Facts to Counter the Fear



Toxicologist, Ashley Everly

### Measles, in Television (1969 vs. 2015)

#### If you have to get sick, sure can't beat the measles

The Brady Bunch (1969) S01E13 Is There A Doctor In The House

Looks like the Bradys are finished with the measles

S01213 - Is There A Doctor in The House

### A DEADLY OUTBREAK

unit production managers KENNETH BROWN AMANDA SLATER

## HE EPIDEMIC

boom operator dolly grip JOHN GUTIERREZ JOSEPH best boy FINNER ERANK ROSARIO assistant

assistants to the executive producers LYDIA MAYBERRY KRISTEL CREWS

# What Happened?



#### Is measles a childhood rite of passage? Or is it deadly and to be feared?

# Measles Symptoms & Complications

#### \* Typical symptoms:

- Fever, runny nose, red and watery eyes, small white spots on the inside of the mouth, then days later, the rash appears starting on the face and upper neck, and spreading downward.
- Severe measles:
  - Blindness, encephalitis (infection that causes brain swelling), diarrhea and dehydration, and respiratory illnesses such as pneumonia.

**Source**: World Health Organization <a href="https://www.who.int/immunization/diseases/measles/en/">https://www.who.int/immunization/diseases/measles/en/</a>

### **Global Statistics**

- \* Incidence: 19 cases of measles per million persons in the world.
- \* **110,000 deaths** from measles in 2017.
- \* Case fatality rates as high as 20% from West Africa.
  - \* "The overwhelming majority (more than 95%) of measles deaths occur in countries with low per capita incomes and weak health infrastructures."
  - \* "Severe measles is more likely among poorly nourished young children, especially those with insufficient vitamin A, or whose immune systems have been weakened by HIV/AIDS or other diseases."

Sources: World Health Organization, Reviews of Infectious Diseases <u>https://www.who.int/en/news-room/fact-sheets/detail/measles</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/6878998</u>

## US Statistics - Conflicting Data

#### \* In 1960 (before the vaccine):

- The CDC website states that before 1963 there were 500,000 reported cases of measles and 500 deaths annually. Suggesting 1 in 1000 died of measles. [0.1% death rate]
- 1 in 500,000 died of measles according to a 1968 report by the National Center for Heath Statistics. [0.0002% death rate]
- \* 1985-1992: Surge of measles cases, primarily in low-income children. 1-2 in 1000 died of measles.\*

Sources: CDC, J. Infectious Diseases <u>https://www.cdc.gov/nchs/data/vsus/vsrates1940\_60.pdf</u> <u>https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html</u> <u>https://academic.oup.com/jid/article/189/Supplement\_1/S91/825077</u>



\*We will refer back to this.

## US Statistics - Unreported Cases

#### Under-reporting factors:

- Before the vaccine, the completeness of reporting was around 10%. The actual number of cases was estimated at 4-5 million annually.
- \* Revised death rate using 500 annual deaths out of 5 million cases = 1 in 10,000. [0.01% death rate].
- Estimates of completeness in reporting from the 1980s and 90s range from 3% to 58% of actual measles cases.
- As low as 3 in 100,000 to 1 in 862 [0.003% 0.12% death rate]

**Sources**: CDC, J. Infectious Diseases, Clinical Microbiology Reviews <u>https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html</u> <u>https://academic.oup.com/jid/article/189/Supplement\_1/S185/822206</u> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC172858/pdf/080260.pdf</u>

### Completeness of Measles Case Reporting: Review of Estimates for the United States @

#### Walter A. Orenstein, Rafael Harpaz 🐱

The Journal of Infectious Diseases, Volume 189, Issue Supplement\_1, 1 May 2004, Pages S185–S190, https://doi.org/10.1086/378501
Published: 01 May 2004

#### Abstract

Measles surveillance is complex: the patient must seek health care, the diagnosis must be recognized by the physician, and the case must be reported to health departments. The portion of total (incident) measles cases> that is reported to health departments is termed "completeness of reporting." Few studies describe this measure of the quality of surveillance in the United States; these studies use different methods, but they are all limited because the actual number of measles cases needed to derive completeness of reporting could not be determined. Estimates of completeness of reporting from the 1980s and 1990s vary widely, from 3% to 58%. One study suggests that 85% of patients with measles sought health care, the proportion of compatible illnesses for which measles was considered varied from 13% to 75%, and the proportion of; suspected cases that were reported varied from 22% to 67%. Few cases were laboratory-confirmed, but all were reported. Surveillance in the United States is responsive, and its sensitivity likely increases when measles is circulating. Continued efforts to reinforce the clinical recognition and reporting of measles cases are warranted.

Data does not include un-diagnosed and un-reported cases of measles which may occur as a result of MMR vaccination.

### Debate on Measles Risk is Valid



## Recent Measles Deaths in the US

- \* The last confirmed measles death occurred in 2015.
  - \* A fully vaccinated woman in her 20s living in Washington died from measles.
  - \* The woman was said to have several health conditions and on immune suppressing drugs, and therefore did not show typical signs of measles.
- \* Prior to 2015, the last confirmed measles death occurred in 2003.
  - Two measles deaths in 2003: (1) Immunocompromised child, aged 13 years.
    (2) International traveler aged 75 years, infected in Israel.
- \* *Unconfirmed* doctor's reports suggest one measles death occurs each year.

Sources: CDC, The Seattle Times, Forbes: <u>https://www.cdc.gov/measles/downloads/measlesdataandstatsslideset.pdf</u> <u>https://www.seattletimes.com/seattle-news/health/undetected-measles-led-to-womans-death/</u> <u>https://www.forbes.com/sites/tarahaelle/2015/07/02/first-u-s-measles-death-in-more-than-a-decade/</u>

### In the Absence of a Vaccine

### Current US population 326 million

- \* Using the revised death rate of 0.01% based on the CDC website:
  - \* There would be **32,600** measles deaths per year.
- \* Using the National Center for Heath Statistics 0.0002% death rate:
  - \* There would be 652 measles deaths per year.
- Comparables:
  - Car accidents: Fatalities occur at a rate of 0.01% = 33,578 deaths per year.
  - Falling: In 2016 there were 34,673 deaths from unintentional falls.

#### Assuming every person in the US contracts measles.

**Sources**: CDC, U.S. News, National Safety Council <u>https://www.cdc.gov/vitalsigns/motor-vehicle-safety/index.html</u> <u>https://www.usnews.com/news/healthiest-communities/slideshows/top-10-causes-of-death-in-america</u> <u>https://www.nsc.org/work-safety/safety-topics/slips-trips-falls</u>

## Incidence Rate-Adjusted Deaths

- US population in 1960: 180.7 million
  - \* 5 million people out of 180.7 million = 2.8% incidence rate.
- Current US population: 326 million
  - \* (326 million)(2.8% incidence rate) = 9,020,476
  - Therefore, in the absence of a vaccine for measles, there would be around 9 million cases of measles per year.
- Using the revised death rate of 0.1%:
  - \* 9,020 measles deaths per year.
- \* Using the National Center for Health Statistics rate of 0.0003%:
  - \* 18 measles deaths per year.

# In Reality

- This information is important in order to compare the risks of harm from measles to the risk of harm from vaccination.
- \* This topic is important and people are searching for answers.
- The true number of deaths from measles would likely be somewhere in between 20 9,000 deaths per year.
- For comparison, there were around 10,000 deaths in 2016 due to congenital malformations and chromosomal abnormalities.

#### Google

#### death rate from

death rate from **measles** death rate from **flu** death rate from **prostate cancer** death rate from **colonoscopy** death rate from **pneumonia** death rate from **pneumonia** death rate from **breast cancer** death rate from **mmr** death rate from **vaccines** death rate from **cancer** death rate from **cancer** death rate from **alcohol** Major disasters · Safety · Statistics · Investigation

#### Source: CDC https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67\_05.pdf

## Success of the MMR Vaccine

- \* The combination Measles / Mumps/ Rubella vaccine was introduced in 1971, to prevent illness and associated risk of harm.
- Incidence rates fell after after vaccine was introduced.
- Considered highly effective and successful.
- US celebrates as measles is declared "eliminated" in the year 2000.



**Source**: History of Vaccines <u>https://www.historyofvaccines.org/content/graph-us-measles-cases</u>

### The Year of Elimination

In the year 2000, twenty states reported confirmed measles cases, and there was a total of 86 confirmed cases of measles.



Sources: New England Journal of Medicine <u>https://www.nejm.org/doi/full/10.1056/NEJMp1408696</u> <u>https://www.cdc.gov/MMWR/Preview/MMWRhtml/mm5106a2.htm</u>

### Measles Cases in the US

There were no deaths from measles despite 667 cases in 2014.

From 2004 - 2018, there were over 2000 reported cases of measles. There were no infant or child deaths during this time.



\*Cases as of December 29, 2018. Case count is preliminary and subject to change.

\*\*Cases as of February 7, 2019. Case count is preliminary and subject to change. Data are updated weekly.

**Sources**: Centers for Disease Control <u>https://www.cdc.gov/measles/cases-outbreaks.html</u>

## Measles Cases in Young Children

- \* **2011**: 27 infants, 51 children (age 1-4)
- \* 2013: 18 infants, 40 children (age 1-4)
- \* 2014: 20 infants, 48 children (age 1-4)
- \* 2015: 26 infants, 18 children (age 1-4)

#### No cases of encephalitis and no deaths were reported. Data unavailable for 2012.

Sources: CDC <u>https://www.cdc.gov/measles/cases-outbreaks.html</u> <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6322a4.htm</u> <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a1.htm</u>

### MMR Effectiveness

- \* Despite claims of efficacy, **measles outbreaks** have occurred in fully vaccinated populations or in areas of near-complete coverage.
  - 1,363 cases of measles outbreak in Quebec, Canada, in 1989, despite 99% vaccination rate for the total population.
  - In 1984, a measles outbreak occurred in a high school with a documented vaccination rate of 98% in Massachusetts.
  - \* An outbreak occurred in Texas in 1985, in a fully vaccinated secondary school population. **More than 99% of the students had been vaccinated**.
  - \* Outbreak in New York in 2011 was traced to a fully vaccinated 22 year old.

### Herd immunity is unattainable with the vaccine.

Sources: Canada Journal of Public Health, New England Journal of Medicine, Science Magazine, Oregon Law Review <u>https://www.ncbi.nlm.nih.gov/pubmed/1884314?</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/3821823</u> <u>https://www.sciencemag.org/news/2014/04/measles-outbreak-traced-fully-vaccinated-patient-first-time</u> <u>https://scholarsbank.uoregon.edu/xmlui/bitstream/handle/1794/18592/Holland.pdf</u>

## Vaccine-Associated Measles

- \* MMR and MMRV-vaccinated individuals can contract measles from the vaccine, due to vaccine virus shedding.
  - Case study: healthy 18-month-old child living in Italy developed symptoms of measles 7 days after MMRV vaccination. Measles virus was detected via throat swab up to 25 days later.
  - Case study: two-year-old child from Canada developed measles five weeks post-MMR-vaccination.

Source: Euro Surveillance <u>https://www.eurosurveillance.org/images/dynamic/EE/V20N20/art21134.pdf</u> <u>https://www.eurosurveillance.org/content/10.2807/1560-7917.ES2013.18.49.20649</u>

### Vaccine-Associated Measles



 Case study: healthy 13-month-old living in the US developed measles symptoms 9 days post-MMR-vaccination.

**Source**: Clinical Case Reports <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5676287/</u>

## Vaccine Details

- \* MMR II is manufactured by **Merck** and is a live-virus vaccine.
- Listed ingredients & excipients:
  - Chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride.
- \* Administered at 12 or 15 months of age, and again at 4-6 years.
  - During outbreaks, doctors are advised that they may administer the MMR vaccine to children as young as 6-9 months, however it has not been tested for safety in children under a year of age.

Sources: CDC <u>https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf</u> <u>https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf</u>

### Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger United States, 2019 United States, 2019

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Table 1. To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.

Vaccine	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 yrs	17-18 yrs
Hepatitis B (HepB)	1ª dose	2 <sup>nd</sup> (	dose		◄ 3 <sup>rd</sup> dose			>									
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See Notes												
Diphtheria, tetanus, & acellular pertussis (DTaP: <7 yrs)			1ª dose	2 <sup>rd</sup> dose	3 <sup>rd</sup> dose			<b>∢</b> 4 <sup>th</sup> d	oseÞ			5 <sup>n</sup> dose					
Haemophilus influenzae type b (Hib)			1ª dose	2 <sup>nd</sup> dose	See Notes		3 <sup>d</sup> or 4 See 1	n dose, Notes									
Pneumococcal conjugate (PCV13)			1ª dose	2 <sup>rd</sup> dose	3 <sup>rd</sup> dose		<b>∢</b> 4 <sup>th</sup> c	iose•									
Inactivated poliovirus (IPV: <18 yrs)			1ª dose	2 <sup>rd</sup> dose	•		3 <sup>id</sup> dose -		>			4 <sup>n</sup> dose					
Influenza (IIV)						Annual vaccination 1 or 2 doses						Annual vaccination 1 dose only					
Influenza (LAIV)											Annua 1 o	l vaccinatio r 2 doses	n	Annual	lvaccinatio	n 1 dose on	ly
Measles, mumps, rubella (MMR)					See M	Notes	<b>∢</b> 1° c	iose•				2 <sup>nd</sup> dose					
Varicella (VAR)							<b>∢</b> 1° c	iose•				2 <sup>nd</sup> dose					
Hepatitis A (HepA)					See Notes 2-dose series, See Notes												
Meningococcal (MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)								See Notes						1ª dose		2 <sup>nd</sup> dose	
Tetanus, diphtheria, & acellular pertussis (Tdap: ≥7 yrs)														Tdap			
Human papillomavirus (HPV)														See Notes			
Meningococcal B															See Not	es	
Pneumococcal polysaccharide (PPSV23)					See Notes												
Range of recommended ages for a children	all Range of recommended ages for catch- up immunization Range of recommended ages for certain high-risk groups ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision-making																

### WI-38 Human Diploid Lung Fibroblasts

- Derived from the lung tissues of a female fetus at three months gestation in 1964.
- \* Fetus was aborted because the family felt they had too many children.
- \* DNA fragments from fetal lung fibroblasts remain in the final vaccine solution.
- \* Independent research has found that these fragments can spontaneously integrate into the host's genome. "Insertional mutagenesis".

Carcinogenesis, Mutagenesis, Impairment of Fertility M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

> Sources: ATCC, <u>ProCon.org</u>, Sound Choice, FDA <u>https://www.atcc.org/products/all/CCL-75.aspx</u> <u>https://vaccines.procon.org/view.resource.php?resourceID=005206#wi\_38</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/26103708</u> <u>https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM123789.pdf</u>

- Panniculitis (inflammation of adipose/fat tissue under the skin)

- Atypical MEASLES
- Fever
- Syncope (temporary loss of consciousness)
- Headache
- Dizziness
- Malaise
- Irritability
- Vasculitis (inflammation of blood vessels which can lead to restricted blood flow and damage to organs)
- Pancreatitis (inflammation of the pancreas)
- Diarrhea
- Vomiting
- Parotitis (Inflammation of a parotid gland, especially infectious parotitis aka MUMPS)
- NauseaDiabetes mellitus
- Thrombocytopenia (low platelets / severe bleeding due to reduced ability to form blood clots)
- Purpura (Red/purple discolored spots on the skin due to bleeding underneath the skin)
- Regional lymphadenopathy (enlargement / disease of the lymph nodes)
- Leukocytosis (abnormally high number of white blood cells due to inflammation from infection, tumors, or leukemia)
- Anaphylaxis and anaphylactoid reactions, angioneurotic edema / peripheral or facial edema (severe swelling of the lower layer of skin and tissue just under the epidermis) and bronchial spasm.
- Arthritis or Arthralgia (Arthralgia and/or arthritis, transient or chronic, and polyneuritis are features of infection with wild-type RUBELLA.)
- Myalgia (muscle pain)
- Encephalitis (brain inflammation)
- Encephalopathy (brain disease, damage, or malfunction)
- Measles inclusion body encephalitis (MIBE). Presents with seizures within one year of measles vaccination or measles infection.
- Subacute sclerosing panencephalitis (SSPE). SSPE is a chronic form of progressive brain inflammation caused by a persistent infection with measles virus.
- Guillain-Barré Syndrome (GBS). GBS is a disorder in which the body's immune system attacks your nerves, causing weakness, severe pain, difficulty breathing, and paralysis.
- Acute disseminated encephalomyelitis (ADEM). ADEM is a demyelinating disease of the central nervous system / widespread attack of inflammation in the brain and spinal cord.
- Transverse myelitis (Inflammation of the spinal cord which causes pain, abnormal sensations, weakness, incontinence, or total paralysis.)
- Febrile convulsions / seizures
- Afebrile convulsions / seizures
- Ataxia (loss of full control of bodily movements)
- Polyneuritis (disorder of the peripheral nerves)
- Polyneuropathy (degeneration / malfunction of peripheral nerves in various parts of the body at the same time)
- Ocular palsies (Damage to third cranial nerve affecting eye movements, leading to strabismus and double vision)
- Paresthesia (abnormal burning or prickling sensation in in various parts of the body)
- Aseptic meningitis (inflammation of layers lining the brain, causing fever, headache, vomiting, persistent crying and poor eating in children, mental confusion...)
- Pneumonia and pneumonitis
- Sore throat, cough, rhinitis
- Stevens-Johnson syndrome / Erythema multiforme (form of toxic epidermal necrolysis. A painful red or purple rash that spreads and blisters, eventually causing the top layer of the skin to die and shed. May lead to vision loss.) - Urticaria / hives
- Rash / Measles-like rash
- Pruritus / severe itching of the skin
- Burning / stinging at injection site
- Wheal and flare / allergic skin reaction
- Redness
- Swelling
- Induration (hardening of soft tissues of the skin / loss of elasticity)
- TendernessVesiculation / blistering
- Henoch-Schönlein purpura / Acute hemorrhagic edema of infancy (rash caused by inflammation and bleeding in small blood vessels, accompanied with swollen joints, abdominal pain, or bloody urine)
- Nerve deafness / hearing loss
- Otitis media (ear infection)
- Retinitis (inflammation of the retina of the eye)
- Optic neuritis / papillitis / retrobulbar neuritis (demyelinating inflammation of the optic nerve. Vision loss, pain with movement of the eye.)
- Conjunctivitis (eye infection)
- Epididymitis / Orchitis (inflammation of the testicles, characterized by pain, swelling, and burning with urination)
- Death

## Adverse Events

### Adverse Events

#### \* Measles, mumps, or rubella.

- \* **Mild**: Fever, loss of consciousness, headache, dizziness, irritability, sore throat, cough, rash, ear infection, nausea, vomiting.
- \* **Moderate**: diabetes, thrombocytopenia, arthritis, myalgia, severe itching of the skin, febrile seizure.
- Severe: anaphylaxis or allergic reaction, seizure, encephalitis, GBS, demyelinating diseases, polyneuropathy, aseptic meningitis, pancreatitis, hearing loss, vision loss, epidermal necrolysis, death.

Source: FDA https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM123789.pdf

### VAERS

Vaccine Adverse Events Reporting System

- \* VAERS is a passive reporting system, relying on individuals to send in reports of their experiences to the CDC and FDA.
- \* Less than 1% of all vaccine adverse events are reported to VAERS.
- \* VAERS data for 2017:
  - \* 2,387 reported adverse events from the MMR vaccine.
  - Applying the under-reporting factor:

#### 238,700 adverse events

Source: HHS <u>https://vaers.hhs.gov/about.html</u> <u>https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf</u> <u>https://vaers.hhs.gov/data/datasets.html</u>

### VAERS Data

VAERS_ID	SYMPTOM1	SYMPTOMVERSION1	SYMPTOM2	SYMPTOMVERSION2	SYMPTOM3
644081	Injection site swelling	19	Pruritus	19	Urticaria
644082	Syncope	19			
644083	Chest X-ray abnormal	19.1	Pneumonia	19.1	
644084	Erythema	19.1	Induration	19.1	Pruritus
644085	Body temperature increased	19.1	Chills	19.1	Hyperhidrosis
644085	Malaise	19.1	Pain	19.1	
644086	Crying	19.1	Erythema	19.1	Pallor
644087	Cellulitis	19	Injection site erythema	19	Injection site swelling
644097	Audiogram abnormal	19	Deafness	19	Deafness neurosensory
644097	Pain	19	Scan with contrast normal	19	Sudden hearing loss
644098	Pyrexia	19	Vertigo	19	
644099	Death	19			
644100	Body temperature increased	19	Contusion	19	Head injury
644100	Syncope	19			
644148	Ear discomfort	19	Lymph node pain	19	Rhinorrhoea
644149	Injection site discolouration	19			
644152	Pertussis	19	Vaccination failure	19	
644154	Loss of consciousness	19			
644155	Dysphagia	19	Hypersensitivity	19	Pharyngeal oedema
644158	Chills	19	Pain	19	Pyrexia
644168	Hypersensitivity	19			
644217	Allergy to vaccine	19	Erythema	19	Swelling

## Rate of Adverse Events

#### \* What we know.

- \* The MMR vaccine was not tested for safety against a placebo.
- In clinical vaccine trials, manufacturers typically do not monitor for adverse events long term.
- \* Often times adverse events do not manifest until 1-3 weeks postvaccination, 2-3 months later, sometimes longer.
- \* Health care professionals fail to recognize and report adverse events. Parents aren't aware of possible reactions.

Sources: BMJ, FDA, HHS <u>https://www.ncbi.nlm.nih.gov/pubmed/5902680</u> <u>https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM123789.pdf</u> <u>https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf</u>

# Comparing Adverse Event Rates

- Using a conservative estimate of measles mortality (1 in 10,000) and records of adverse events (AEs) in 1960:
  - \$ 500 deaths + 48,000 hospitalizations + 1,000 cases of encephalitis = 49,500 adverse events from measles.
  - \* 49,500 AEs / 5 million cases = **0.99%** AE rate
- \* 10 million doses of the MMR vaccine is administered each year in the US.
  - \* 238,700 AEs / 10 million doses = **2.4**% **AE rate**
- \* The risk of adverse events from the MMR vaccine today, is over twice the risk of adverse events from measles, in 1960.\*

\*This does not include data from the MMRV vaccine.

**Source**: CDC <u>https://www.cdc.gov/measles/vaccination.html</u>

## Vaccine Injury Compensation Program

- In 1986 the NCVIA removed liability from manufacturers and administrators due to the high number of lawsuits being filed and won against vaccine manufacturers for injuries and deaths.
- If your child is harmed by a vaccine and wish to take legal action, you must file a petition to the VICP.
- \* Cases are decided by court-appointed "Special Masters".
- Limited to certain types of injuries occurring within a certain time frame.
- Reduced the number of claims filed annually against vaccine companies.

Source: Maglio Christopher & Toale, HRSA <u>https://www.mctlawyers.com/vaccine-injury/cases/</u> <u>https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf</u> <u>https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-infographic-2017.pdf</u>

## Vaccine Injury Table

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IV. Vaccines containing rubella virus ( <i>e.g.,</i> MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus ( <i>e.g.,</i> MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	≤12 months.
III. Vaccines containing measles, mumps, and rubella virus or any of its components ( <i>e.g.</i> , MMR, MM, MMRV)	A. Anaphylaxis B. Encephalopathy or encephalitis	≤4 hours. 5-15 days (not less than 5 days and not more than 15 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.

Source: HRSA

https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf

# Exclusion of Legitimate Cases

- Vaccine injury table can change.
- \* Currently, it limits awards for thrombocytopenia to cases manifesting 30 days or less.
- 1996 report by the CDC states that thrombocytopenia can manifest two months post-MMR-vaccination.

#### Thrombocytopenia

Surveillance of adverse reactions in the United States and other countries indicates that MMR vaccine can, in rare circumstances, cause clinically apparent thrombocy-topenia within the 2 months after vaccination. In prospective studies, the reported incidence of clinically apparent thrombocytopenia after MMR vaccination ranged from one case per 30,000 vaccinated children in Finland (22) and Great Britain (23) to one case per 40,000 in Sweden, with a temporal clustering of cases occurring 2–3 weeks after vaccination (24). With passive surveillance, the reported incidence was approxi-

 Thrombocytopenia or ITP is a disorder caused by low levels of platelets, leading to excessive bruising and bleeding.

Source: CDC, Mayo Clinic

https://www.cdc.gov/mmwr/pdf/rr/rr4512.pdf

https://www.mayoclinic.org/diseases-conditions/idiopathic-thrombocytopenic-purpura/symptoms-causes/syc-20352325

#### **Client Compensation for Vaccine Injuries**

			Search: ммк	
Amount Compensated	Illness or Symptoms	Vaccine Name	Link to Court Decision	Date
\$101,000,000	Encephalopathy	Measles Mumps Rubella (MMR)	Case 16- 119V	11/20/17
\$25,000	Hearing Loss, Tinnitus	MMR	Case 15- 1328V	11/29/16
\$77,000	Aplastic Anemia	MMR, Varicella, Dtap	Case 13- 780V	1/4/16
\$225,000	Demyelinating Polyneuropathy	Tdap, MMR	Case 13- 756V	10/3/14
\$200,000	Multi-Organ Failure, Streptococcal A Infection, Toxic Shock	DTaP, HiB, MMR Pneumococcal	Case 11- 50V	9/26/14
\$600,000	Strep A infection, Toxic Shock, Multi-Organ Failure	Dtap, HiB, MMR, Pneumococcal	Case 11- 50V	9/26/14
\$72,000	GBS	Tdap, MMR	Case 13- 08V	4/21/14
\$72,000	Guillain Barre Syndrome (GBS)	Tdap, MMR Vaccines	Case 13- 08V	4/21/14
\$550,000	Myopathy, Polyneuropathy, Quadraparesis	MMR, Hep B Vaccines	Case 10- 129V	11/14/12
\$550,000	Myopathy, Polyneuropathy, Quadraparesis	MMR, Hepatitis B	Case11- 0143V	11/14/12
\$75,000	Acute Allergic reaction, Gastrointestinal and Behavioral Symptoms	Diphtheria, Tetanus Pertussis Vaccine (DTaP),Measles, Mumps, Rubella (MMR),Hepatitis A Vaccines	Case 08- 158V	9/22/10

Showing 1 to 11 of 11 entries (filtered from 611 total entries)

#### **Source**: Maglio Christopher & Toale <u>https://www.mctlawyers.com/vaccine-injury/process/</u>

## Deaths from MMR

- VICP Data from Oct 1988 Feb 2019
  - \* 61 petitions filed for death from the MMR vaccine & 1,034 petitions total.
  - 56% of all petitions for the MMR were denied. Assuming 56% of the petitions for death were denied, there were 27 awarded cases of death from the MMR vaccine, or nearly one death per year.
- \* Applying the VAERS 1% under-reporting factor:
  - \* 2,700 deaths from 1988-2019 or 87 per year.
  - \* This is an underestimation due to the unknown percentage of deaths which occur post-MMR vaccination but are not filed.

Source: HRSA, Maglio Christopher & Toale <u>https://www.hrsa.gov/vaccine-compensation/eligible/index.html</u> <u>https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf</u> <u>https://www.mctlawyers.com/vaccine-injury/process/</u>

# Challenges for Petitioners

- Petitions for deaths from vaccines must be made within 2 years of the death or 4 years from the first symptom which led to death.
- Presenting and defending VICP cases is a lengthy, very difficult, hard-fought legalistic process involving complicated legal and medical issues. This discourages individuals filing claims.
- \* VICP is limited to certain types of injuries occurring within a certain time frame.

"There continues to be **a lack of scientific understanding** of the specific biological mechanisms involved in most vaccine-associated injuries and deaths and an absence of pathological profiles to conclusively prove which health problems following vaccination are, in fact, vaccine-induced and which are not."

- Barbara Loe Fisher, NVIC Co-founder & President

**Source**: HRSA, Maglio Christopher & Toale, NVIC <u>https://www.hrsa.gov/vaccine-compensation/eligible/index.html</u> <u>https://www.mctlawyers.com/vaccine-injury/process/</u> <u>https://www.nvic.org/injury-compensation/vaccineinjury.aspx</u>

### VACCINE INJURY PYRAMID



### **Decline in Measles Mortality**

 What was the reason for the decline prior to the introduction of the vaccine?



## Infectious Disease Mortality



## Factors in the Decline

- 92% of the decline in infectious disease mortality in the 20th century occurred prior to 1950, and the introduction of vaccines.
  - Improved nutrition
  - Drinking water treatment
  - Sanitary living conditions
  - Better hygiene



Figure 1. Crude death rate\* for infectious diseases - United States, 1900-1996

Sources: columbia.edu, CDC

http://www.columbia.edu/itc/hs/pubhealth/rosner/g8965/client\_edit/readings/week\_2/mckinlay.pdf https://www.cdc.gov/healthywater/drinking/history.html

### Malnutrition & Measles

- \* Malnourished children and populations will experience:
  - Severe and prolonged measles infection.
  - \* More severe measles infections at a greater frequency.
  - \* Greater risk of secondary infections.
  - Increased risk of complications and longer hospital stays.
- \* **Malnutrition** is largely responsible for the elevated mortality rate and risk of complications in developing nations.

Sources: BMJ, Nutrition Reviews, Journal of Ayub Medical College <u>https://www.ncbi.nlm.nih.gov/pubmed/871699</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/6181440</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/19385448</u>

### Malnutrition & Measles

- \* Case fatality rates as high as 20% from West Africa.
  - "The overwhelming majority (more than 95%) of measles deaths occur in countries with low per capita incomes and weak health infrastructures."
  - \* "Severe measles is more likely among poorly nourished young children, especially those with insufficient vitamin A, or whose immune systems have been weakened by HIV/AIDS or other diseases."

Sources: World Health Organization, Reviews of Infectious Diseases <u>https://www.who.int/en/news-room/fact-sheets/detail/measles</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/6878998</u>

## Measles & Vitamin A

- \* 1990: Measles virus depletes vitamin A. Vitamin A deficiency is associated with increased mortality from measles.
- \* 1992 & 1993: Children with no known vitamin A deficiency show a significant decline in vitamin A during measles infection. The degree to which vitamin A levels are depressed governs the severity of the illness.
- \* **2002**: The World Health Organization recommends vitamin A supplementation as treatment for measles.

Sources: New England Journal of Medicine, Nutrition Reviews, Pediatrics, Journal of Tropical Pediatrics <u>https://www.ncbi.nlm.nih.gov/pubmed/2194128</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/1436764</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/8502524</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/12521271</u>

## Measles & Vitamin A

- \* 2008: Vitamin A is found to directly inhibit measles virus.
- \* **2009**: Vitamin A up-regulates the immune system in uninfected cells to protect against viral infection and replication.
- 2011: Vitamin A supplementation can reduce the *incidence* of measles, and prevent death, blindness and subsequent illness in children aged 6 months to 5 years, and potentially save 600,000 lives per year.

The benefit of vitamin A in the treatment of measles was first suggested in 1932, but was ignored until 1987.

Sources: Antiviral Research, FASEB Journal, BMJ, Science Daily, BMJ <u>https://www.ncbi.nlm.nih.gov/pubmed/18547655</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/19447880</u> <u>https://www.bmj.com/content/bmj/343/bmj.d5094.full.pdf</u> <u>https://www.sciencedaily.com/releases/2011/08/110825193059.htm</u> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2521770/</u>

### Measles & SSPE

### Subacute Sclerosing Panencephalitis

- Very rare, highly delayed, chronic progressive brain inflammation associated with measles infection.
- Symptoms: Personality changes, myoclonic seizures and / or muscle spasms, loss of vision, dementia, rigidity, respiratory distress, coma, and death. No cure exists.
- \* Fewer than 10 cases per year in the US. Greater incidence in developing nations.
- \* The MMR vaccine can cause SSPE.

**Sources**: MedlinePlus, NBC News <u>https://medlineplus.gov/ency/article/001419.htm</u> <u>https://www.nbcnews.com/health/health-news/fatal-measles-complication-killed-patients-years-later-n674706</u>

### **SSPE Risk Factors**

- Large families / several siblings / crowded home
- Being a third child or subsequent child
- \* Measles infection under 1 year
- Head injury
- Low birth weight
- Unhealthy mothers
- Rural living
- Contact with domestic animals, esp.
   birds and pigs
- Genetic factors

Sources: Acta Neurologica Scandinavica, International Journal of Epidemiology, American Journal of Epidemiology, Virologie, Journal of Pediatrics and Child Health, Archives of Neurology, Neuroepidemiology, Archives of Neurology

https://www.ncbi.nlm.nih.gov/pubmed/9696527 https://www.ncbi.nlm.nih.gov/pubmed/1468866 https://www.ncbi.nlm.nih.gov/pubmed/7377184 https://www.ncbi.nlm.nih.gov/pubmed/9588651 https://www.ncbi.nlm.nih.gov/pubmed/6659364 https://www.ncbi.nlm.nih.gov/pubmed/508150 https://www.ncbi.nlm.nih.gov/pubmed/3374729 https://www.ncbi.nlm.nih.gov/pubmed/12020266

### Benefits of Measles?

In the majority of children the whole episode had been well and truly over in a week...

and many mothers have remarked "how much good the attack has done their children," as they seem so much better after the measles.

Vital Statistics: Measles Reports from General Practitioners. 1959.

- Natural infections provide lifetime immunity, herd immunity and protection for the immune compromised, and protection for infants who cannot be vaccinated (antibodies via breastmilk) vs incomplete and waning immunity from vaccines, which requires additional booster shots.
- Childhood measles infection has been associated with a reduced risk of cancer later in life.
- \* Case studies of spontaneous remission of lymphomas as a result of measles infection.

Sources: CDC, International J. of Cancer, Leukemia Research, Lancet, BMJ <u>https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/15700307/</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/22940258/</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/6112483/</u> <u>https://www.ncbi.nlm.nih.gov/pubmed/4100922/</u> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1992477/pdf/brmedj02957-0102.pdf</u>



- \* If the rate of adverse events from measles in the 1960s was less than that of the MMR vaccine today,
  - If nutrition is largely responsible for the reduction in mortality from measles,
    - \* If the MMR vaccine does not prevent outbreaks,
      - If vitamin A can effectively treat measles and even reduce the incidence of measles,
        - And if natural measles infection itself is beneficial...
  - Why is the the MMR vaccine being pushed so heavily?

## The Push

- Vaccines are a \$60 billion per year market for the pharmaceutical industry.
- Merck pulls in 12% of the global market for vaccine sales.
- \$1.4 billion in sales for the MMR vaccine in 2010.
- Goal of the CVI Strategic Plan in 1998 was to increase demand for vaccines.

■ Bloomberg Subscribe
Business

#### Merck Measles Vaccine Sales Surged as California Outbreak Grew

Drew Armstrong and Cynthia Koons April 28, 2015, 10:03 AM PDT

There's nothing like an outbreak to get parents to vaccinate -- or to help vaccine sales.

As a measles outbreak that started in California grew from seven cases on Jan. 7 to more than 100 a month later, sales of Merck & Co.'s measles vaccine surged as well.

Sources: WHO, Bloomberg <u>https://www.who.int/influenza\_vaccines\_plan/resources/session\_10\_kaddar.pdf</u> <u>https://apps.who.int/iris/bitstream/handle/10665/64635/CVI\_GEN\_97.04.pdf</u> <u>https://www.bloomberg.com/news/articles/2015-04-28/merck-measles-vaccine-sales-surged-as-california-outbreak-grew</u>

## Merck: Profits over People

- In 2009, court proceedings revealed that Merck had created a fake scientific journal to publish fabricated data on its drug, Vioxx.
- \* Merck knew that Vioxx was causing heart attacks in their clinical trials, and removed the data when submitting it to the FDA.
- Merck is also currently in court over fraudulent claims of the efficacy of the mumps portion of the MMR vaccine.

Merck Created Hit List to "Destroy," "Neutralize" or "Discredit" Dissenting Doctors

Sources: CBS News, New Scientist, Huffington Post <u>https://www.cbsnews.com/news/merck-created-hit-list-to-destroy-neutralize-or-discredit-dissenting-doctors/</u> <u>https://www.newscientist.com/article/dn13685-drug-giant-merck-accused-of-deaths-cover-up/</u> <u>https://www.huffingtonpost.ca/entry/5881914</u>

### **Additional Concerns**

- \* CDC Scientists lodge ethics complaint against the agency.
  - Scientists Preserving Integrity, Diligence, and Ethics in Research: Research at the CDC is being influenced and shaped by industry interests. Covering up and falsifying data is becoming the norm and not the rare exception.
- \* FDA caught burying evidence of fraud in medical trials.
- Pharmaceutical companies spend twice as much money on promotion than they do on research and development.
- News media receives 70% of their advertising revenue from pharmaceutical companies on non-election years.
- Medical schools and textbooks are heavily influenced by the industry.

Sources: Huffington Post, Slate, PLoS Medicine, RFK Jr., STAT News
<a href="https://www.huffingtonpost.com/carey-gillam/spider-bites-cdc-ethics-c\_b\_12525012.html">https://www.huffingtonpost.com/carey-gillam/spider-bites-cdc-ethics-c\_b\_12525012.html</a>
<a href="https://slate.com/technology/2015/02/fda-inspections-fraud-fabrication-and-scientific-misconduct-are-hidden-from-the-public-and-doctors.html">https://slate.com/technology/2015/02/fda-inspections-fraud-fabrication-and-scientific-misconduct-are-hidden-from-the-public-and-doctors.html</a>
<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2174966/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2174966/https://www.statnews.com/2018/03/06/conflict-of-interest-medical-textbook/https://www.statnews.com/2018/03/06/conflict-of-interest-medical-textbook/">https://www.statnews.com/2018/03/06/conflict-of-interest-medical-textbook/</a>

# What Would Happen If...

- \* What if we all stopped vaccinating for measles?
- \* The surge in the late 80s/early 90s showed us what would happen.
  - \* Low-income children at highest risk of contracting measles.
  - \* Low-income children experience food and nutrition insufficiency, and would also be at a greater risk of severe measles.
  - Malnourished, vitamin A deficient, and immunocompromised would be at risk.
  - Infants would be at risk, due to lack of antibodies transferred across the placenta from mothers who don't have immunity from wild-virus infection.

Sources: J. Infectious Diseases, Archives of Pediatrics and Adolescent Medicine, CDC <u>https://academic.oup.com/jid/article/189/Supplement\_1/S91/825077</u> <u>https://jamanetwork.com/journals/jamapediatrics/fullarticle/190498</u> <u>https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html</u>

## Conclusion

- Measles can be deadly in malnourished individuals.
- \* SSPE is a valid concern, but cases are extremely rare.
- The MMR vaccine has a convincing record of effectiveness, however, the amount of severe and chronic harm it can inflict may not be worth the risk.
- \* MMR vaccination rates over 99% do not prevent outbreaks of measles.
- Low mortality rates and popular culture of the 60s provide evidence that measles infection was a minor concern in the US prior to the vaccine, due to improved nutrition and vitamin A sufficiency.
- Vitamin A sufficiency can help prevent severe measles, complications, and death, and is easy to obtain following a healthy diet.
- \* Can we trust the information we're receiving from public health agencies, the media, and the medical system, if industry influence appears to be such a significant problem?
- The goal should be to improve nutrition in low-income families and children to prevent severe measles.





Have a Cheery Chickenpox

JEANNE BENDICK with CANDY BENDICK and ROB BENDICK, jr.

And just about everybody gets measles, mumps, and chickenpox, sometime or other. They don't always come at the handiest time. They might interfere with Christmas or birthdays or the circus,



once you have had them, you almost certainly will never have them again.

so

have a happy measle, a merry mumps, a cheery chickenpox, and grin and bear whatever else comes along.



**1958 Children's Book**, sold on Amazon: <u>https://www.amazon.com/Happy-Measle-Merry-Cheery-Chickenpox/dp/B005LEBDUG</u>