition of their causative role in the so-called macrophagic myofasciitis (MMF) lesion detected in patients with myalgic encephalomyelitis/chronic fatigue/syndrome. MMF revealed **an unexpectedly long-lasting biopersistence of alum within immune cells in presumably susceptible individuals,** stressing the previous fundamental misconception of its biodisposition. We previously showed that **poorly biodegradable aluminum-coated particles** injected into muscle are promptly phagocytosed in muscle and the draining lymph nodes, and **can disseminate within phagocytic cells throughout the body and slowly accumulate in the brain**. This strongly suggests that long-term adjuvant biopersistence within phagocytic cells is a prerequisite for slow brain translocation and delayed neurotoxicity."[9]

> "Main clinical manifestations observed in adult patients with persistent MMF lesions at muscle biopsy are the following: (i) chronic *musculoskeletal pain* (arthromyalgias); (ii) chronic *fatigue*; and (iii) *cognitive disorders*."[10]

Aluminum's history as a toxin; shown to cause epilepsy

Neil Miller, a medical research journalist and director of the Thinktwice Global Vaccine Institute, writes:

> "For example, as early as 1921 The Lancet described a 46-year-old metal worker in whom "aluminium produced a rather slow intoxication. In this case it caused memory loss, tremor, jerky movements and incontinence of urine."15 In 1927, Dr. Victor Vaughn, a toxicologist with the University of Michigan, testified before the Federal Trade Commission that "all salts of aluminum are poisonous when injected subcutaneously or intravenously."16 By 1951, Chusid et al. showed that chronic epilepsy could be induced in monkeys through intra-cerebral administration of aluminum hydroxide cream.17 In 1968, Driver et al. performed a similar experiment by placing aluminum hydroxide cream unilaterally on the posterior parietal cortex of six monkeys.18 From 3 to 8 weeks after surgery, electrical abnormalities could be seen on an electroencephalogram and the monkeys exhibited "episodic twitching of the limbs and face." The animals were also impaired at learning new tasks and at relearning tasks first learned prior to the intervention."[11]

Aluminum can provoke an allergic reaction

Cases of persistent itchy (pruritic) nodules have occurred in children vaccinated with aluminum containing vaccines; they had extremely itchy nodules at the vaccination site, made worse during upper respiratory tract infections, and local skin alterations. Symptoms usually started after about 1 month post vaccination and were found to last at least 7 years. "The condition is not commonly known but is important to recognise, as the child and the family may suffer considerably." Future vaccination with aluminum containing vaccines may aggravate the symptoms and the allergy.[12]

---

[9] Biopersistence and Brain Translocation of Aluminum Adjuvants of Vaccines, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4318414/

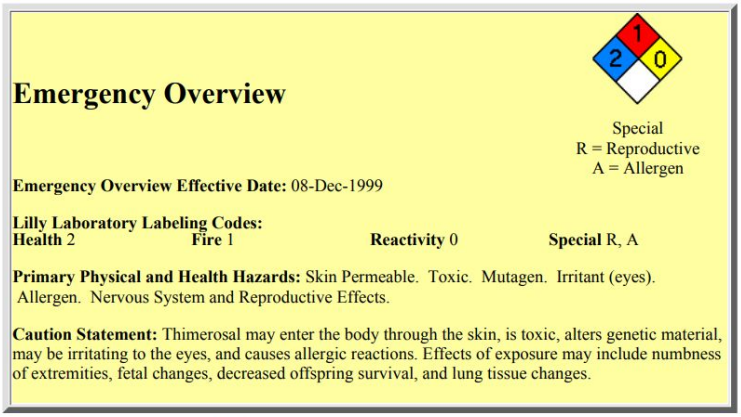
[10] Clinical Features in Patients with Long-Lasting Macrophagic Myofasciitis, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4246686/

[11] Aluminum in Childhood Vaccines is Not Safe, https://www.jpands.org/vol21no4/miller.pdf p110

[12] Nineteen cases of persistent pruritic nodules and contact allergy to aluminium after injection of commonly used aluminium-adsorbed vaccines, https://link.springer.com/article/10.1007/s00431-005-1704-1

Aluminum and Mercury may be more toxic together

> "...Rigorous and replicable studies (in different animal species) have shown evidence of EtHg [mercury] and Al toxicities. More research attention has been given to EtHg and findings have showed a solid link with neurotoxic effects in humans; however, **the potential synergic effect of both toxic agents has not been properly studied.** Therefore, early life exposure to both EtHg and Al deserves due consideration."[13]



Emergency Overview

Special
R = Reproductive
A = Allergen

Emergency Overview Effective Date: 08-Dec-1999

Lilly Laboratory Labeling Codes:
Health 2 **Fire** 1 **Reactivity** 0 **Special** R, A

Primary Physical and Health Hazards: Skin Permeable. Toxic. Mutagen. Irritant (eyes). Allergen. Nervous System and Reproductive Effects.

Caution Statement: Thimerosal may enter the body through the skin, is toxic, alters genetic material, may be irritating to the eyes, and causes allergic reactions. Effects of exposure may include numbness of extremities, fetal changes, decreased offspring survival, and lung tissue changes.

Routes of Entry: Inhalation and skin absorption.

Effects of Overexposure: Topical allergic dermatitis has been reported. Thimerosal contains mercury. Mercury poisoning may occur and topical hypersensitivity reactions may be seen. Early signs of mercury poisoning in adults are nervous system effects, including narrowing of the visual field and numbness in the extremities. Exposure to mercury in utero and in children may cause mild to severe mental retardation and mild to severe motor coordination impairment. Based on animal data, may be irritating to the eyes

Multi-dose vials of influenza vaccine contain mercury. These may be given to pregnant women and children who may also receive an aluminum containing vaccine such as DTaP. The image at the right is Eli Lilly's Material Safety Data Sheet for Thimerosal, from Dec. 1999.[14] **Note the warning of genetic damage, fetal harm, and nervous system effects.**

Government Agencies and Scientists Voice Concerns About Aluminum

Department of Health and Human Services - Workshop on Aluminum in Vaccines

From May 11-12, 2000, the National Vaccine Program Office of the Department of Health and Human Services held a Workshop on Aluminum in Vaccines.[15] Participants included vaccinologists, rheumatologists, metal ion specialists, individuals with an interest in aluminum from academia, various government agencies from more than one government, the WHO, vaccine manufacturers, and interested individuals.

The workshop objective was to "explore and consider the complexities of the use and need for adjuvants and vaccines; to consider the potential benefits and potential hazards of the use of [aluminum] salts, of aluminum of adjuvants; and ... the newly described entity of macrophagic myofasciitis."[16]

Martin Myers, the acting director of the National Vaccine Program Office, noted that he learned at the last meeting (where thimerosal was discussed) that "**those of us who deal with vaccines have really very little applicable background with metals and with toxicological research**."[17]

Papers presented included:

- Overview of vaccine adjuvants: present and future
- Aluminum toxicokinetics regarding infant diet and vaccinations
- Mechanisms of stimulation of the immune response by aluminum adjuvants

[13] Exposure to Mercury and Aluminum in Early Life: Developmental Vulnerability as a Modifying Factor in Neurologic and Immunologic Effects, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4344667/
[14] Eli Lilly Material Safety Data Sheet - Thimerosal, http://whale.to/vaccine/thimerosal_data.pdf
[15] Workshop on Aluminum in Vaccines, May 11, 2000, https://autismhelpforyou.com/AL%20-%201.pdf, Workshop on Aluminum in Vaccines, May 12, 2000, https://autismhelpforyou.com/AL%20-%202.pdf
[16] ibid. May 11, p3
[17] ibid., May 11, pp1-2

- Lack of consistent relationship between quantity of aluminum in diphtheria–tetanus–acellular pertussis vaccines and rates of extensive swelling reactions
- The global impact of vaccines containing aluminium adjuvants
- Aluminum-containing vaccine associated adverse events: role of route of administration and gender
- Macrophagic Myofasciitis: a summary of Dr. Gherardi's presentations[18]

Some excerpts from the workshop transcript:

> "Dr. Gerber: Michael Gerber, National Institutes of Health.
>
> "Norman, **the standard of .85 milligrams of aluminum per dose** [allowable in each vaccine] set forth in the Code of Federal Regulations, **can you tell us where that came from** and how that was determined?
>
> "Dr. Baylor: **Unfortunately, I could not.** I mean, We have been trying to figure that out. **We have been trying to figure that out** as far as going back in the historical records and determining how they came up with that and going back to the preamble to the regulations. We just have been unsuccessful with that but we are still trying to figure that out."[19]

Dr. Clements from the WHO:

> "... Well, with minor qualifications that we have already touched on, in part, they are safe. ... And as far as we can tell, at this point, we have no evidence that they cause immune complex disorders ..."[20]
>
> "It is clear that the adjuvants that have been used in the past for the classical vaccines are unlikely to be suitable without modification for the future vaccines.
>
> "Secondly, just as thimerosal emerged its -- can I call it -- its ugly head last year and we we were all thrown into a situation of siege momentarily until we got the facts out to the public, the public is very much interested in what is in vaccines and what their children are getting ,and I believe this is something that we need to discuss in the the next two days.
>
> "The public is very much concerned with mercury and it is not so surprising that thimerosal with its mercury generated so much interest. **Aluminum is not perceived, I believe, by the public a dangerous metal and, therefore, we are in a much more comfortable wicket in terms of defending its presence in vaccines**. ...
>
> "I think the public does have a right to know what is going on. ... We must share what we know. And if we do not say what we know then it will be made up and we need to get our point across about vaccine safety from a strong point of view with good communications.
>
> "So, in wrapping up ... my conclusions would be that these vaccines that have had aluminum adjuvants in them have had an excellent track record of safety and efficacy for over 70 years."[21]

Dr. Carl Alving, Chief of the Department of Membrane Chemistry, Walter Reed Army Institute of Research delineated 5 expectations of adjuvants:

1. Bring the antigen in close contact with the immune system
2. Influence the type of immunity - humoral, antibodies, or mucosal
3. Influence the quality of the immune response

[18] Aluminum Adjuvants in Vaccines: Workshop Summary, https://www.sciencedirect.com/journal/vaccine/vol/20/suppl/S3
[19] Workshop on Aluminum in Vaccines, May 11, 2000, https://autismhelpforyou.com/AL%20-%201.pdf, pp46-47
[20] Workshop on Aluminum in Vaccines, May 11, 2000, https://autismhelpforyou.com/AL%20-%201.pdf, p54
[21] Ibid., pp 64-65

4. Influence the quantity of the immune response, such as the magnitude and duration
5. That the vaccines are safe - that they do not stimulate autoimmunity[22]

Dr. Gherardi:

> ”Aluminum hydroxide is very slowly eliminated as compared with many others and this may be why some people retain for a long period of time an adjuvant which has per se an immunoactivity (sic). So the persistence of an immunoactivator somewhere in the body for years can -- why not -- possibly induce immune activation -- systemic immunocativation at low levels with systemic cytokine, for instance, myalgias and so on.”

Dr. Myers:

“One of the difficult things that we all deal with all the time and one of the difficult -- one of the issues that is problematic with dealing with something like MMF, for example, is how we communicate information and how we communicate information that we are not clear about.”[23]

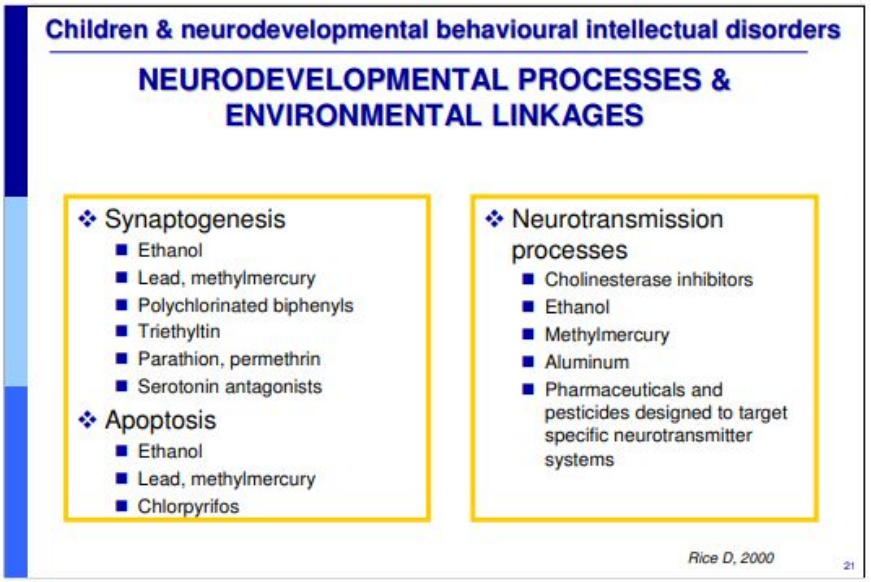
Workshop Summary - Dr. Theodore Eickhoff:

> “What troubles me are the uncertainty factors because they are -- well, just exactly what the name says. They are uncertainty factors and the fact that one conceivably could have 10^5 since there were five uncertainty factors listed... the maximum uncertainty factor, therefore, would be 10 raised to the fifth power or 100,000.
>
> “ATSDR [Agency for Toxic Substances and Disease Registry] took a look at that and said that is probably unacceptable and reduced it perhaps somewhat arbitrarily to 10ut we are still dealing with 1,000-fold uncertainty factor. it strikes me as a very imprecise science at best but it is a good place to start and probably the only place to start.
>
> “Nonetheless, it does bring up the issue of vaccine formulation and while I will certainly admit that it is more than black magic as someone alluded to yesterday, it still -- there is a great deal of empiricism that seems to go into selection of dose of aluminum adjuvants that goes into vaccine.
>
> “So an imprecise science at best.”[24]

The WHO: Aluminum is a neurotoxin

The WHO Training Package for the Health Sector identifies aluminum as interfering with neurotransmission processes in children’s neurodevelopmental processes.

> “Neurotransmission processes may be adversely affected by cholinesterase inhibitors, ethanol, methylmercury, aluminum, as well as pharmaceuticals and pesticides designed to target specific neurotransmitter systems.”[25]



[22] Ibid, pp. 68-69
[23] Workshop on Aluminum in Vaccines, May 12, 2000, https://autismhelpforyou.com/AL%20-%202.pdf, p124
[24] ibid, pp156-157
[25] Children and Neurodevelopmental Behavioural Intellectual Disorders, https://www.who.int/ceh/capacity/neurodevelopmental.pdf, p21

Weak studies are used to verify the safety of aluminum in vaccines

Scientists (including those at the vaccine workshop) who rely on prior aluminum safety studies and government statistics may be relying on insufficient and/or flawed/manipulated data.

> "The Keith et al. (2002) model was problematic for a number of reasons. The 1999 ATSDR MRL [minimum risk level] was based on ingested aluminium which is not comparable to injected aluminium. The Priest et al. (1995) and Flarend et al. (1997) studies on which Keith etal. (2002) depends are both characterised by a financial conflict of interest and their sample sizes are too small to be statistically valid. Keith et al. (2002) takes no account of differences in the blood brain barrier or renal function between adults and infants.
>
> "Even with an MRL that was arguably too high, the standard vaccine schedule exceeded it. Then ACIP [Advisory Committee on Immunization Practices] added even more aluminium containing vaccines to the schedule pushing the exposure levels even further above the MRL. ATSDR (2008) lowered the MRL to 1 mg Al/kg of body weight per day based on new animal studies on the dangers of ingested aluminium. The federal government, rather than changing the vaccine schedule, decided to create a new toxicokinetic model to show that the vaccine schedule was safe.
>
> "Mitkus et al. (2011) was written by five employees of the FDA, Center for Biologics Evaluation and Research and it updates the model from Keith et al. (2002) in light of ACIP increasing aluminum content in the schedule even as ATSDR was showing harms from ever-lower doses. ... Mitkus et al. (2011) change a number of assumptions about aluminium disposition and toxicity and conclude that 'the body burden of aluminum from vaccines and diet through an infant's first year of life is significantly less than the corresponding safe body burden of aluminum modeled using the [ATSDR (2008)] regulatory minimum risk level' (p. 9538). But that is not what their data show. Their data shows that the aluminium in the birth dose of hepatitis B vaccine and the vaccines in the 2 month visit exceed the MRL, the 4 month vaccines meets the MRL, and the 6 month vaccines nearly reach the MRL (Mitkus et al. 2011, p. 9541). They call these periods that exceed the MRL, 'brief excursions' without providing any discussion of the potential toxicological risks of those 'excursions' (Mitkus et al. 2011, p. 9541). Later in the paper they relax one of the assumptions (about the rate of release of aluminium from the injection site) and the 'brief excursions' then fall below the MRL and they thus declare the schedule safe (Mitkus et al., 2011, pp. 9541–9542).
>
> "Mitkus et al. (2011) acknowledge that there are reasons to question some of the assumptions in their model. The retention rate of aluminum that they use 'is based on results for only one person' — the adult male volunteer described above in Priest (1995) (Mitkus et al., 2011, p. 9542). They go on to say that 'pharmacokinetic data in infants or in more than one adult' would have been desirable and then quickly close the door to that possibility by writing, 'an expansion of this study is unlikely' (Mitkus et al., 2011, p. 9542). Then they acknowledge that their 'estimate of the rate and extent of absorption of aluminum hydroxide and [aluminium] phosphate following intramuscular injection [that comes from Flarend et al., 1997], are based on data from only two rabbits for each of the two adjuvants tested' — however they failed to acknowledge that all of the bone samples were lost as was the brain sample of one of the rabbits (Mitkus et al., 2011, p.9542).[26]

[26] The Political Economy of Autism, https://ses.library.usyd.edu.au/bitstream/handle/2123/20198/Rogers_T_thesis.pdf?sequence=2&isAllowed=y, pp304-306

Addendum

The Political Economy of Autism

Toby Rogers

A thesis submitted to fulfil the requirements for the degree of Doctor of Philosophy, Department of Political Economy, School of Social and Political Sciences, Faculty of Arts and Social Sciences, University of Sydney, 2019.

299

9.2.4 Is aluminium toxic (at the doses contained in the vaccine schedule)?

Nearly 100 years ago, scientists discovered that simply injecting killed viruses into people usually did not produce a robust immune response. So they started experimenting with adjuvants — substances that shock the body into producing a greater immune response. Ramon [1925] pioneered the use of adjuvants including 'starch, plant extracts, or fish oils combined with the diphtheria toxoid administered to horses' (Garçon, Hem, & Friede, 2018, p. 61). Glenny, Pope, and Waddington [1926], in experiments for the Pasteur Institute observed that if they combined aluminium potassium sulphate (also known as alum) with diphtheria toxoid that it improved the immune response to the vaccine (Garçon et al., 2018, p. 61). Over time various aluminium compounds were added to many vaccines, 'aluminum salts, in the form of aluminum oxyhydroxide or hydroxyphosphate, are the most widely used adjuvants in human vaccines' (Garçon et al., 2018, p. 61). However, 'there is still no consensus regarding the mechanisms by which aluminium-containing adjuvants potentiate the immune response' (Garçon et al., 2018, p. 66). Aluminium adjuvants have been injected 3 billion times into human bodies (Garçon et al., 2018, p. 66) and yet scientists are still not sure how they work.

14 'A Hedges' g is a measure of effect size... a g of 1 indicates the two groups differ by 1 standard deviation, a g of 2 indicates they differ by 2 standard deviations' (Glen, 2016).

300

The recent history of thimerosal and aluminium adjuvants are intertwined in important ways. Thimerosal was removed from many vaccines starting in 1999; manufacturing of many thimerosal containing vaccines stopped in 2001, but vaccines that were not past their expiration date were allowed to remain on the market until January 2003 (CDC, 2015a). The removal of thimerosal from vaccines was an extremely important natural experiment that would reveal whether in fact ethylmercury was responsible for the autism epidemic. But the CDC took actions during this period that introduced confounding factors that muddied the waters (Miller, 2016b). In February 2000, ACIP added 4 doses of the pneumococcus vaccine to the childhood schedule and each dose contains 125 µg of aluminium (Miller, 2016b, p. 109). In 2002, ACIP added two doses of influenza vaccine to the schedule for all children 6 to 23 months of age even though the majority of doses contain thimerosal (Miller, 2016b, p. 109). In 2004, ACIP recommended adding the flu vaccine for pregnant women even though thimerosal has been shown to cross the placenta barrier and the blood brain barrier in the fetus is not yet developed at that stage (Miller, 2016b, p. 109). In 2005, ACIP added two doses of hepatitis A vaccine to the childhood schedule and each dose contains 250 µg of aluminium (Miller, 2016b, p. 109). In 2011, ACIP added DTaP to the schedule for pregnant women which contains 625 µg of aluminium (Miller, 2016b, p. 109) even though aluminium has been shown in animal studies to cross the placenta barrier and foetal blood brain barrier (Yumoto et al. 2001). In all during this period, ACIP added to the schedule as much 25 µg of thimerosal and 625 µg of aluminium for pregnant women along with up to 50 µg of thimerosal and 1,000 additional µg of aluminium for children in the first two years of life (Miller, 2016b, p. 109). Offit, Reiss, and others routinely claim that the ‘removal of thimerosal from the schedule’ proves that vaccines are safe which is disingenuous because thimerosal was not completely removed from the

301

children's schedule, it was also added to the schedule for pregnant women, and the aluminium content increased for both pregnant women and young children and all of those are confounding factors. Regarding thimerosal, the actions of ACIP members during this period give lie to the notion that they are committed to proceeding out of an abundance of caution. Regarding aluminium, ACIP's actions appear to be guided by the belief that such adjuvants are safe. However, I will show below that the evidence used to demonstrate the safety of injected aluminium is weak.

Unlike metals such as copper or iron, 'aluminium has no known beneficial physiological action in the human body' (Morris, Puri, & Frye, 2017, p. 1347). The FDA, CDC, and vaccine spokespeople like Offit and Jew (2003) all tend to refer to aluminium adjuvants as 'aluminium salts' whereas critics point out that these are metals and often refer to 'aluminium nanoparticles'. Proponents tend to express units of adjuvants in milligrams whereas critics tend to write the units in micrograms both of which appear to be discursive choices to minimise or maximise the perception of the quantity. The technical names of the three aluminium adjuvants used in vaccines are crystalline aluminium oxyhydroxide (AlOOH), aluminium phosphate (made up of both Al-OH and Al-OPO3), and potassium aluminium sulphate (alum) AlK(SO4) (Garçon et al., 2018, pp. 63–64). Proponents point out that 'aluminium is the most abundant metal' on the surface of the earth; they also argue that aluminium adjuvants have been used in vaccines for over 80 years and then conclude that therefore it is safe (Offit & Jew, 2003; Garçon et al., 2018). Critics argue that the 80 year history of aluminium adjuvants fits their narrative just as well if not better (it is unclear whether Sukhareva's patients were exposed to aluminium adjuvants but Kanner's and Asperger's independent discoveries of autism occurred after the introduction of aluminium adjuvants in vaccines). The

302

scientific case in support of the safety of aluminium adjuvant is based mainly on experiments by Priest, Newton, Day, Talbot, and Warner (1995), and Flarend et al. (1997), and toxicokinetic models developed by Keith, Jones, and Chou (2002) for the ATSDR and Mitkus, King, Hess, Forshee, and Walderhaug (2011) for the FDA. Taking each of these studies in turn:

Priest et al. (1995) injected 0.7 μg of the radioactive isotope 26Al into a healthy 41-year old Caucasian male (p. 287). Blood samples were taken regularly for 880 days, urine and faeces were collected for 14 days, and whole-body radioactivity was measured daily for the first 10 days and then less frequently over a period of 1,178 days (Priest et al., 1995, p. 289). They found that 65% of the 26Al was excreted in the first 24 hours, that elimination continued but at a slower rate after that, and that 4% of the 26Al was still in the body after three years (Priest et al., 1995, p. 289). They speculated but were not able to confirm that the 4% of the 26Al that remained was deposited in the bone and that further depletion depended on bone turnover (Priest et al. 1995, p. 292). Two of the largest aluminium trade associations in the world funded the study — 'the Aluminum Association, Washington D.C. and the International Primary Aluminium Institute, London' (Priest et al., 1995, p. 292).

Flarend et al. (1997) injected intramuscularly 850 μg of aluminium hydroxide adjuvant (labeled with radioactive 26Al), into each of two New Zealand White rabbits and 850 μg of aluminium phosphate adjuvant (also labeled with radioactive 26Al) into each of two other New Zealand White rabbits. Blood and urine were collected before the start of the experiment and regularly for 28 days after injection (Flarend et al., 1997). The rabbits were killed on day 28 and tissues samples were taken from the 'brain, heart, left kidney,

303

liver, mesenteric lymph node, and spleen'; bone samples from the femur were taken but lost and the brain sample of one of the rabbits was lost as well (Flarend et al., 1997, p. 1315).

Over the course of 28 days, 6% of the aluminium hydroxide adjuvant and 22% of the aluminium phosphate was eliminated via urine (Flarend et al., 1997, p. 1316). The adjuvant that remained in the tissues was distributed as follows: 'kidney > spleen > liver > heart > lymph node > brain' (Flarend et al., 1997, p. 1317). In the discussion section, Flarend et al. (1997) declared that since the increase of aluminium in the blood of these rabbits was relatively small, the corresponding increase in plasma aluminium concentration in adult humans could be projected at 0.8% and that therefore aluminium adjuvants are safe (Flarend et al., 1997, p. 1318). This conclusion rests on two leaps of logic — that the conversion from rabbits to people is correct and that low levels in the blood cause no harms. No evidence is supplied to support either assertion. Furthermore, Flarend et al., (1997) performed no behavioral tests on the rabbits and they have no measure of what the long term effects of the aluminium deposits in the brain and other tissues would have been. It is also clear from the discussion section (and the small sample size and the fact they did not bother to fix problems like losing the brain tissue of 25% of their sample) that they saw this study as just a preliminary experiment and that other studies on aluminium adjuvant safety would surely follow. However, further studies of this type have not been done and public health officials have used Flarend et al. (1997) when they attempt to model the toxicity of aluminium in the vaccine schedule. Flarend et al. (1997) 'was supported in part by the Showalter Trust' (p. 1318); Robert E. Showalter was a former Vice-President and Board Member of Eli Lily and Company — one of the largest vaccine producers in the world.

304

Keith, Jones, and Chou (2002) at ATSDR built a model to estimate 'infant body burdens during the first year of life for breast milk and formula diets and for a standard vaccination schedule' (p. S13). They wanted to see whether infant body burdens exceeded the minimal risk level (MRL) of 2 mg Al/kg of body weight per day previously established by ATSDR (1999) for ingested aluminium (Keith et al., 2002). They rely on Priest et al. (1995) for the transfer rate from blood, the elimination rates, and retention functions and rely on Flarend et al. (1997) for the distribution pattern of aluminium in the body. They calculate that the body burden from aluminium in vaccines 'exceeds that from dietary sources' but is below the MRL except on the day of birth as a result of the hepatitis B vaccine and at the two-month vaccinations; the four month and six month vaccinations also reach the MRL but do not exceed it (Keith et al., 2002, p. S15).

The Keith et al. (2002) model was problematic for a number of reasons. The 1999 ATSDR MRL was based on ingested aluminium which is not comparable to injected aluminium. The Priest et al. (1995) and Flarend et al. (1997) studies on which Keith et al. (2002) depends are both characterised by a financial conflict of interest and their sample sizes are too small to be statistically valid. Keith et al. (2002) takes no account of differences in the blood brain barrier or renal function between adults and infants. Even with an MRL that was arguably too high, the standard vaccine schedule exceeded it. Then ACIP added even more aluminium containing vaccines to the schedule pushing the exposure levels even further above the MRL. ATSDR (2008) lowered the MRL to 1 mg Al/kg of body weight per day based on new animal studies on the dangers of

305

ingested aluminium. The federal government, rather than changing the vaccine schedule, decided to create a new toxicokinetic model to show that the vaccine schedule was safe. Mitkus et al. (2011) was written by five employees of the FDA, Center for Biologics Evaluation and Research and it updates the model from Keith et al. (2002) in light of ACIP increasing aluminum content in the schedule even as ATSDR was showing harms from ever-lower doses. As I showed in chapter 5, the FDA is a conflicted party because it relies on fees from companies they regulate and because they accept corporate donations through the Reagan-Udall Foundation for the FDA, Inc. Given the stakes, it is problematic, to say the least, that this paper was not written by an independent body. Mitkus et al. (2011) change a number of assumptions about aluminium disposition and toxicity and conclude that 'the body burden of aluminum from vaccines and diet through an infant's first year of life is significantly less than the corresponding safe body burden of aluminum modeled using the [ATSDR (2008)] regulatory minimum risk level' (p. 9538). But that is not what their data show. Their data shows that the aluminium in the birth dose of hepatitis B vaccine and the vaccines in the 2 month visit exceed the MRL, the 4 month vaccines meets the MRL, and the 6 month vaccines nearly reach the MRL (Mitkus et al. 2011, p. 9541). They call these periods that exceed the MRL, 'brief excursions' without providing any discussion of the potential toxicological risks of those 'excursions' (Mitkus et al. 2011, p. 9541). Later in the paper they relax one of the assumptions (about the rate of release of aluminium from the injection site) and the 'brief excursions' then fall below the MRL and they thus declare the schedule safe (Mitkus et al., 2011, pp. 9541–9542).

306

Mitkus et al. (2011) acknowledge that there are reasons to question some of the assumptions in their model. The retention rate of aluminum that they use 'is based on results for only one person' — the adult male volunteer described above in Priest (1995) (Mitkus et al., 2011, p. 9542). They go on to say that 'pharmacokinetic data in infants or in more than one adult' would have been desirable and then quickly close the door to that possibility by writing, 'an expansion of this study is unlikely' (Mitkus et al., 2011, p. 9542). Then they acknowledge that their 'estimate of the rate and extent of absorption of aluminum hydroxide and [aluminium] phosphate following intramuscular injection [that comes from Flarend et al., 1997], are based on data from only two rabbits for each of the two adjuvants tested' — however they failed to acknowledge that all of the bone samples were lost as was the brain sample of one of the rabbits (Mitkus et al., 2011, p. 9542). So by their own admission, the safety of the vaccine schedule, administered to more than 90% of all children in the U.S., comes down to a model based on estimates of the toxicokinetics of aluminium from one adult male human and three rabbits.

Criticisms of Mitkus et al. (2011) have been withering. Masson, Crépeaux, Authier, Exley, and Gherardi (2017) point out that Mitkus et al. (2011) once again used an ingested MRL that is not comparable to injected aluminium toxicity, failed to distinguish between different types of aluminium adjuvants, misunderstood or misrepresented aluminium transport in the body, ignored animal studies that show that the ATSDR MRL is too high (by a factor of 17), and overestimated the rate of elimination of aluminium from the body, amongst other concerns. Masson et al. (2017) was funded by an interesting mix of institutions — ANSM (roughly the French equivalent of the FDA), the Ile-de-France Region of the PICRI Program (Institutions

307

and Citizens for Research and Innovation), and well known vaccine safety critics, the Children's Medical Safety Research Institute (CMSRI).

Critics of vaccine safety have created a large body of research on the toxicity of aluminium and the dangers of aluminium in vaccines.

Christopher Exley, perhaps the world's leading expert on aluminium toxicity, has authored 98 journal articles on the toxicity of aluminium beginning with toxicokinetics in animals, then studying the possible role of aluminium in Alzheimer's Disease, and more recently looking at whether aluminium in vaccines might be a factor in causing autism. Christopher Shaw and Lucija Tomljenovic, both at the University of British Columbia, have produced more than 20 studies on aluminium toxicity and many of them have focused on the possible role of aluminium in ASD. The volume of critical literature is so large that it is not possible to cover it all in this section so I will highlight a few key studies.

Miller (2016b) provides a brief historical literature review of critical aluminium studies including a case of industrial aluminium poisoning [Spofforth, 1921] and animal experiments that showed harm when aluminium hydroxide cream was applied to the brains of monkeys [Chusid, Pacella, Kopeloff, & Kopeloff, 1951; Driver, Ettlinger, Moffett, & St. John-Loe, 1968]. Baylor, Egan, and Richman (2002) note that 'the British Ministry of Health recommended aluminium-free vaccines in 1957' (p. S20).

Bishop, Morley, Day, and Lucas (1997) randomly assigned 227 premature infants who required intravenous feeding to receive either standard feeding solution (that contained

308

25 µg of aluminium per decilitre) or a special feeding solution (that contained 2.2 µg of aluminium per decilitre); the neurodevelopment of the surviving infants (n = 182) was then assessed at 18 months of age (p. 1557). They found that the 'aluminum exposure from the standard intravenous solutions was... associated with a mean loss of one point on the Bayley Mental Development Index per day of full intravenous feeding, after adjustment for potentially confounding factors' (Bishop et al., 1997, p. 1561). Longterm exposures were associated with even more severe outcomes. 'In infants fed intravenously for 10 or more days, those receiving the standard solution had a major (10 point) deficit in their Mental Development Index and were twice as likely to have a Mental Development Index below 85' which is a key threshold that indicates the risk of later learning problems (Bishop et al., 1997, p. 1561).

Zheng (2001) shows that, in animal studies, aluminium exposure increases the permeability of the blood-brain barrier. Tomljenovic and Shaw (2011a), ran a correlation analysis between rising amounts of aluminium in national vaccine schedules around the world and rising prevalence rates of autism. They found that

(i) children from countries with the highest ASD prevalence appear to have the highest exposure to Al from vaccines; (ii) the increase in exposure to Al adjuvants significantly correlates with the increase in ASD prevalence in the United States observed over the last two decades (Pearson $r=0.92$, $p<0.0001$); and (iii) a significant correlation exists between the amounts of Al administered to preschool children and the current prevalence of ASD in seven Western countries, particularly at 3–

309

4 months of age (Pearson r=0.89–0.94, p=0.0018–0.0248)' (Tomljenovic and Shaw, 2011a, p. 1489).

What is more, they argue that their results satisfy eight out of nine of Hill's (1965) criteria for establishing causality. Tomljenovic and Shaw (2011a) was supported by the Katlyn Fox Foundation founded by a mother who lost her daughter to Sudden Infant Death Syndrome following vaccination and the Dwoskin Family Foundation that funds vaccine safety research among other areas. Christopher Shaw is also the chair of the Scientific Advisory Board for the CMSRI that was founded by Claire Dwoskin.

The Global Advisory Committee on Vaccine Safety (GACVS) at the World Health Organization (WHO) in their meeting of 6–7 June 2012 felt compelled to respond to Tomljenovic and Shaw (2011a and 2011b). The GACVS called the two papers 'seriously flawed'; they pointed out that Tomljenovic and Shaw (2011a and 2011b) are ecological studies that are best used for generating hypotheses rather than drawing causal comparisons (WHO, 2012). Then GAVCS went one step further and held up Mitkus et al. (2011) as 'a comprehensive risk assessment that further supports the clinical trial and epidemiological evidence of the safety of aluminium in vaccines' (WHO, 2012). Given everything that is known about the limitations of Mitkus et al. (2011) to call it 'comprehensive' is not credible and raises troubling questions about the objectivity of the GACVS and WHO.

Khan et al. (2013) injected intramuscularly three different mice strains with 18 μg of aluminium oxyhydroxide adjuvant — a dose designed (via allometric conversion) to match the aluminium dose given to children via the U.S. vaccine schedule. They found

310

that aluminium oxyhydroxide adjuvant was well tolerated in normal mice but that aluminium nanoparticles ended up in the brains of mice specifically bred with a weak blood brain barrier or high tissues levels of what is called CCL2 — a key protein in the immune system (Khan et al. 2013, p. 16). The authors concluded that 'continuously escalating doses of this poorly biodegradable adjuvant in the population may become insidiously unsafe...' (Khan et al., 2013, p. 1). The research was supported by funding from two French patients' associations representing those suffering from muscle diseases (Khan et al., 2013, p. 16).

Crépeaux et al. (2017) injected aluminium oxyhydroxide (known as Alhydrogel) adjuvant into mice at 200, 400 and 800 µg/kg of body weight. They found that Alhydrogel does not follow a linear dose response curve and that the group exposed to lower doses (200 µg/kg) exhibited more neurobehavioral changes and had higher levels of cerebral Al levels than groups exposed to higher doses (Crépeaux et al. 2017, p. 48). Further testing revealed that the 200 µg dose was composed exclusively of 'small aluminium nanoparticles' that they speculated may travel into the brain more easily. One of the important takeaways from their study is that the classic 'the dose makes the poison' rule of toxicology does not appear to apply to Alhydrogel — the most used adjuvant in vaccines today (Crépeaux et al. 2017, p. 48).

Mold, Umar, King, and Exley (2017) examined the post-mortem brain tissue of four men and one woman who had received a diagnosis of autism during their lives. House, Esiri, Forster, Ince, and Exley (2012) had previously conducted a study of aluminium in the brain tissue of 60 donors; based on that study, Mold et al. (2017) established baselines of ≤1 µg/g dry weight as 'pathologically benign', ≥2.0 µg/g dry weight as

311

'pathologically concerning', and ≥3.0 μg/g dry weight as 'pathologically significant' (p. 78). 'The brains of all 5 donors had at least one tissue sample with a pathologically significant content of aluminium' (Mold et al., 2017, p. 78). They commented, 'We recorded some of the highest values for brain aluminium ever measured in healthy or diseased tissues in these male ASD donors including values of 17.10, 18.57, and 22.11 μg/g dry weight' (Mold et al., 2017, p. 81) with the only similar comparator being 'a 42 year old male with familial Alzheimer's disease' (Mirza, King, Troakes, & Exley, 2017). Mold et al. (2017) has been criticised for small sample size (n = 5), not having a control group, and the fact that it was funded by the CMSRI — a well-known vaccine safety advocacy group (Gorski, 2017).