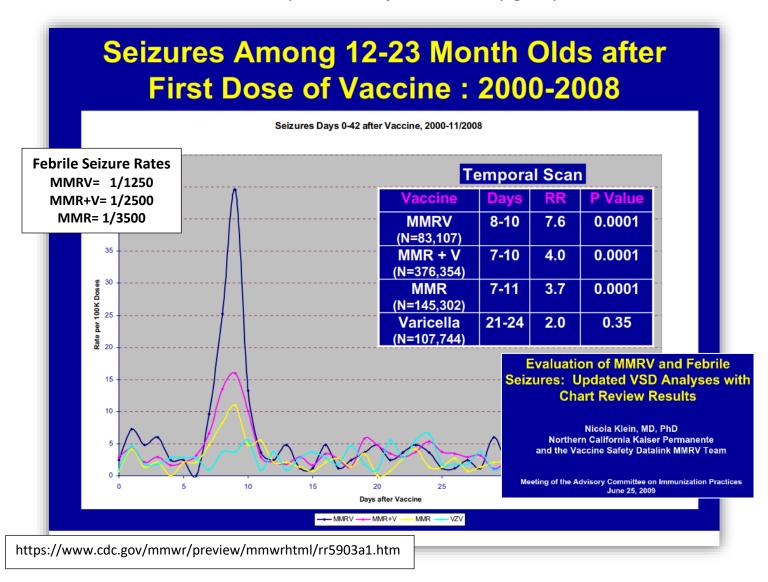
During the discussions about how to handle the exempt children during outbreaks, or in relation to non-medical exemption legislation, several common responses are, "If they want to stay in school, they can simply get the shot"; and "Why don't they get the shot, are they stupid?".

Who are the people who "Don't want the shot?"

The short answer? They are the families and friends of children who had a serious reaction. This Vaccine Safety Database Slide comparing seizure rates between the MMR and Chicken Pox (Varicella) vaccines singly, in combination, and the MMRV "Pro-Quad" 4 in 1 quantifies hundreds of children hospitalized in just this study group.



This issue displays the differing definitions between Public Health and Parental concepts of what constitutes a 'Rare' rate of injury, or what is a "Moderate Reaction".

From the MMR VIS, Vaccine Information Sheet for parents, it discloses:

VACCINE INFORMATION STATEMENT

MMRV Vaccine

What You Need to Know

(Measles, Mumps, Rubella and Varicella)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

Moderate problems

 Seizure caused by fever (about 1 child in 1,250 who get MMRV), usually 5–12 days after the first dose. They happen less often when MMR and varicella vaccines are given at the same visit as separate shots (about 1 child in 2,500 who get these two vaccines), and rarely after a 2nd dose of MMRV.

These febrile seizures are not discrete events but the crescendo of 1 to 2 weeks of a child who feels poorly shortly after vaccination, deteriorating over time with an illness that is not responding to antipyretic and analgesic medications and culminates in rushing a frequently nonresponsive child to the Emergency Room.

The typical parent does not consider hospitalization from routine vaccination to be moderate, but serious, and a 1/1250, or 1/2500 frequency is not especially "rare".

Parents are told that combination vaccines are no more reactive than single antigen vaccines, and multiple injections in a visit is not more reactive than a single injection, yet this VIS & graph clearly and unequivocally contradicts this assertion. MMR & V is more reactive than either vaccine singly, and the MMRV "Pro Quad" combo 4 in 1, doubles that increase again. There is obviously some interaction.

In medical parlance, "rare" is a quantified statement that something that occurs less than 1/1000, "very rare" is less than 1/10,000. When a parent is told, "rare", they think "hardly ever", and "very rare", is "almost never". Many parents think that "1/2500" is "very common", and when they hear "1/1250" they think "why is this product even allowed on the market?".

When you project these seizure rates over the number of vaccine administrations in WA we are talking dozens and dozens of injuries annually. 160,000 WA children receive a 1st (32-64 seizures) or 2nd injection(s) (8 seizures) of MMR + V, or MMRV every year. Depending on what combination(s) of shots, we know with scientific, statistical certainty these <u>vaccines alone</u>, (other vaccines have similar reaction profiles), are sending 40 to 90 children to the ER, year in and year out.

This explains the strong, often emotional opposition frequently encountered by Health and other officials when trying to compel or coerce certain parents to resume vaccinating. The Officials are puzzled why parents are resisting these beneficial interventions. It is because for these parents their opposition is not theoretical or academic- they are being asked to repeat the administration of a drug that put their child, (or their niece or nephew, or friend's child), in the ER. What responsible caretaker would risk that again?

It can be calculated using these seizure ratios that some 1000 of these children are currently attending the WA K-12 system. Their siblings, family members, friends and associates have direct experience of a child being hospitalized as a result of their routine vaccinations. If their circle of influence is 5 or 10 that is up to 10,000 people. There are only 29,500 or so of WA's 1.1 million students who exempt from 2 injections of MMR, this group alone could be a significant portion of exemptions.

What does one of these events look like?

The Vaccine Information Sheet attached also advises parents that should their child have a reaction their Doctor should report to VAERS.

5

What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS).
 Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

This is VAERS ID 494964

Case Details

 VAERS ID: 494964 (instance)
 Vaccinated: 2013-06-03

 Age:
 1.0
 Onset:
 2013-06-11, Days after vaccination: 8

 Gender:
 Female
 Submitted:
 2013-06-24, Days after onset: 13

Location: Vermont Entered: 2013-06-24

Vaccination	Manufacturer	Lot	Dose	Route	Site
HEPA: HEP A (HAVRIX)	GLAXOSMITHKLINE BIOLOGICALS	AHAVB355AA	0	IM	LL
MMR: MEASLES + MUMPS + RUBELLA (MMR II)	MERCK & CO. INC.	H011885	0	sc	RL
VARCEL: VARICELLA (VARIVAX)	MERCK & CO. INC.	H018790	0	sc	LL

Administered by: Private Purchased by: Public

Symptoms: Bladder catheterisation, Blood culture negative, Blood gases abnormal, Blood glucose increased, CSF culture negative, CSF glucose increased, Chest X-ray abnormal, Convulsion, Cough, Culture urine negative, Cyanosis, Dyskinesia, Endotracheal intubation, Enterovirus test negative, Extubation, Febrile convulsion, Herpes simplex serology negative, Hypopnoea, Hypotonia, Intensive care, Lethargy, Lymphocyte percentage increased, Mechanical ventilation, Mental status changes, Monocyte percentage increased, Neutrophil percentage decreased, Oxygen saturation decreased, Platelet count increased, Pyrexia, Red blood cells CSF positive, Respiratory arrest, Respiratory distress, Rhinorrhoea, Rhonchi, Skin discolouration, Upper respiratory tract infection, Urine ketone body present, Vomiting, White blood cell count increased

SMQs:, Anaphylactic reaction (broad), Acute pancreatitis (broad), Angioedema (broad), Haematopoietic leukopenia (broad), Lactic acidosis (broad), Peripheral neuropathy (broad), Hyperglycaemia/new onset diabetes mellitus (narrow), Neuroleptic malignant syndrome (narrow), Systemic lupus erythematosus (broad), Anticholinergic syndrome (broad), Dementia (broad), Convulsions (narrow), Dyskinesia (narrow), Acute central respiratory depression (narrow), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (broad), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (narrow), Hypersensitivity (broad)

Write-up: 8 dys after 12 month imms. pt experienced high fever (104 degrees) and seizure, with respiratory distress. Due to respiratory distress pt. intubated and hospitalized. The following information was obtained through follow-up and/or provided by the government. 6/26 & 27/2013 ER records received for DOS 6/11/2013. Transfer Dx: respiratory arrest. Pt c/o fever, vomiting, & lethargy followed by altered mental status, poor color, jerking movements. EMS activated, transported to ER. PE: limp, cyanotic, O2 sat 40s (L), lethargic, shallow respirations, severe rhonchi. URI symptoms (runny nose, cough) for 1 wk prior to event. Pt intubated, transferred in critical condition for higher level care. 6/26 & 7/11/2013 hospital records received for DOS 6/11-13/2013. D/c Dx: complex febrile seizure. Pt admitted w/ above hx. Tx"t: IVF, mechanical ventilation, anticonvulsant, ABX, PICU, foley. Successfully extubated 6/12. No further evidence of seizure activity. Pt d/c"d home in good, stable, improved condition w/ care & f/u instructions.

Died? No Permanent Disability? No Recovered? Yes ER or Doctor Visit? No

Life Threatening? No

Hospitalized? No Previous Vaccinations:

Other Medications: Current Illness: Runny nose; Congestion The

following information was obtained through follow-up and/or provided by the government. Recently resolved heat rash, watery eyes, nasal congestion, It TM w/ fluid.

Preexisting Conditions: The following information was obtained through follow-up and/or provided by the government. PMH: ? allergies.

Diagnostic Lab Data: The following information was obtained through follow-up and/or provided by the government. 6/26/2013 lab/diagnostic records received for DOS 6/11-13/2013. Blood: WBC 20 K/mm3 (H), neutros 43% (L), lymphs 41% (H), monos 15% (H), Plt 466 K/mm3 (H), glucose 204 mg/dL (H). UA: ketones (+). ABGs abnormal. CSF: glucose 83 mg/dL (H), RBC 21 (H). Enterovirus, HSV, blood/urine/CSF cx (-). CXR: borderline enlarged heart & mediastinum, parahilar linear opacities

CDC Split Type:

This Health Care
Provider generated
VAERS report proves
that parents who
relate serious vaccine
reactions are not
hallucinating,
mistaken, or lying.

This report describes a 1-year old girl who was examined at her 12 month "wellness" checkup and determined to be healthy enough to receive 4 vaccines- Hep A, MMR, and Chicken Pox. She developed a course of illness exactly as described in the VIS. 8 days following vaccination she experienced a respiratory arrest and was transported by EMS (Emergency Medical Services) to the ER arriving limp, with a 40% O2 level and requiring intubation and a foley urinary catheter. She spent 2 days in the hospital, after 8 days of misery at home.

Imagine the experience for this family, their relatives, neighbors and friends. The intubation of a 12-month-old is a very delicate process, requiring special equipment and a steady, practiced hand. Every interaction with the Health Care System like this subjects the patient to the possibility of a medical error, which is the 3rd leading cause of mortality in the US. The child could have a previously unknown allergy or sensitivity to an analgesic, antibiotic, anesthetic, or other administered substance. There is the potential exposure to a difficult to treat Hospital Acquired Infection, another extremely common and dangerous occurrence.

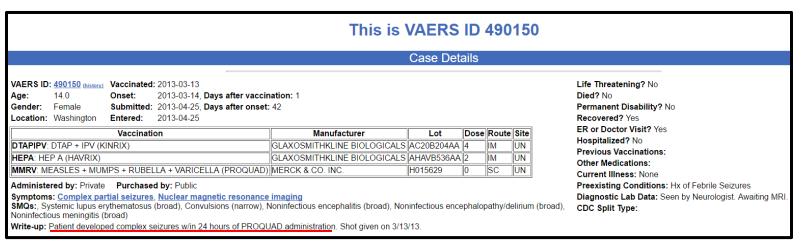
What if the respiratory arrest had occurred outside of her parent's observation? Without the emergency medical intervention this girl required she could have died. Would it have been called a "SIDS"?

How excited will this family be for their next "well baby" visit at 18 months? Do you think they will, "Just get the shots", or will they perhaps be more cautious? Do you think they will want to do another MMR at age 4-6?

If this was your daughter, or niece, or the child of a close friend or coworker, who you knew was not crazy and you witnessed a child being hospitalized as a direct result of their routine vaccinations, how would you react? What if you sat vigil with your niece, or friend's daughter?

It is not just infants who have serious reactions.

This report describes a 14-year-old girl developing complex seizures within 24 hours of her MMRV administration.



As counter intuitive as it may seem febrile seizures and other reactions requiring emergency treatment do not automatically qualify for a Medical Exemption, (ME). Many Health Care Providers are unable or unwilling to grant a medical exemption for a number of reasons, including liability concerns, license board scrutiny, practice policies, etc. This issue is explored in depth in another report.

Many HCP will instead direct the parent to use the personal belief exemption, bypassing the ME. Other HCP are reluctant to admit that the medication they administered could have caused the reaction. This is not exclusive to vaccines, HCP in general resist attaching negative consequences to the care they provide or medications they administer.

This is how the Personal Exemption acts as a Parent Administered Medical Exemption. Otherwise, if a child has an unacceptable reaction their parents could be forced into having to argue causality in a potentially adversarial manner with a Health Care Provider.

Should any parent have to justify their concern? If your older child has a strong reaction, are you likely to subject their younger sibling to the risky procedure? If your niece ends up in the ER, will you risk your son?

Obviously if 1/1250 or 2500 is becoming so ill they suffer a seizure, a larger number is getting almost that sick, coming up just short of the hospitalization. Referring to the CDC materials, the VIS discloses:

Mild problems

Fever (about 1 child out of 5).

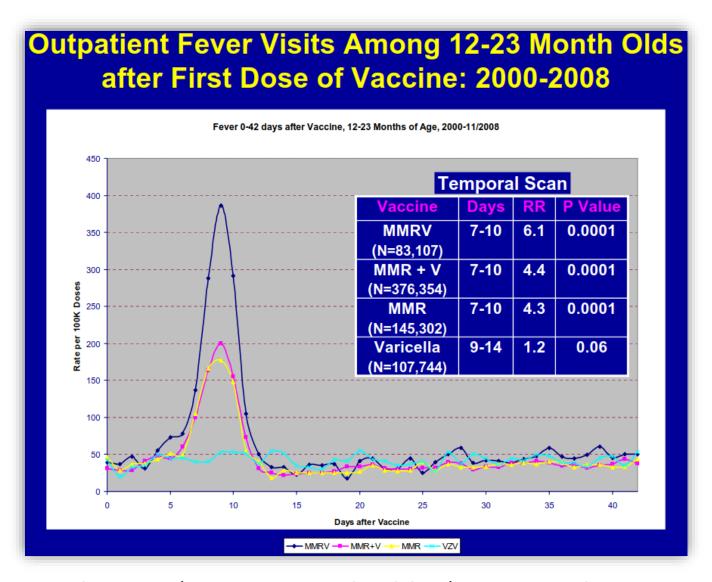
But when we look at the form for the Health Care Provider Information sheet, there is greater detail:

Summary of Risks and Benefits Discussing whether to use the MMRV vaccine or MMR and varicella vaccines for a 12- through 47-month-old's first vaccination centers on helping parents understand the risk/benefit tradeoff.				
	MMR and Varicella Vaccines (Administered at the same doctor visit)	MMRV Vaccine		
Protection against measles, mumps, rubella and varicella	Provides the same protection against the four diseases as the MMRV vaccine	Provides the same protection against the four diseases as the MMR and varicella vaccines		
Number of shots	Two shots needed at the same doctor visit to provide protection against measles, mumps, rubella, and varicella	One shot needed to provide protection against measles, mumps, rubella, and varicella		
(Fever)	Fewer children have fevers of 102°F or higher within 42 days of being vaccinated (about 15 out of every 100 children vaccinated; the highest risk for fever occurs during 5–12 days after vaccination)	More children have fevers of 102°F or higher within 42 days of being vaccinated (about 22 out of every 100 children vaccinated; the highest risk for fever occurs during 5–12 days after vaccination)		
(Seizures caused by fever)	Fewer children have febrile seizures during the 5–12 days after vaccination (about 4 out of every 10,000 children vaccinated)	More children have febrile seizures during the 5–12 days after vaccination (about 8 out of every 10,000 children vaccinated)		

15-22% of children experience fevers greater than 102f.

A fever greater than 102f is "mild"? What parent, if given the choice, would choose a vaccine formulation that doubles the "risk"- which is the rate- of seizure or high fever for the "benefit" of a single injection?

The same VSD study that looked at seizure rates looked at Outpatient Fever visits, where a parent is so concerned about the vaccine reaction that they bring their child back to the Health Care Provider for reassurance, i.e. "Is this really a normal and expected outcome?".



Again, we see that parents are not imagining these poor reactions.

These children with high fevers are arguably experiencing courses of illness that are equal to or greater than an uncomplicated course of the infections the vaccines are intended to prevent.

To recap-

1250 children are administered MMRV

275 experience a fever greater than 102f.

45 become so feverish their parents return to the Doctor's office.

1 becomes so ill they develop a Febrile Seizure requiring ER admission.

2500 children are administered the MMR & V

375 experience a fever greater than 102f.

75 become so feverish their parents return to the Doctor's office.

1 becomes so ill they develop a Febrile Seizure requiring ER admission.

This example also demonstrates the tension between the Public Health's community priorities versus a parent's responsibility to protect their child. 1/1250 children going to the ER is apparently an acceptable Public Health tradeoff for having the other 1249 children vaccinated.

Parent Quote:

"I am fine with a sore spot on my daughter's arm, and a fussy feverish day or two. This last round of shots was unacceptable, she was sick as a dog for almost 2 weeks, and punky for another month after that. My mother told me she was sicker than any of my older siblings who had the regular infections (they grew up with only Polio and DPT shots). And that they recovered very quickly back to normal in just days, not this long, extended malaise. I am not saying we are stopping shots altogether, but we are definitely going to space them out, and maybe not do them all, only the important ones."

Does this statement sound irrational, or uniformed?

This report is only addressing the MMR & V set of vaccines. Others vaccine combinations have similar reaction profiles.

This article details that administration of Flu and PCV vaccines has a seizure rate of 1/2250.



TIV and PCV13. The risk increase was lowest for 59-month-old children.

There are 160,000 under 24 month old WA children who are scheduled to receive this combination every year.

This is another 70 plus seized children.

WA has 160,000 >24 month olds, scheduled to get 21 injections and 3 oral doses of vaccines every year, total 3,840,000 procedures.

If only .0001% of the children have an unacceptable reaction, that is still hundreds of families who were trying to comply with the schedule but now use an exemption to modify the "one size fits all" vaccine requirements to their personal situation. These are the people who won't take the risk of "Just Get the Shot".