Pediatric Dosing of Aluminum in Vaccines:
Comparisons of Schedules

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1/5/2020

at the

**University of California Los Angeles** 





## Journal of Trace Elements in Medicine and Biology

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Reconsideration of the immunotherapeutic pediatric safe dose levels of



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### ARTICLEINFO

Provisional tolerable weekly intake Regulatory elements Pediatric dosing No observed adverse effect level Neonatal vaccination

FDA regulations require safety testing of constituent ingredients in drugs (21 CFR 610.15). With the exception of extraneous proteins, no component safety testing is required for vaccines or vaccine schedules. The dosing of aluminum in vaccines is based on the production of antibody titers, not safety science. Here we estimate a Pediatric Dose Limit that considers body weight. We identify several serious historical missteps in past analyses of provisional safe levels of aluminum in vaccines, and provide updates relevant to infant aluminum exposure in the pediatric schedule considering pediatric body weight. When aluminum doses are estimated from Federal Regulatory Code given body weight, exposure from the current vaccine schedule are found to exceed our estimate of a weight-corrected Pediatric Dose Limit. Our calculations show that the levels of aluminum suggested by the currently used limits place infants at risk of acute, repeated, and possibly chronic exposures of toxic levels of aluminum in modern vaccine schedules. Individual adult exposures are on par with Provisional Tolerable Weekly Intake "limits", but some individuals may be aluminum intolerant due to genetics or previous exposures Vaccination in neonates and low birth-weight infants must be re-assessed; other implications for the use of aluminum-containing vaccines, and additional limitations in our understanding of neurotoxicity and safety levels of aluminum in biologics are discussed.

1. Introduction

Aluminum is used as an adjuvant in vaccines licensed by the US

time, there are no known or published studies specifically defining le-

vels of Al in any vaccine product based on safety studies of Al. Safety for aluminum from all sources is based on the No Observed

## Blinded peer-review





## Journal of Trace Elements in Medicine and Biology



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### Toxicology

Acute exposure and chronic retention of aluminum in three vaccine schedules and effects of genetic and environmental variation



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### ARTICLE INFO

Keywords: Vaccines Aluminum Autoimmunity Chronic health

### ABSTRACT

Like the mechanisms of action as adjuvants, the pharmacodynamics of injected forms of aluminum commonly used in vaccines are not well-characterized, particularly with respect to how differences in schedules impact accumulation and how factors such as genetics and environmental influences on detoxification influence clearance. Previous modeling efforts are based on very little empirical data, with the model by Priest based on whole-body clearance rates estimated from a study involving a single human subject. In this analysis, we explore the expected acute exposures and longer-term whole-body accumulation/clearance across three vaccination schedules: the current US Centers for Disease Control and Prevention (CDC) schedule, the current CDC schedule using low aluminum or no aluminum vaccines, and Dr. Paul Thomas' "Vaccine Friendly Plan" schedule. We then study the effects of an implicit assumption of the Priest model on whether clearance dynamics from successive doses are influenced by the current level of aluminum or modeled by the assumption that a new dose has its own whole-body dynamics "reset" on the day of injection. We model two additional factors: variation (deficiency) in aluminum detoxification, and a factor added to the Priest equation to model the potential impact of aluminum itself on cellular and whole-body detoxification. These explorations are compared to a previously estimated pediatric dose limit (PDL) of whole-body aluminum exposure and provide a new statistic: %alumTox, the (expected) percentage of days (or weeks) an infant is in aluminum toxicity, reflecting chronic toxicity. We show that among three schedules, the CDC schedule results in the highest %alumTox regardless of model assumptions, and the Vaccine Friendly Plan schedule, which avoids > 1 ACV per office visit results in the lowest (expected) % alumTox. These results are conservative, as the MSL is derived from data used by FDA to estimate safety of aluminum in adult humans. These results demonstrate high potential utility of modeling variation in patient responses to aluminum. More empirical data from individuals who are suspected of being intolerant of aluminum from vaccines, evidenced by high aluminum retention, neurodevelopmental disorders and/or a myriad of



2020

# CDC

Vaccine	Aluminum Content (ug)* per dose	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16-18 yrs
lepatitis B1 (HepB)	250	1st dose		2nd dose		3rd dose											
Botavirus2 (RV)	0			1st dose	2nd												
RV1 (2-dose series): RV5 (3-dose series)				101 0000	dose												
Diphtheria, tetanus, & acellular entussis3 (DTaP: <7 yrs)	625			1st dose	2nd dose	3rd dose				←4th dose→			5n dose				
daemophilus influenzae type b4. Hib)	225			1st dose	2nd dose			←3rd or 4th dose,									
Pneumococcal conjugate5 PCV13)	125			1st dose	2nd dose	3rd dose		←4th dose->									
nactivated poliovirus6 (IPV:<18, (rs)	0			1st dose	2nd dose	←3rd dose→							←4th dose→				
InfluenzaZ (IIV: LAIV)	0					Annua		ation (IIV only) doses	1 or 2	vaccina	nual tion (IIV r 2 doses	vaccina	nual tion (IIV r 2 doses		Annual vac	ocination (IIV o doses	only) 1 or 2
Measles, mumps, rubella8 (MMR)	0							1st dose					2nd dose				
Varicella9 (VAR)	0							1st dose					2nd dose				
depatitis A10 (HepA)	250							1st dose		2nd. dose							
Meningococcal11 (Hib-MenCY ≥ 5 weeks: MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)	0														1st dose		
Tetanus, diphtheria, & acellular pertussis12 (Tdap: ≿7 yrs)	330														(Tdap)		
Human papillemavirus13. 2vHPV:females only: 4vHPV. 2vHPV:males and females)	0														(3 dose series)		
Veningococcal B11	0																
Pneumococcal polysaccharide5 PPSV23)	Unknown																
	* Total ug not adjusted to	250		1225	975	1000		600		875							

# Vaccine Friendly Plan









# Vaccine Plan Dr. Paul Thomas, M.D., F.A.A.P.

Since 2008, Dr. Paul and the team at Integrative Pediatrics LLC have been using the plan outlined below. Combining this vaccine plan with exclusive breastfeeding, eating a diet of real food, getting enough vitamin D, exercising, and avoiding toxins like acetaminophen, aspartame, and glyphosate, the children in his practice have experienced superior health, and a significantly lower rate of autism (0 in 1176) than the national average, which is 1 in 45.

If you have autism in the family, a history of autoimmune disorders, or an MTHFR mutation: delay vaccines until at least age five.

No vaccines (No Tdap, No flu) Pregnancy:

Birth: No Hep B

Hib, DTaP (No Hep B, Rotavirus, IPV) 2 months:

3 months: Prevnar

4months: Hib, DTaP (No Rotavirus, IPV)

5 months: Prevnar

6 months: Hib, DTaP (No Hep B, Rotavirus, IPV)

7-9 months:

1 year: Hib, Prevnar (No MMR, Hep A, Varicella)

DTaP, 18 months: 2 years (No Hep A)

Consider MMR (always give MMR by itself) 3 years:

4 - 6 years: DTaP, (consider Varicella, IPV) 10 years: **Tdap** (boost every 5 - 10 years)

Menveo or Menactra (meningococcal), Varicella 11 years:

12-14 years: Hepatitis B (3 dose series)

Menveo or Menactra & consider meningococcal B, Hepatitis A 16 - 18 Years:

# Why Reduce Aluminum?

- Aluminum is found in amyloid, the protein/non-protein aggregates in Alzheimer's brain
- Aluminum hydroxide is used to routinely and reliably induce autoimmune conditions in animals (mice & rats)

Disruption of erythropoesis and RBC function

- Osteomalacia in bone
- Cholestasis in liver
- Aluminum inhibits defensive mechanisms connected with white blood cells and macrophages
- https://www.ncbi.nlm.nih.gov/pubmed/16146022



## Aluminium Induced Endoplasmic Reticulum Stress Mediated Cell Death in SH-SY5Y Neuroblastoma Cell Line Is Independent of p53



Syed Husain Mustafa Rizvi<sup>1</sup>, Arshiya Parveen<sup>1</sup>, Anoop K. Verma<sup>2</sup>, Iqbal Ahmad<sup>3</sup>, Md Arshad<sup>4</sup>, Abbas Ali Mahdi<sup>1</sup>\*

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## Abstract

Aluminium (Al) is hold utensils, me variety of neurod in endoplasmic r

"Overall our findings suggest that Al induces ER stressand ROS generation which compromises the antioxidant defenses of neuronal cells thereby promoting neuronal apoptosis in p53 independent

observed that AI caused extress by increasing ROS production and intracellular calcium levels together with depletion of intracellular CSIP levels. We also studied modulation of key pro- and anti-apoptotic proteins and found significant alterations in the levels of Nrf2, NQO1, pAKT, p21, Bax, Bcl2, Aβ1-40 and Cyt c together with increase in endoplasmic reticulum (ER) stress related proteins like CHOP and caspase 12. However, with respect to the role of p53, we observed downregulation of its transcript as well as protein levels while analysis of its ubiquitination status revealed no significant changes. Not only did AI increase the activities of caspase 9, caspase 12 and caspase 3, but, by the use of peptide inhibitors of specific and pan-caspases, we observed significant protection against neuronal cell death upon inhibition of

# Aluminum-induced Defective Mitochondrial Metabolism Perturbs Cytoskeletal Dynamics in Human Astrocytoma Cells

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Although aluminum (Al), a known environmental toxin, has been implicated in a variety of neurological disorders, the molecular mechanism responsible for these conditions is not fully understood. In this report, we demonstrate the ability of Al to trigger mitochondrial dysfunction and ineffective adenosine triphosphate (ATP) production. This situation severely affected cytoskeletal dynamics. Whereas the control cells had well-defined structures, the Al-exposed astrocytoma cells

gradient, which is tapped to drive ATP formation (Yoshida et al., 2001). Complex eukaryotes also rely on other sources of ATP such as phosphogens in order to sustain energy demands (Sauer and Schlattner, 2004). Highly oxidative tissues such as the human brain and skeletal muscle invoke creatine kinase (CK) to produce ATP from phosphocreatine when energy is in high demand (Saks et al., 1996).

The brain consumes the most energy in the human

LEMIRE ET AL.
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IMPAIRS
CELLULAR
ENERGETICS
AND
CYTO SKELETAL
STRUCTURE

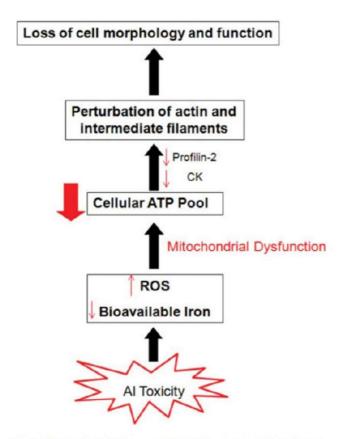
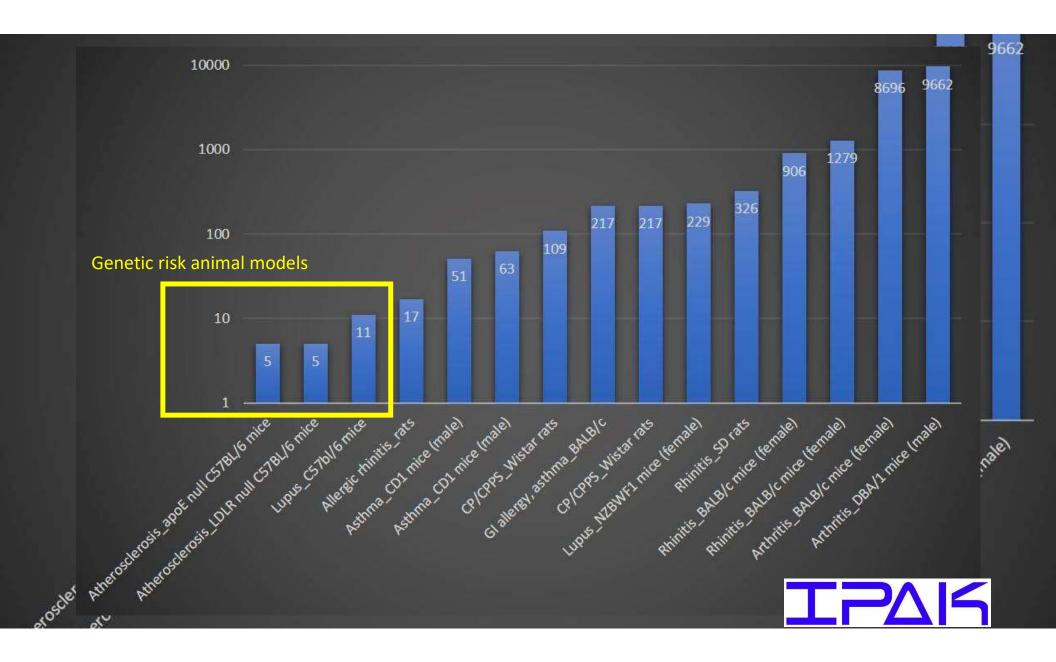


Fig. 9. Molecular link between Al toxicity and morphological perturbation in human astrocytoma cells. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Citation (et al.)	Condition	Animal	bw (g)*	bw (kg)	AL dose (mcg)	AL dose (mg)	mcg/kg	mg/kg	human max exposure** (mcg/kg)	x human max exposure
Zhu[37]	Atherosclerosis	apoE null C57BL/6 mice	20	0.02	25	0.025	1250	1.25	230	5
Zhu[37]	Atherosclerosis	LDLR null C57BL/6 mice	20	0.02	25	0.025	1250	1.25	230	5
Kelly-Scumpia[38]	Lupus	C57bl/6 mice	20	0.02	50	0.05	2500	2.50	230	11
Yasar[39]	Allergic rhinitis	Rats	250	0.25	1000	1	4000	4.00	230	17
Elsakkar[40]	Asthm a	CD1 mice (male)	25	0.025	292	0.292	11680	11.68	230	51
Elsakkar[40]	Asthm a	CD1 mice (male)	20	0.02	292	0.292	14600	14.60	230	63
Qi[41]	CP/CPPS	Wistarrats	250	0.25	6250	1.25	25000	5.00	230	109
Brandt[42]	GI allergy, asthma	BALB/c	20	0.02	1000	1	50000	50.00	230	217
Qi[41]	CP/CPPS	Wistarrats	250	0.25	12500	2.5	50000	10.00	230	217
Agmon-Levin[43]	Lupus	NZBWF1 mice (female)	38	0.038	2000	40	52631	1052.63	230	229
Yang[44]	Rhinitis	SDrats	400	0.4	30000	30	75000	75.00	230	326
Xi[45]	Rhinitis	BALB/c mice (female)	24	0.024	5000	5	208333	208.33	230	906
Xi[45]	Rhinitis	BALB/c mice (female)	17	0.017	5000	5	294117	294.12	230	1279
Sagawa[46]	Arthritis	BALB/c mice (female)	20	0.02	40000	40	2000000	2000.00	230	8696
Sagawa[46]	Arthritis	DBA/1 mice (male)	18	0.018	40000	40	2222222	2222.22	230	9662

\*\* estimated at 1225 mcg AL/5.326 kg (median body weight @ 2 mos.). Meant to be typical.





Observed Adverse Effects Level (LOAEL).

Each of the established FDA-approved doses of 850 μ 1250 μg were converted to the equivalent dose expressusing Clark's Rule [28,39]:

Child's Dose (mg) = Adult Dose (mg) 
$$\times \frac{BW(Child)lbs}{BW(Adult)lbs}$$

The body weights for infants from birth through 24 mc the Clark's Rule calculation were obtained using calcular growth velocities obtained from Weight for Age standards females from the 5th to the 95th percentile [40,41]. The diatric doses were compared to the same doses in an adby the body weight of 60 kg.

\*inimal risk level of aluminum in children



## Clark's Rule

- •FDA Adult Limit 850 mcg *per dose*
- •FDA Pediatric Limit: ???????????

# Mitkus et al. – The FDA's Paper on Aluminum

- Used a model by Priest et al .which is based on human clearance of citrated aluminum forms (form in vaccines are not citrated)
- Data for the models in two studies were from 1 and 6 males (adults)
- Mitkus adjusted the model using data from creatine in infants
- MRL was derived from ATSDR oral limits
- ATSDR had picked 1 study and misrepresented the findings of Golub et al. [Next Slide]
- In P/K, the focus tends to be on plasma/serum clearance
- Mitkus assumes excretion via the kidney is similar to creatine (aluminum damages animal tissue) [Incorrect]
- Our concern is the accumulation (body burden) originally realized in the first Priest et al. study [because aluminum has known toxic effects in human tissue]



In 1996, the Committee on Nutrition in their article on neurotoxicity in children reported the 1989 JECFA provisional to weekly intake of  $1000\,\mu\text{g/kg}$  [12] as a provisional daily intake [14]. fortunately, that error overestimates the provisional tolerable daily intake of aluminum from all sources in adults by a factor of at least 2. As the  $1000\,\mu\text{g/kg/week}$  PTWI was in fact replaced with a PTWI of  $2000\,\mu\text{g/kg/week}$  week in 2011, the daily provisional tolerable intake should be around  $286\,\mu\text{g/kg}$  per day, and in consideration that the highest mean intake of a hild at 2 years is  $500\,\mu\text{g/kg}$  per day [15]. The value  $1000\,\mu\text{/kg/day}$  has eem to bring the  $850\,\mu\text{g}$  per dose into range, but it is off by a factor has 2 and perhaps seven. The role of the reliance on the incorrect highlic health may be significant, especially for infants, especially highly infants and those born prematurely.

Provenance of PTWI Limit ERROR found by Lyons-Weiler & Ricketson (2018)

# Disagreement Between Two Committees

## **JEFCA**

Joint FAO/WHO Expert Committee on Food Additives

- 1989. Provisional Tolerable Weekly Intake (PTWI) established at 1 mg/kg all dietary sources and additives.
   Mean highest daily intake US children 0.5 mg Al/kg per day<sup>1</sup>
- 2011. Previous PTWI of 1 mg Al/kg withdrawn. Revised PTWI to 2 mg/kg (adults)<sup>2</sup>

## **ATSDR**

**Agency for Toxic Substances Disease Registry** 

- 2008 (CAS ID #: 7429-90-5)<sup>3</sup>
- Daily dietary intake of Al 2 mg/kg-day in adults
- Minimal Risk Level (MRL) 1 mg/kg-day (adults) same as No Observed Adverse Effect Level (NOAEL)



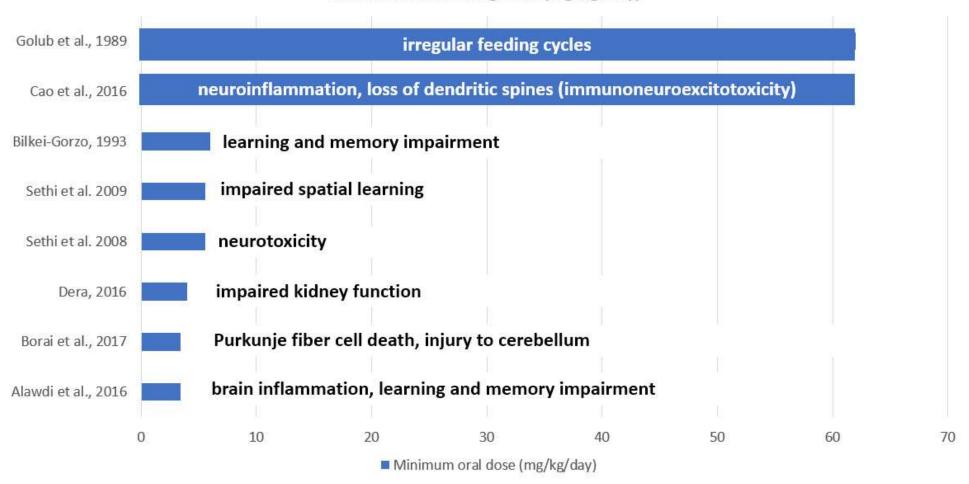
<sup>1</sup>Evaluation of certain food additives and contaminants [Thirty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 776, 1989 <sup>2</sup> Evaluation of certain food additives and contaminants (Seventy fourth report of the Joint FAO/WHO Expert Committee on Food Additives) WHO Technical Report Series, JECFA/74/SC, 2011 <sup>3</sup>Agency for Toxic Substances and Disease Registry (ATSDR) CAS ID #: 7429-90-5

# How did 1 mg Al/kg week become 1 mg/kg –day and 850 mcg per dose regardless of body weight

- 1981-CFR amended to include 1250 µg/dose
- 1996-2007 PTWI estimated at 1 mg/kg/week; 0.5 mg/kg-day US child > 2 years of age (WHO Evaluation and Certain Food Additives and Contaminants. Section 4.1 Aluminum, 1996-2007)
- 1996 Committee on Nutrition Aluminum Neurotoxicity in Infants and Children (J Pediatrics),
  - 1 mg/kg-day (in error as to PTWI- "provisional tolerable intake")
- 2001 **0.85** mg "selected empirically from data because it enhance the antigenicity and effectiveness of the vaccine" (Baylor et al 2001)
- 2001-2008 ATSDR set MRL/NOAEL to 1 mg/kg-day from all sources based on Golub 26 mg/kg-day NOAEL (ATSDR references Baylor et al (2001),
- 2001 MRL/NOAEL 2 mg/kg-day in adult humans from dietary sources (Golub et al 2001 (62 mg/kg-day, Keith et al)
- 2011 MRL=1 mg/kg bw/day (ATSDR, 2008), Mitkus (2011)
- 2017: CFR is 850 μg/DOSE.



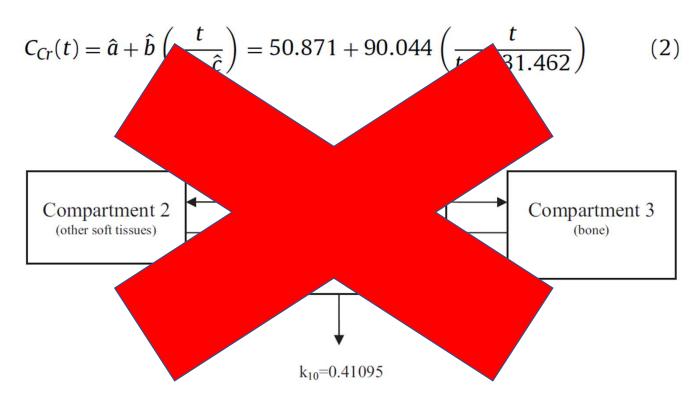
## Minimum AL dose ingested (mg/kg/day)







# Mitkus' Three-Compartment Model



**Fig. 1.** Three-compartment model of aluminum disposition in adults. Rate constants were derived from the retention equation of Priest [5].

# Flarend Rabbit Study (N=6)

Adjuvant	AUC for 0-28 days (mg h g <sup>-1</sup> )	% Absorbed in 28 days	Cumulative aluminium in urine after 28 days (%)
Aluminium hydroxide		499	
Rabbit 1	$2.0 \times 10^{-4}$	13	5.0
Rabbit 2	$3.5 \times 10^{-4}$	22	6.2
Average	$2.7 \times 10^{-4}$	17	5.6
Aluminium phosphate			
Rabbit 3	$2.7 \times 10^{-4}$	47	10
Rabbit 4	$8.7 \times 10^{-4}$	55	33
Average	$8.1 \times 10^{-4}$	51	22

- Injected radioactive ALPO4 and ALOH3 into rabbits
- Only 5.6% of the ALOH3 had been cleared from the body after 28 days (22 days fors ALPO4)

## Flarend found low clearance rate from blood

 "The aluminum concentration [in blood] produced by AH [Al hydroxide] adjuvant at 1 hour was similar to the concentrations found from 2 to 28 days."

Clearly something is different between rabbits and humans?

# Movsas Infant Study (N=15)

Found aluminum serum levels rose 1% immediately after vaccination.

"We were reassured to find no significant postvaccine rise in serum aluminum level after vaccination of preterm infants with vaccines containing a total of 1200 μg of aluminum." (JAMA Pediatrics, Letter)



## Our Question

- If 850-1150 mcg is a **regulated level per dose in human adults (FDA)**, since FDA has never published a pediatric dose limit (PDL) for humans, what might a scaled human dose limit look like?
- We considered bodyweight and allometric scaling (Clark's Rule)
- We adapted Priest's model as a liberal model of excretion.

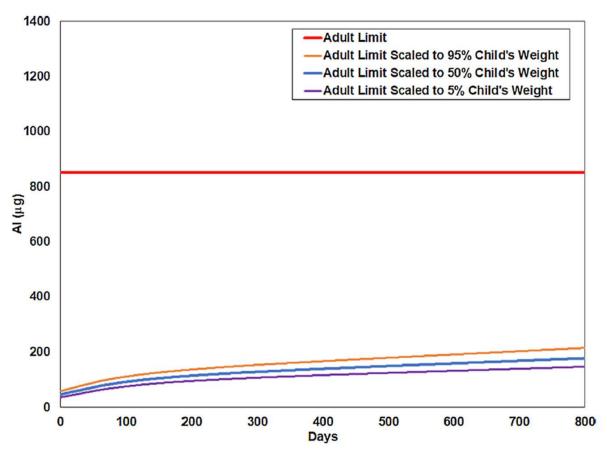


Fig. 1. FDA Adult aluminum per dose limit scaled to child's weight (Clark's Rule) following Lyons-Weiler and Ricketson [27].

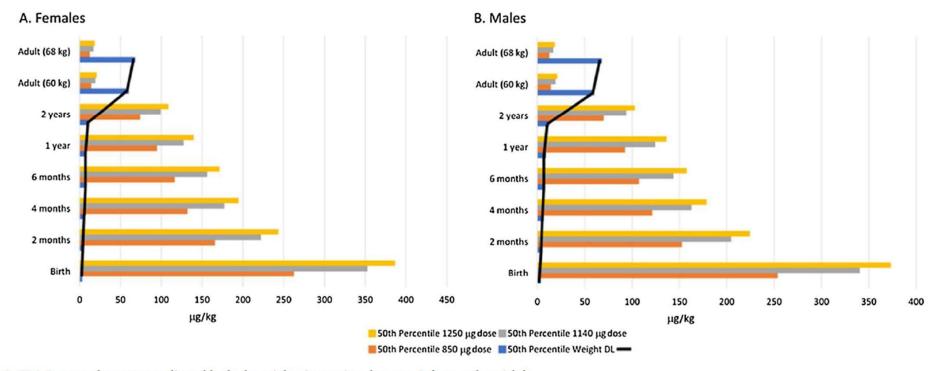


Fig. 2. FDA Doses and exposures adjusted by body weight: Comparison between Infants and an Adult.

In a male child from birth through 36 months at the 50th percentile body weight, the FDA dose of 850 µg adjusted by body weight demonstrates that an adult weighing 60 kg receives significantly less aluminum per injection per kg compared to a child, particularly those children with lower body weights.

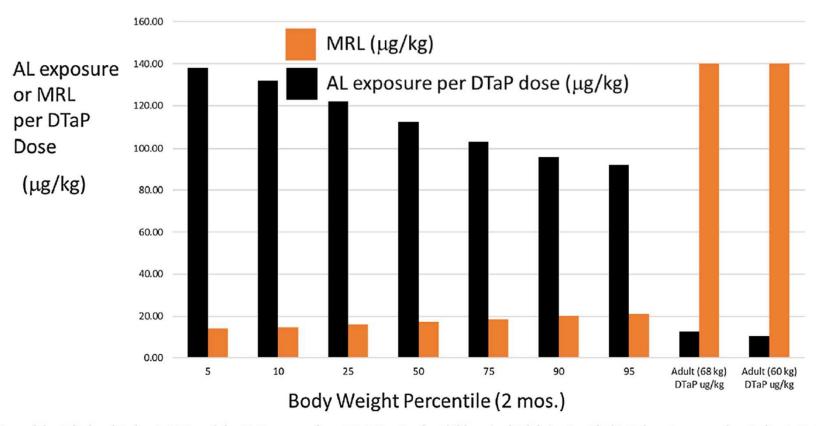
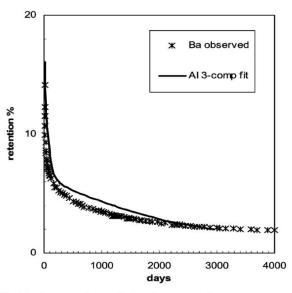


Fig. 4. Comparison of the Calculated Pediatric MRL and the AL Exposures from DTaP Vaccine for Children (and Adults) using Clark's Rule to Accommodate Pediatric Body Weights ( $\mu$ g/kg, per day, at 2 months and for Adult).

# Priest model

## Clearance of single doses in a few individuals



**Fig. 14** A comparison of the long-term clearance patterns of aluminium-26 and barium-133–a bone-seeking element–from a volunteer injected with both isotopes, but at different times.

CRITICAL REVIEW

The biological behaviour and bioavailability of aluminium in man, with special reference to studies employing aluminium-26 as a tracer: review and study update†

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Received 7th November 2003, Accepted 26th March 2004 First published as an Advance Article on the web 23rd April 2004

Until 1990 biokinetic studies of aluminium metabolism and biokinetics in man and other animals had been substantially inhibited by analytical and practical difficulties. Of these, the most important are the difficulties in differentiating between administered aluminium and endogenous aluminium—especially in body fluids and excreta and the problems associated with the contamination of samples with environmental aluminium. As a consequence of these it was not possible to detect small, residual body burdens of the metal following experimentations. Consequently many believed aluminium to be quantitatively excreted within a





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## Toxicology

Acute exposure and chronic retention of aluminum in three vaccine schedules and effects of genetic and environmental variation



Grant McFarland<sup>a</sup>, Elaine La Joie<sup>a</sup>, Paul Thomas<sup>b</sup>, James Lyons-Weiler<sup>a,\*</sup>

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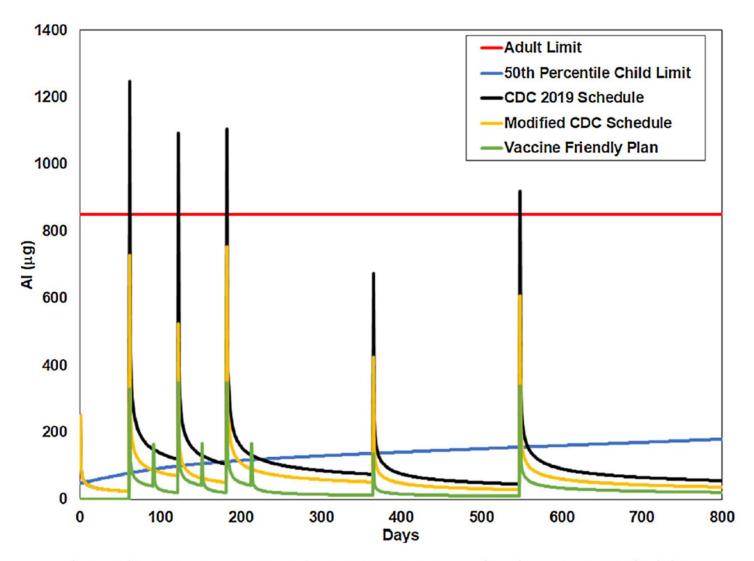


Fig. 2. Aluminum Content in Body over First Two Years for Three Vaccine Schedules.

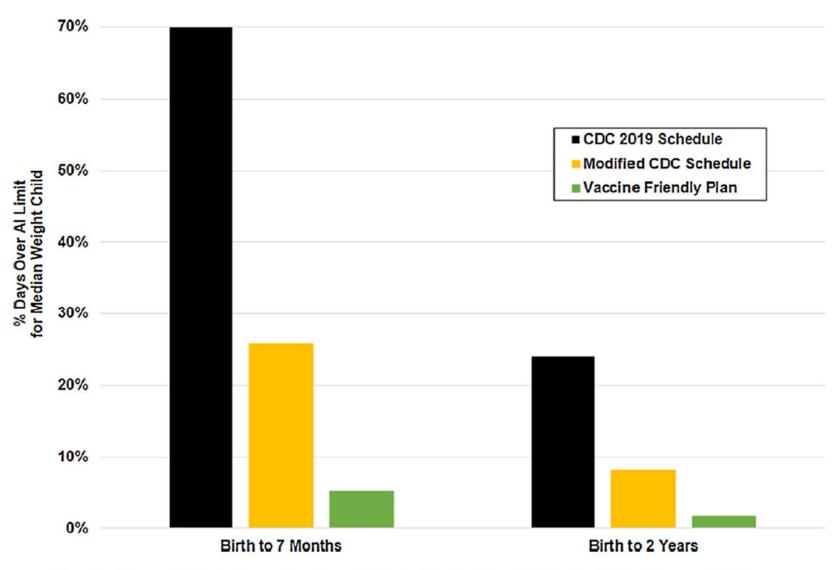
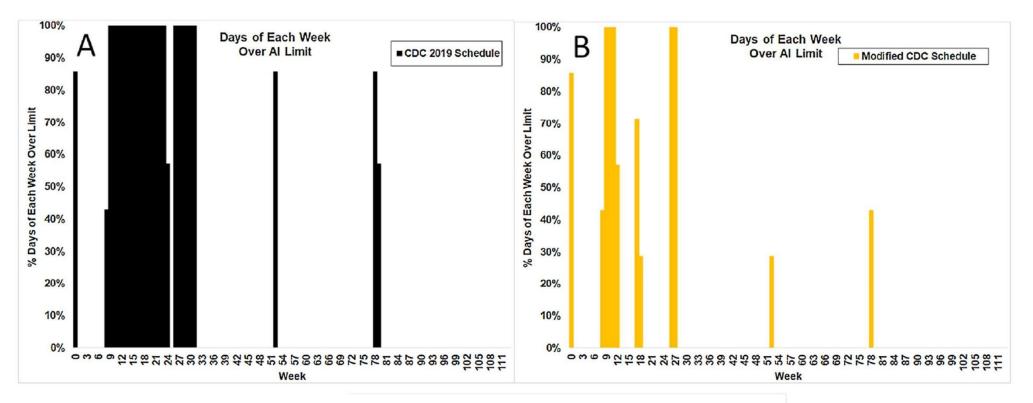
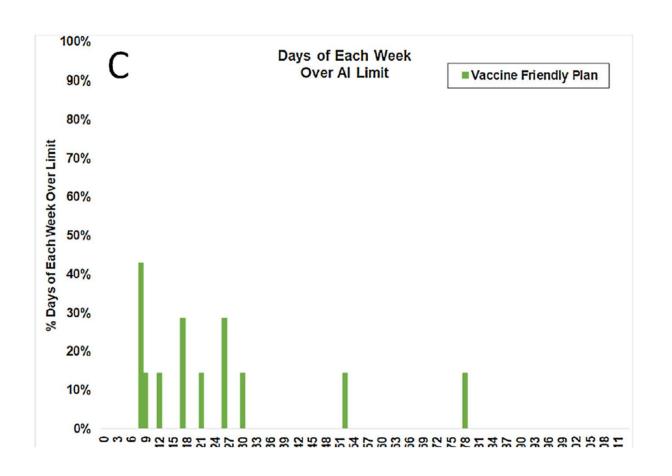
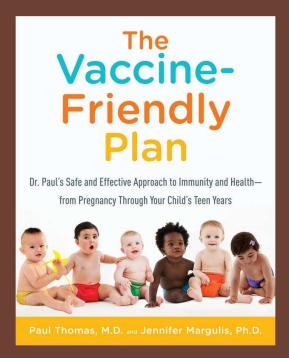


Fig. 3. Percent Days Over aluminum Limit (%alumTox) Birth to 7 Months and 2 Years.



Days of Each Week Over Al Limit





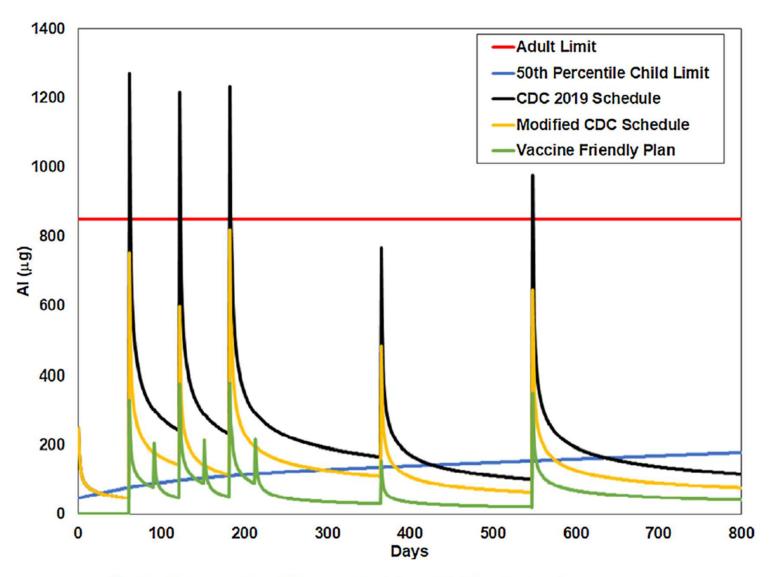


Fig. 6. Aluminum for different schedules with "slow" aluminum clearing.

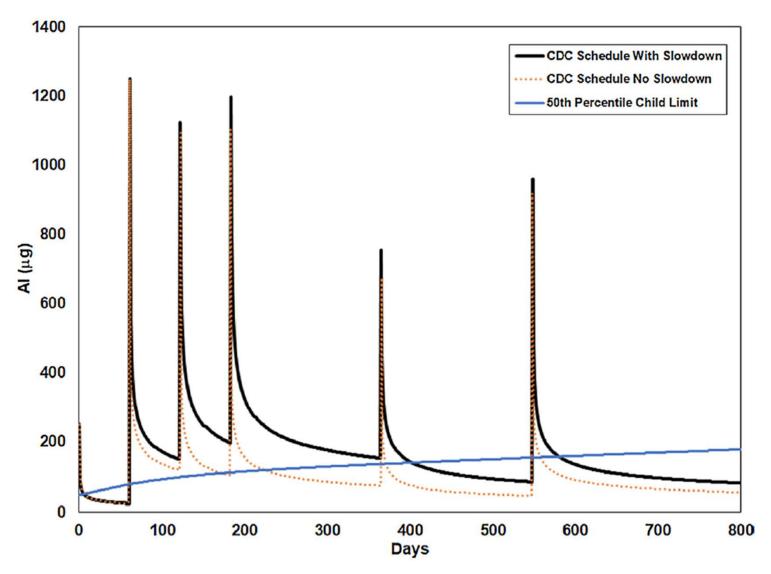


Fig. 8. Slowdown model results in higher retention and increased expected toxicity.

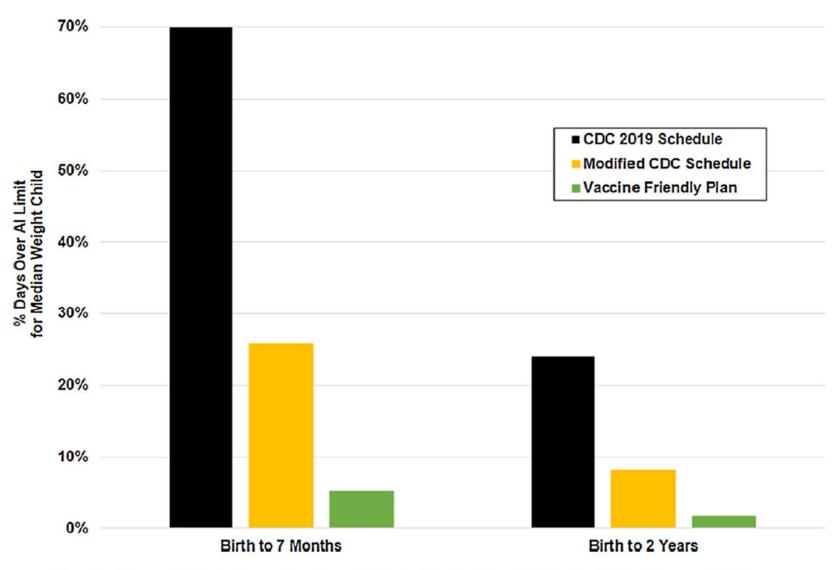


Fig. 3. Percent Days Over aluminum Limit (%alumTox) Birth to 7 Months and 2 Years.

## Recommendations

- **Perform** per body-weight dose escalation studies in mice using injected forms of aluminum in infant mice
- **Re-evaluate** the use of aluminum in vaccines altogether
- **Encourage** awareness of the differences between vaccine risk awareness, which can lead to improvements in vaccines, and "Anti-vaccination" positions

# Next Steps



IPAK VAXXED VS. UNVAXXED STUDY



ANALYSIS OF HEALTH
OUTCOMES IN >3300
CHILDREN BORN
INTO DR. PAUL'S
PRACTICE



681 UNVACCINATED, 2647 VARIABLY VACCINATED (VFP)



**IRB APPROVED** 



PHASE 1 IS COMPLETE, UNDER REVIEW



RESULTS INCLUDE
HEALTH OUTCOMES
RISK FROM ACV'S CF.
ALL VACCINES (%
LIABILITY)

## Science, Public Health Policy & the Law

An IPAK PHPI Publication

In spite of billions of dollars invested into biomedical research and practice, western civilizations are characterized by chronic illness. Papers published in this journal will focus on the nexus between science, public health policy, biomedical practice and the laws and regulations that govern health care practices. Solution-focused improvements in translation of science into improved human life are welcome.



Science, Public Health Policy & the Law:

Convergence

James Lyons-Weiler, Editor-in-Chief



Our Flawed Mental Health Policies

Jennifer Giustra-Kozek







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News

## IPAK Launches a Public Health Policy Research Fellowhship Drive

11/19/2019

IPAK, The Institute for Pure and Applied Knowledge, today announced a drive to fund a Public Health Policy Research Fellowship intended to fund one full-time person to study the matches and mismatches between public health policy, medical practices, the law, and science. This is currently in its initial fund-raising stage, Our goal is \$25K and the need is immediate. To support this drive, yist the monthly donation gage here and give generously!

### IPAK Launches New Open Access Peer-Reviewed Journal

August 1, 2019 - Pittsburgh, PA

IPAK, The Institute for Pure and Applied Knowledge, via its Public Health Policy Initiative, today launched a new open access, peer-reviewed journal, "Science, Public Health Policy & the Law". The first volume contains four articles on issues impacting public health policy, Specifically, the jurnal will publish articles evaluating the goodness-of-fit of public health policy. Brown and binomedical brest practices—and law to available scientific knowledge. The journal's Editor-in-Chief, Dr. James Lyons-Weiler, CEO and Director of PAKs, says the journal fills a gap in the published iterature by providing a forum in which objective, non-corporatist views may be published.

"It is our goal to publish brief, well-referenced articles that leverage one or two specifically important and factual points that corporate-owned Journals may or may not be inclined to publish", he said.

The first volume includes an article on suicide rates and all-cause death rates reported in the original data submitted by Merck to FDA for approval of the quadrivalent Gardiol vaccine, and article reviewing controversies and issues with the latest MMR vaccine autism link, an article on thans in mental health policies and practices, and an article on whether the continued use of any vaccines has become a threat to national security in the US. According to Lyons-Weller, "We are not limiting our scope to vaccines by any means, and intend to publish anticles on the sudatility the training of ordors and public health officials on