

Vaccine Safety and Efficacy: There's Never Been a Better Time Than Now

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- Arizona Alliance for Community Health Centers is accredited by the Arizona Medical Association to provide continuing medical education for physicians.
- The Arizona Alliance for Community Health Centers Designates the 2025 Public Psychiatry Academy: Early Career Program educational activity for a maximum of 1 AMA PRA Category 1 Credits. Physicians should only claim credit commensurate with the extent of their participation in the activity"
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Learning Objectives

- Describe the efficacy of current vaccines
- Discuss the risks associated with vaccines
- Be able to address common fears related to vaccines

Lee's Ferry

- May 1891 a family travels from Richfield, UT to Tuba City, AZ
- They had buried one of their children in a previous town a few days before, cause unknown
- They stay the night with the family managing the ferry across the Colorado river at Lee's Ferry in Northern Arizona



Lee's Ferry

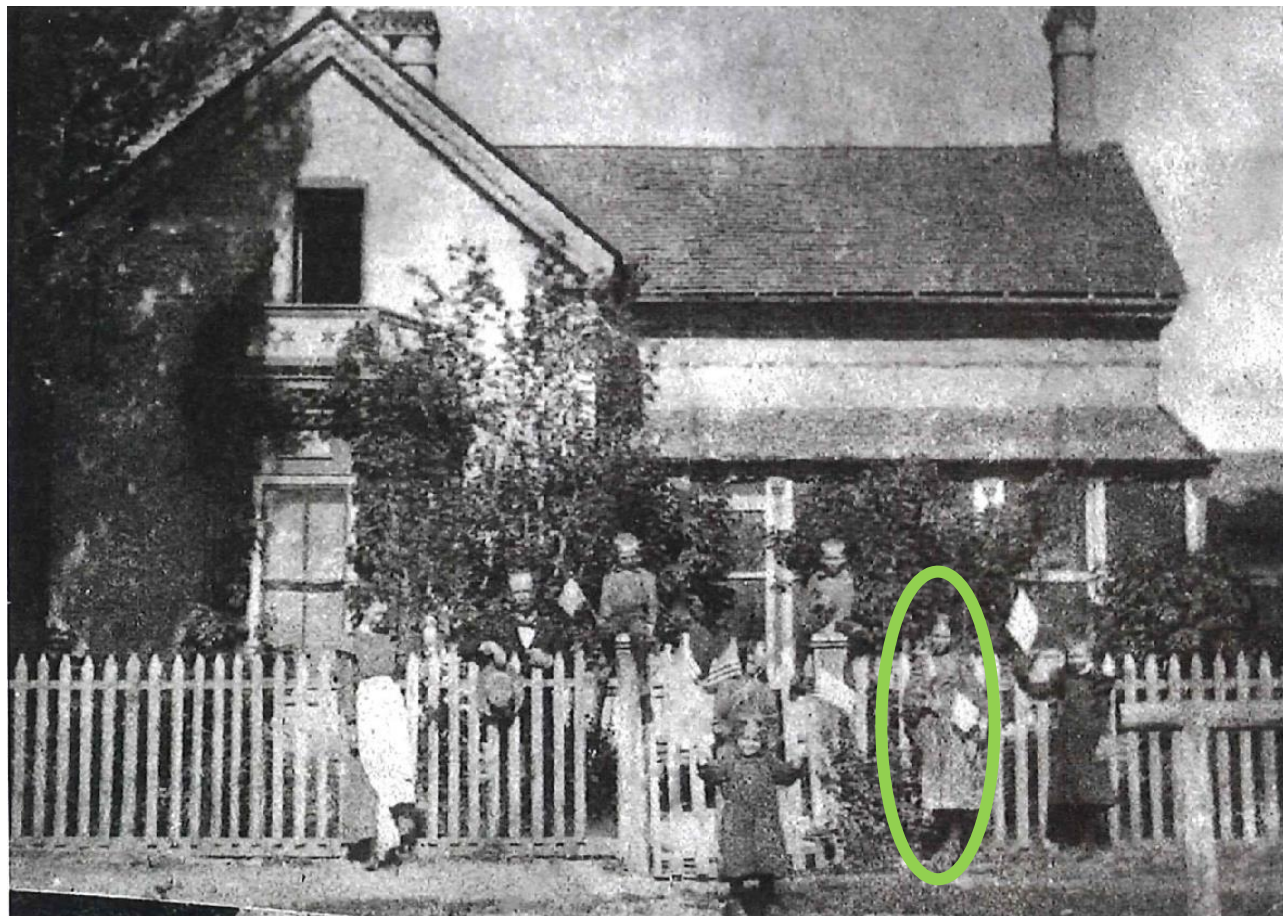
- 4 days later the 5 year old son gets a sore throat and fever. Within days he chokes to death in his father's arms
- The family's 7 year old girl contracts the illness and dies a few days later
- The 9 year old girl then gets it and dies
- Then the 15 year old daughter dies a few days later
- 3 other children get the disease and survive



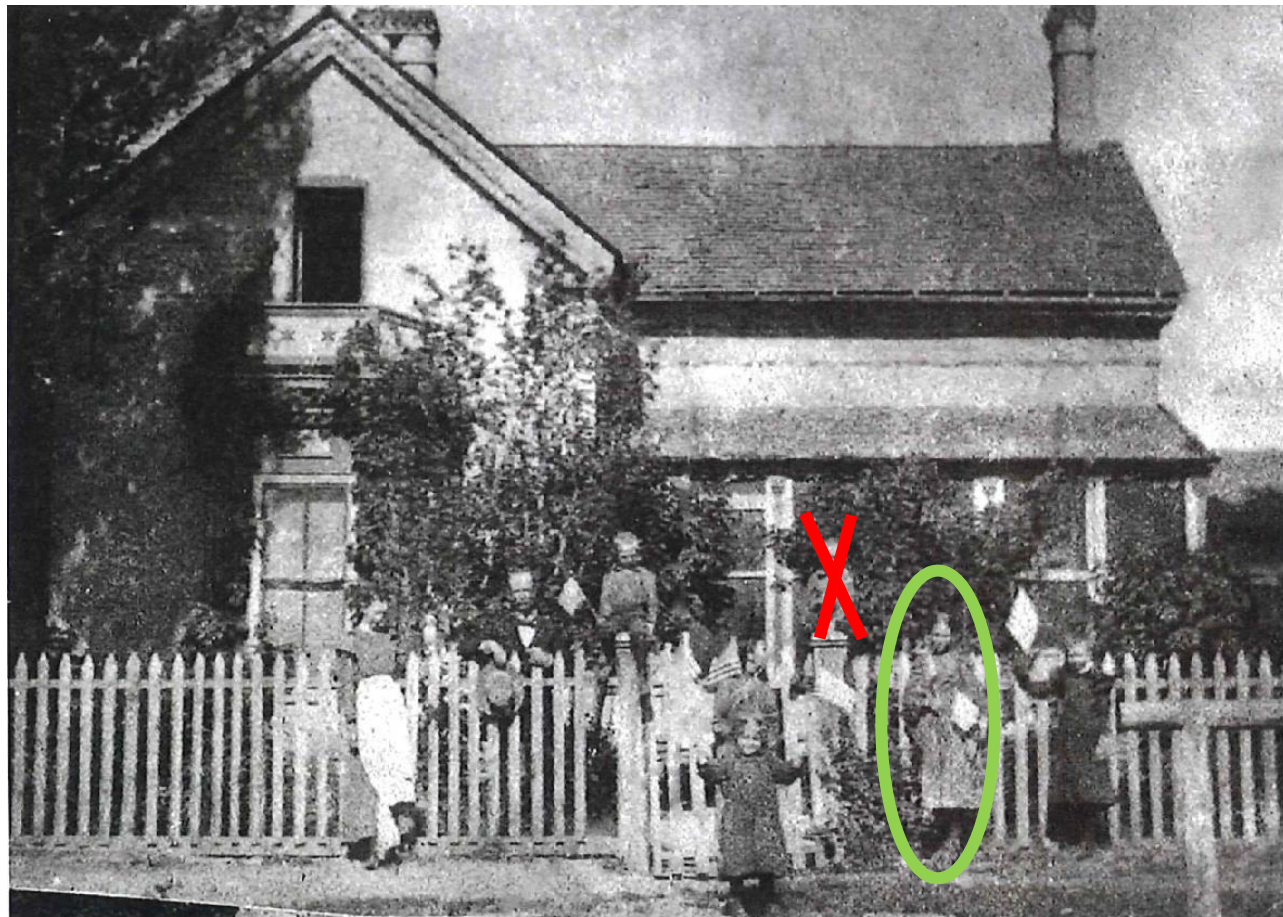
Diphtheria



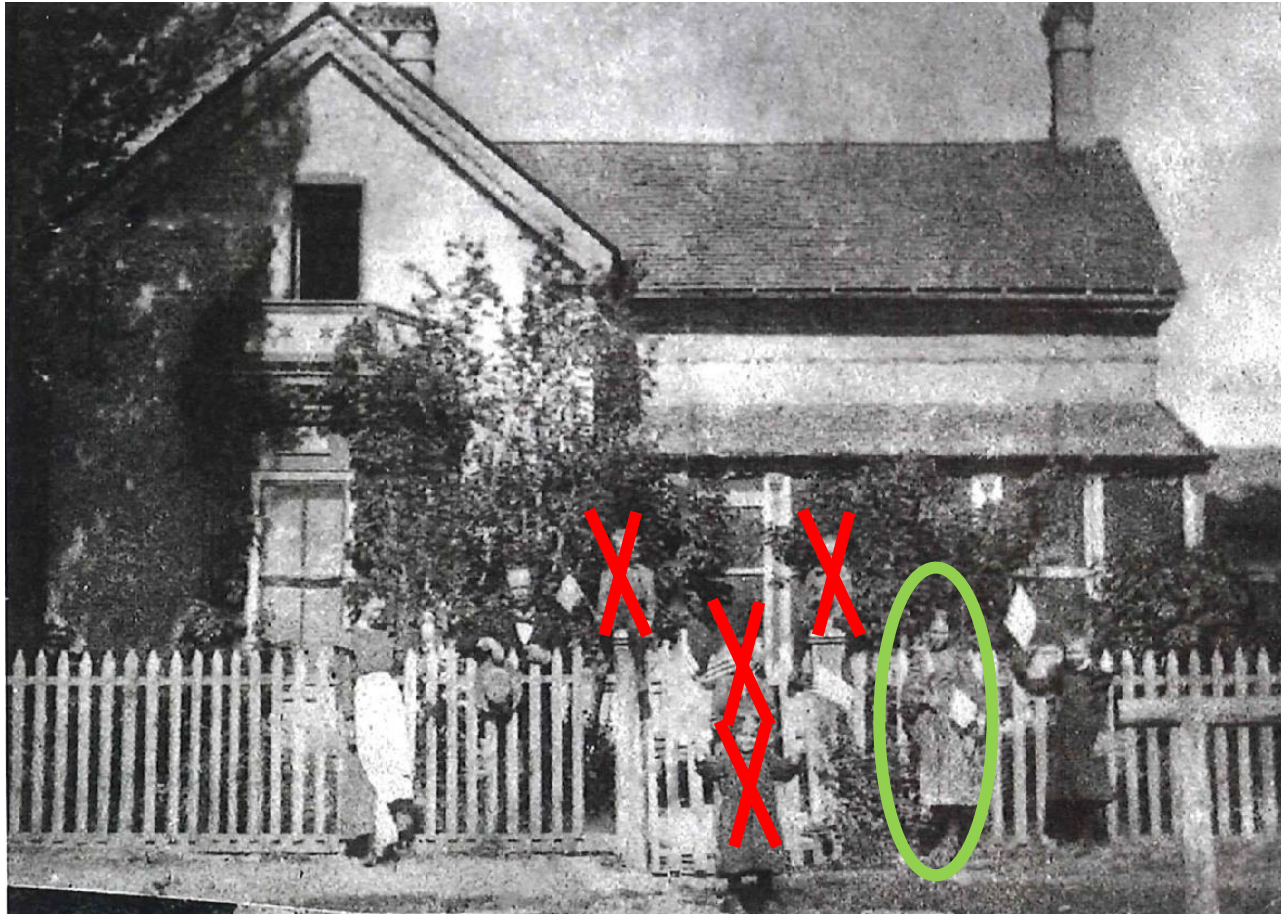
July 4th, 1898: Agnes Jones with her family



July 1902



July 1902



George: age 12

Daniel: age 10

Louise: age 7

Evan: age 3

Margaret Lloyd: age 9

1934 El Paso, TX



Mary Ardelle

A More Modern Story: Tucson 2008

- Visitor from Switzerland develops fever, cough rash
- Traveled on airplane, visited ER and then again the next day and admitted with fever, cough, rash
 - Not isolated until 2 days later when measles was suspected
- 14 confirmed cases over a 13 week period (additional 363 suspected, 8 probable)
 - 7 acquired in healthcare facilities
 - None of the cases had evidence of immunity prior to exposure
 - Could have been much worse
 - Only 70% of the healthcare providers at the hospitals had documented evidence of immunity
 - 92-96% vaccine coverage rate in the community at that time

Tucson 2008 Measles Outbreak

- 2nd patient was in same waiting room as index patient for 1 hour
- 4th patient was in a room across the hall in the same ED as pt 2. Went to pediatrician's office 3 times while contagious
- Patients 5 & 6 were sibs visiting their mother in the hospital where one of the measles patients was admitted
- 8th patient was at the pediatricians office for her 1st MMR when patient 4 was there



Measles in Samoa: 2019 Outbreak

- Population: 198,000 people on 4 islands
- Shortage of doctors and nurses over decades
- Decline in vaccine acceptancy
- 2 infants died after MMR vaccination that were wrongly prepared by the nurses
 - Mixed with expired muscle relaxant (atracurium) instead of water
 - Interrupted the vaccine access program for 8 months
 - Vaccine fears spread on social media
 - Many by anti vaccine groups
 - Lack of trust in the medical community
 - Families would chase away nurses from home visits
- Vaccination rates as low as 31% in some communities

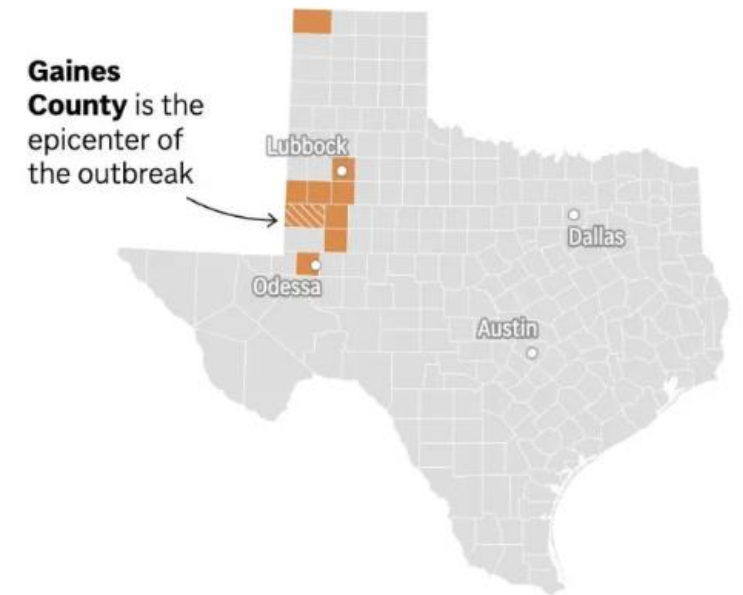
Measles in Samoa: 2019 Outbreak

- 5707 people infected over 3-month period
 - 83 died
 - 1868 admitted to the hospital
 - Led to shutting down schools, banning public gatherings
- Attitudes changed towards vaccination
 - 95% vaccination rate
 - Nurses are welcomed on home visits

Measles Outbreaks as of April 3, 2025

- 6 outbreaks in the US
 - 657 cases
 - 72% in children
 - 97% unvaccinated
 - 40% required hospitalization for complications
 - 2 deaths
 - 1 confirmed in TX, unvaccinated child, no underlying conditions
 - 1 under investigation in NM
- AZ vaccination rate
 - 89.3% of kindergarteners (down from 89.9%)
 - Need a rate of 95% to prevent outbreaks

Cluster of Texas counties affected by measles outbreak



Vaccine Success

- CDC estimates vaccines have prevented in the U.S 1994-2023:
 - 508 million illnesses
 - 32 million hospitalizations
 - 1.29 million deaths
 - \$540 billion in direct costs
 - \$2.7 trillion in societal costs
- Smallpox eradicated in 1977
 - Only human infectious disease eradicated
 - Mortality of up to 35%
- Polio eradicated from the U.S. in 1979
- Marked reduction in bacterial meningitis cases
- Chickenpox

Reduction in Morbidity and Mortality of Some Vaccine-Preventable Diseases in the US

Disease	Maximum No. of Cases (y)	Cases in 2019	% Decrease
Diphtheria	206,939 (1921)	2	>99
Pertussis	265,269 (1934)	18,617	93
Tetanus	1314 (1922–1926)	26	98
Poliomyelitis, paralytic	21,269 (1952)	0	100
Measles	894,134 (1941)	1275	>99
Mumps	152,209 (1968)	3780	98
Rubella	57,686 (1969)	6	>99
Congenital rubella syndrome	20,000 (1964–1965)	1	>99
<i>Haemophilus influenzae</i> type b (<5 y)	20,000 (before 1987)	18	>99
Invasive pneumococcal disease (<5 y)	15,933 (2000)	1115	93
Hepatitis B	21,102 (1990)	3544	83
Varicella	158,364 (1992)	8297	95

Failures and Unanticipated Problems

- 1/230 early rabies vaccine recipients in the 1800s developed seizures, paralysis, coma
- 1940s sera unknowingly infected with Hep B given to stabilize military recipients of yellow fever vaccine. 330,000 infected with hep B, severe disease in 50,000, 62 died
- 1955 one company failed to completely inactivate polio strain, injecting 120,000 with live poliovirus. 40,000 developed mild polio, 200 permanently paralyzed, 10 died
- Increased mortality due to RSV in early RSV vaccine candidate trial in the 1960s

Failures and Unanticipated Problems

- Small risk of paralytic polio after oral polio vaccine
- Encephalopathy after whole cell pertussis vaccine
- Guillain-Barré associated with 1976 swine flu vaccine
 - 45 million people vaccinated in 10 weeks in the US
 - Likely 1 case of Guillain-Barré per 100,000 vaccinated, caused 53 deaths
 - Current flu vaccines: higher risk of Guillain-Barré after influenza infection compared to after vaccination
- Intussusception associated with original rotavirus vaccine- detected by VAERS and vaccine removed from market. Subsequent rotavirus vaccines have extensive evaluation for intussusception pre and post approval

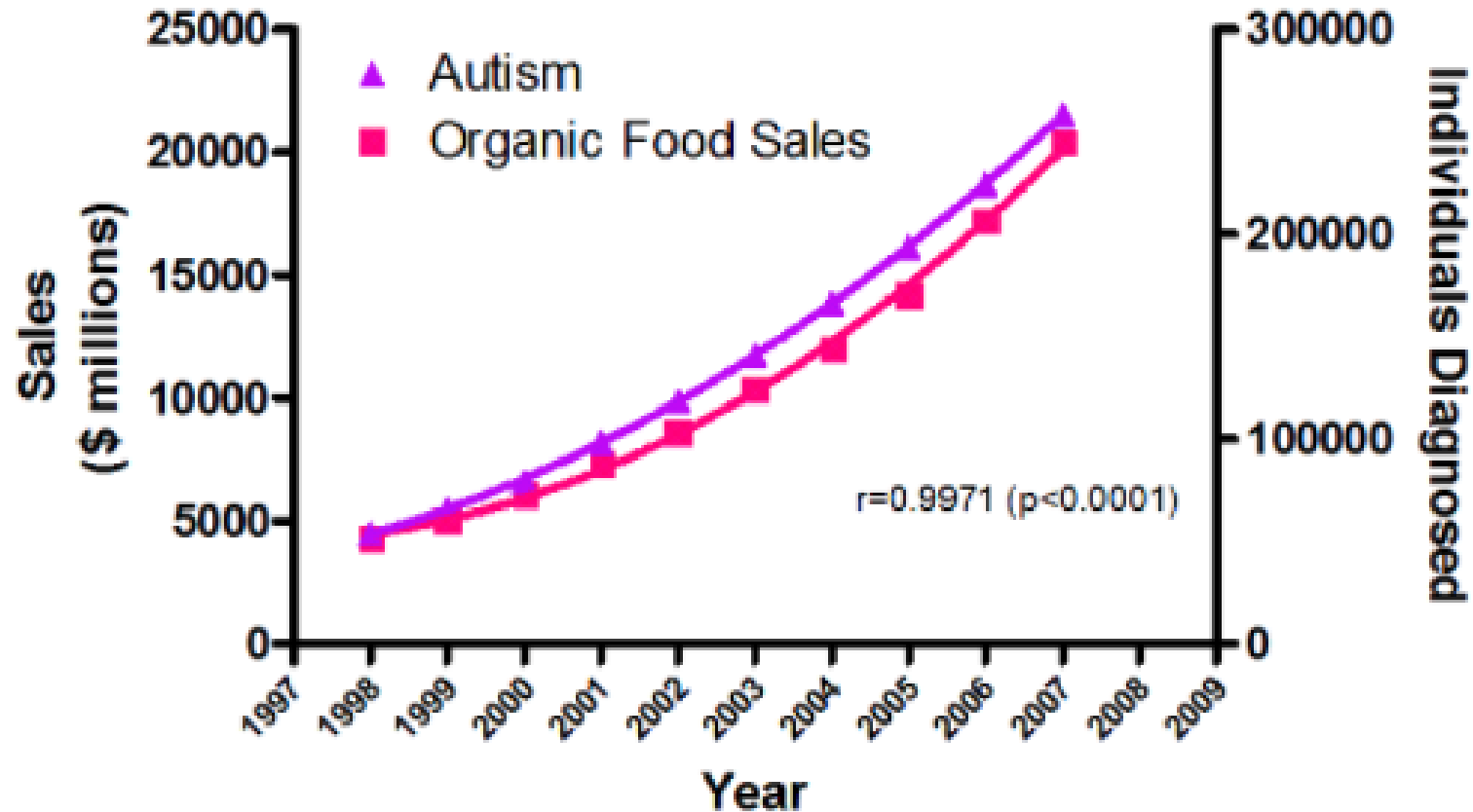
Known Problems

- BCG vaccine in immune compromised patients
- Smallpox vaccine and patients with eczema
- Live virus vaccines and immune compromised patients
- Yellow fever vaccine reaction

Association, Correlation, Causation or Error: Potential for Parm

- 1970s: 22 cases of permanent brain damage in children that got whole cell pertussis vaccine.
 - Vaccination rate in Britain decreased from 81% to 31%
 - 100,000 cases of pertussis with 36 deaths.
 - Many studies later: no association difference in rates of intellectual disability or epilepsy in vaccinated children compared to controls
- Deaths after DTwP vaccination, HPV vaccination, Hep B vaccination in various countries led to suspension of vaccination.
 - Later found to be unrelated to the vaccine.

Association \neq Causation



Sources: Organic Trade Association, 2011 Organic Industry Survey; U.S. Department of Education, Office of Special Education Programs, Data Analysis System (DANS), OMB# 1820-0043: "Children with Disabilities Receiving Special Education Under Part B of the Individuals with Disabilities Education Act"

Put Things in Perspective

What we ARE afraid of	What we SHOULD be afraid of
 <p>28 attacks avg./year</p>	 <p>4,500,000 bites avg./year (46 deaths in 2020)</p>
 <p>50 deaths by peanut allergy avg./year</p>	 <p>27,531 deaths by poisoning avg./year</p>
 <p>321 deaths by plane crash avg./year</p>	 <p>34,017 deaths by car crash avg./year</p>

Vaccines Have Real Risks

- Anaphylaxis
- Known rare and common adverse effects
- Unknown rare effect
- Systems in place to mitigate the risks

Vaccine Development and Safety

- Preclinical studies
 - Cell cultures and other in vitro studies
 - Animal studies
- Clinical trials: Phases I-III (and sometimes IV)
 - Phase I: very small group, usually healthy volunteers, dosing ranges, focuses on safety
 - Phase II: often larger group of healthy volunteers, focuses on safety and efficacy
 - Phase III: larger group, target population, focuses on safety and efficacy

FDA Approval

- Comprehensive evaluation of the data, process, etc
 - Can be hundreds of thousands of pages of data/information
- All data are available showing safety and efficacy for a certain time period after receipt of the vaccine regimen
- Prescribing information, labeling, etc finalized
- Post approval surveillance plan

Advisory Committee for Immunization Practices (ACIP)

- 15 voting members selected by the Secretary of the US Department of Health and Human Services
 - Voluntary service
 - Screened for conflicts of interest
 - Expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health
 - 1 member is a consumer representative
- Non voting Ex-officio members

Advisory Committee for Immunization Practices (ACIP)

- Host of liaisons: AAP, ACP, ACOG, IDSA, SHEA, etc
- Give recommendations for who should get the vaccine based on risk/benefit data after FDA approval (or EUA)
 - Often multiple re evaluations as more data become available over the months/years
 - For Janssen vaccine EUA held 11 public meeting with experts in ID, vaccinology, vaccine safety, public health and ethics to review the data and make recommendations

Vaccine Safety: Post Approval

- Phase IV trials
- VAERS
- V-safe
- Sentinel BEST (Biologics Effectiveness and Safety) system
- CMS
- Vaccine Safety Datalink
- ACIP

National Vaccine Injury Compensation Program (VICP)

- No fault program to compensate patients adversely affected by vaccines
- Funded by excise tax on all vaccines
- Determined based on vaccine, type of injury and timing of injury
- Legal process, not a medical process
 - Tend to err on the side of the affected patient
- Info on the VICP is on the VIS form for every vaccine

Reason for the Timing and Number of Vaccines: Deviating Increases Risk

- Age at which an immune system may respond
- Age at which risk for severe disease is highest
- Protection in place well before exposure
- Timed with other vaccine visits

Vaccine Fears Aren't New



An 1802 engraving, *The Cow Pock—or—the Wonderful Effects of the New Inoculation* plays on the fears of a crowd of vaccinees. [©The Trustees of the British Museum](#)

Modern Safety Fear: Autism

- Autism is on the rise
 - Multifactorial, but improved diagnosis is a major part
 - Spectrum of disease, but can be devastating
 - No cure
 - We don't really know what causes it
- Autism symptoms are often noted around a year of age but can be recognized earlier
 - Similar time frame of the 1st MMR dose

Andrew Wakefield and the 1998 Lancet Article

- British gastroenterologist
- Study 12 children with autism/autism-like disease and chronic GI problems
 - All developed autism symptoms within days of getting the MMR
 - All had GI symptoms
 - Endoscopy showed abnormalities
 - Didn't look for virus
 - Pose the theory that MMR (not the separate measles vaccine) causes autism and GI disturbances
 - Recommends using a single component measles vaccine

Andrew Wakefield: Problems Arise

- Small study (12 children)
- No controls
- Didn't look for evidence of vaccine virus
- Not a high enough quality study to make any conclusions on

Andrew Wakefield: Problems Arise

- Wakefield rapidly works to monetize his findings
 - Gets grants and investments to develop special diagnostics and treatments
- But....
 - He is being paid by an attorney suing the MMR vaccine makers to find a problem with the MMR vaccine
 - £435,643 plus expenses
 - He files for a patent for single component measles vaccine
 - Never replicates his findings

Andrew Wakefield: Even More Problems

- Investigative reporter starts digging
 - Finds the info on the patents, business plans, etc
 - More importantly: interviews the families and finds major discrepancies
 - Some had symptoms of autism before receipt of MMR
 - Many of the patients had their symptoms/timing described incorrectly, making it look like there was more of a link between GI/autism and MMR
 - Some had no abnormality seen on endoscopy and biopsy
 - Several other ethical problems are found in how the study was conducted
- Almost every patient had a significant discrepancy affecting the ability to interpret the results
- Lancet retracts the article
- Wakefield is struck from the British medical register

Can't Find a Link Between MMR and Autism

- Despite problems with the study and the investigator the question is there
- Wakefield found evidence of measles virus in tissue samples in adults with Crohn's disease
 - Can't replicate it with his own repeat study
 - 2 other studies can't replicate it
 - Didn't distinguish between wild type measles or vaccine strain measles virus

Studies Refuting any Link between MMR and Autism

- 2 studies showed no difference in autism and GI symptoms before and after MMR vaccination
- 1 study showed no difference between measles virus RNA between children with autism and GI symptoms vs children with GI symptoms without autism
- 11 additional studies (ecological and case-control) find no link
 - Japan, Canada, US, Poland, Denmark
 - Single component and MMR vaccines
- Announcement of new study to be done?

Safety Fear: Thimerosal

- Preservative used since the 1930's to inhibit bacterial and fungal growth in multidose vaccine vials
- Has Ethylmercury (different from the more toxic methylmercury that you hear about)
- Taken out of most vaccines since 2001 due to initial concern, but studies refute any link to autism or other neurologic disorder (still in some multidose flu, but trace amounts)
- Autism rates have increased since removing thimerosal
- Adverse reactions: pain, anaphylaxis (rare)

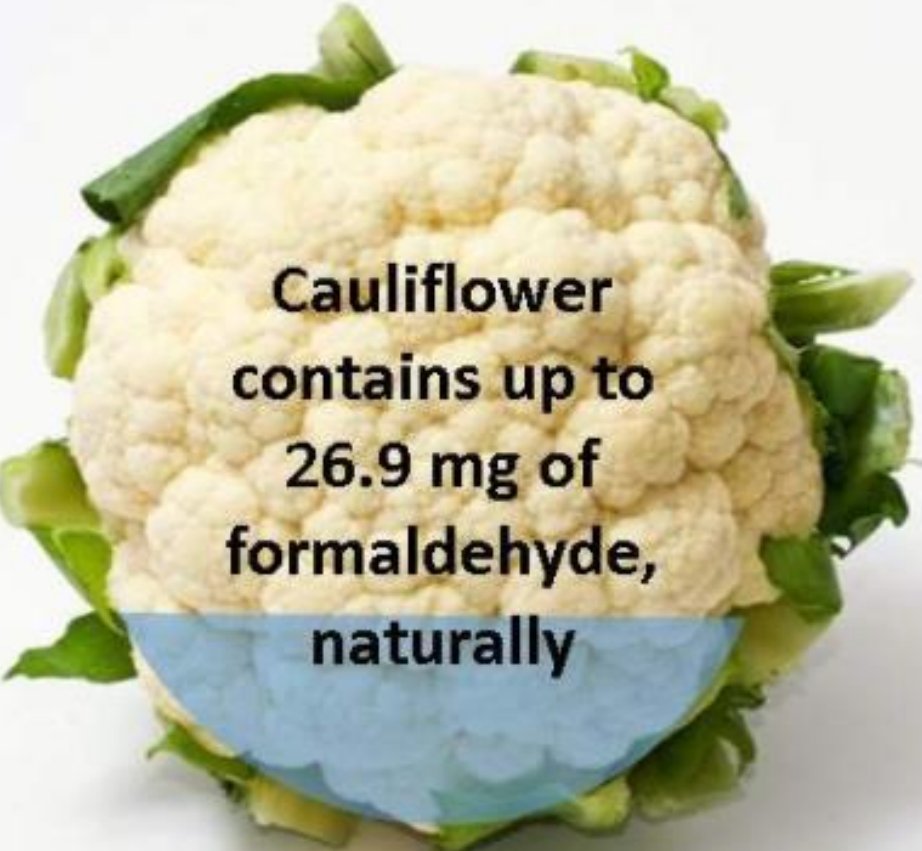
Safety Fear: Aluminum

- Adjuvant used to increase immune response
- DTaP, Hep B, PCV, etc
- More common to get aluminum from food and drinking water
 - 30-50mg/day
 - Vaccines have 0.125-0.625mg/dose
- 60 years of experience with safe use of aluminum in vaccines
- Can get severe local reactions


Safety Fear: Formaldehyde

- Why are we putting poisons in our children?
- Formaldehyde used to inactivate viruses
- Associated risk of cancer and formaldehyde, but among people who inhale it regularly associated with occupation, not from vaccines
- Naturally occurs in the environment
- Found in car exhaust, cosmetics, carpets, upholstery, felt tip markers, antihistamines, cough drops, mouthwash, etc
- Produced by our bodies in metabolic pathways
 - Formaldehyde present at steady state levels of 2.6mg/L in the blood from natural biochemical processes and environmental exposures
 - <0.01mg in a vaccine

Concerned about formaldehyde in vaccines?



**Cauliflower
contains up to
26.9 mg of
formaldehyde,
naturally**



**Vaccines contain
up to 0.1 mg, or
0.37%, of the
formaldehyde
found in
cauliflower**

Safety Fear: Too Many Antigens Overwhelm the Immune System

- The human immune system confronts millions of antigens in a single day
 - 25-50 antigens from strep throat
- Estimated that a person could respond to 100,000 vaccines at one time based on estimate of circulating B cells and # of epitopes/vaccine
- “Worrying about too many vaccines is like worrying about a thimble of water getting you wet when you are swimming in an ocean”

More is Less: Fewer Antigens in Modern Vaccines

- 1960: 5 vaccines, 3217 antigens
 - 3000 whole cell pertussis
 - 198 smallpox
- 1980: 7 vaccines, 3041 antigens
- 2020: 16 vaccines, 198 antigens
 - Many combined to decrease the number of shots given
 - Studies show safety and efficacy of multiple vaccines given at the same time
 - But may sometimes cause minor problems (MMRV) and febrile seizures in 1y/o

Actual Measles Infection Does Weaken the Immune System

- Decreases B and T cells, delays cell mediated immunity
 - “Immunologic Amnesia”
 - One study showed loss of up to 73% of total pathogen specific antibody repertoire after measles infection
 - Antibody rebuilds over time, often due to infection
 - MMR vaccination did not affect the antibody repertoire
 - Higher mortality in children after recovering from measles compared to children who were never infected with measles
 - Estimated 50% of infectious disease related deaths in the pre-vaccine era are related to measles induced immunologic amnesia
 - Can last as long as 5 years post infection

Other Unfounded Safety Concerns

- Autoimmunity (Multiple sclerosis, lupus, etc)
 - Epidemiological studies find no link
 - No biological mechanisms found showing vaccines could cause autoimmunity
 - Many studies showed that vaccination didn't exacerbate MS
 - Autoimmune autoinflammatory disease associated with adjuvants?
 - Not well defined, many non-specific/common symptoms
 - More to come, but unlikely to be a widespread problem
- Asthma, allergies and atopic disease
 - Hygiene hypothesis
 - Only a very small number of illnesses are prevented by vaccination
 - Many studies including over 100k children showed no link to asthma, allergies and atopic disease
 - Some vaccines prevent viral illnesses that can exacerbate asthma

Back to the Measles Vaccine (MMR): Recent Media Comment

- "If you are healthy, it's almost impossible for you to be killed by an infectious disease, in modern times — because we have nutrition ... and access to medicines. What we need is good science on all of these things so that people can make rational choices."
 - Depends on your definition of almost impossible
 - I would argue strongly against that since we know that many healthy children have died from measles, COVID and influenza
 - I have personally taken care of some of those
 - Based on a similar definition you could say that is it almost impossible to be killed by a vaccine or suffer a serious side effect

Back to the Measles Vaccine (MMR): Recent Media Comment

- “There are adverse effects from the (measles) vaccine. It does cause deaths every year. It causes all the illnesses that measles itself causes - encephalitis and blindness, etc.”
 - Context of not wanting the government to force vaccination
 - Completely ignores the difference in rates of adverse effects of the disease vs the vaccine
 - His assessment still isn't completely accurate either

Measles in Perspective

- Mortality rate 1-3 per 1000 infections
 - Pneumonia and encephalitis
 - Pre vaccine era: universal infection by the time you were an adult
- Before 1963, 2.6 million deaths worldwide annually
 - Estimated 60 million deaths prevented from 2000-2023
- Still have 107,500 deaths from measles worldwide in 2023
 - Mostly children under the age of 5
 - Most were unvaccinated
- The 1st death in the US in 10 years was in an unvaccinated healthy child with no other risk factors

MMR Vaccine vs Measles Disease

- Blindness
 - Measles disease: 15,000-60,000 cases worldwide prior to vaccination
 - Usually permanent damage
 - Vitamin A and improved nutrition can make a big difference
 - Vaccine: 7 case reports of optic neuritis within weeks of MMR vaccination
 - Almost all had complete recovery of vision
- Pneumonia
 - Measles Disease: 1 per 20 infections
 - Many require hospitalization
 - 1 in 1000 die
 - Can't find any cases of vaccine associated pneumonia

MMR Vaccine vs Measles Disease

- Encephalitis
 - Measles disease
 - 1-3 per 1000 acute infections
 - 25% have permanent brain damage
 - 15% die
 - 1 per 1000 post infectious encephalitis
 - 20% die
 - 1 per 25,000 will get subacute sclerosing panencephalitis
 - Almost 95% die
 - Vaccine: 1 per 1,000,000
 - The best way to avoid risk is to get vaccinated
 - Focusing on the adverse effects of the vaccine misses the point

It's a Matter of Perspective

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COVID Vaccine Related Deaths?

- 2021 European data
 - 377 **million** doses administered of the 4 major COVID vaccines
 - 5,201 deaths temporally related to vaccination
 - Unable to confirm, make a strong connection to vaccination and death in the majority of cases
 - Real possibility for some: blood clots, etc
 - Background of 3.8 million deaths worldwide by that time
- Oregon Study: sudden cardiac death after COVID vaccine 2021-2022
 - 1292 deaths in 16-30 year olds
 - 30 died from COVID-19 disease
 - 3 deaths within 100 days of COVID vaccine, none able to be attributed to vaccination, but 1 without underlying medical conditions

COVID Vaccine Related Deaths?

- England study: risk of death after COVID vaccine and COVID
 - 12-29 y/o, 2020-2022
 - Similar rate of death 12 weeks after vaccination compared to >12 weeks after vaccination
 - Suggests not related to vaccine
 - Mortality rate higher in unvaccinated patients
- Contrast with mortality from COVID-19 infection
 - 1.2 million deaths in the US since the onset of the pandemic
 - 7 million deaths reported worldwide

What do the Data Show About General Vaccine Related Deaths?

- 2013 study: VSD data evaluated from 2005-2008
 - 13 million vaccinated people
 - Mortality rate in unvaccinated people was almost 2x higher than vaccinated people
- Anaphylaxis
 - Estimated 2 cases per million doses
 - Doesn't guarantee death
 - Questions about prior history
 - Healthcare providers should be prepared to manage anaphylaxis

What do the Data Show About General Vaccine Related Deaths?

- Yellow fever vaccine associated viscerotropic and neurologic disease
 - 35 reported deaths
 - Vaccine administrators need to be certified, and patients informed of risk
- Oral poliovirus vaccine (no longer used in the US)
 - Risk of disease: 1 in 4.7 million, death is rare
 - 2 deaths in the US from 1980-1989

What do VAERS Data Show About Vaccine Related Deaths?

- Many deaths attributed to SIDS
 - Additional studies show that no increased rate of SIDS in vaccinated infants compared to unvaccinated infants
- Immune compromised and live virus
 - Case reports per 2015 review
 - 2 VZV, 6 measles
 - Live virus vaccines contraindicated in immune compromised patients
- Intussusception and rotavirus 2006-2012
 - 2 deaths reported, unable to establish causality
- H1N1 influenza vaccine and Guillain-Barré 2000-2009
 - 2 deaths within 6 months of vaccination, unable to establish causality
- Syncope and head trauma leading to death: 1 case after Hep B vaccination

HPV Vaccine

- VAERS, VSD, specific studies
- Studies show no statistically significant association with
 - Complex regional pain syndrome
 - Positional orthostatic tachycardia syndrome (POTS)
 - Guillain Barre
 - Autoimmune diseases
- VAERS: may be increased risk of syncope and venous thromboembolism (VTE)
 - No increased risk of VTE from Denmark and Sweden study (696,000 doses)

mRNA Vaccines (Pfizer and Moderna COVID Vaccine)

- mRNA is a messenger
 - Tells our cells to make the SARS-CoV-2 spike protein so the immune system can recognize the virus causing COVID-19 when it shows up in our body
 - Like putting up a wanted poster for the virus
 - The mRNA gets broken down and is quickly disposed of by our cells so the message doesn't stick around long
 - May be some evidence that mRNA persists up to a month in some tissues
- mRNA vaccine technology has been in development for over a decade

mRNA Vaccines

- Do not change our DNA
- Don't affect future fertility
- Aren't transmitted to other people
- May increase risk of myocarditis in adolescent and young adult males
 - Though at a much lower rate than COVID-19 disease
- Ongoing evaluation for safety looking for association with rare diseases

Never Better: Recent Vaccine Advances

- RSV
- Ebola
- Malaria
- Chikungunya
- Dengue
- mPox

Vaccine Research

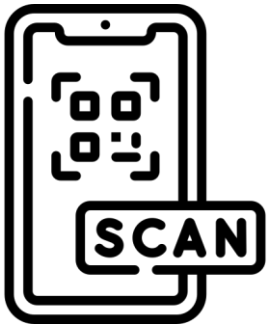
- Valley fever (Coccidioides)
- Bird flu
- HIV
- CMV
- Group B strep
- MRSA
- Candida auris

Conclusion

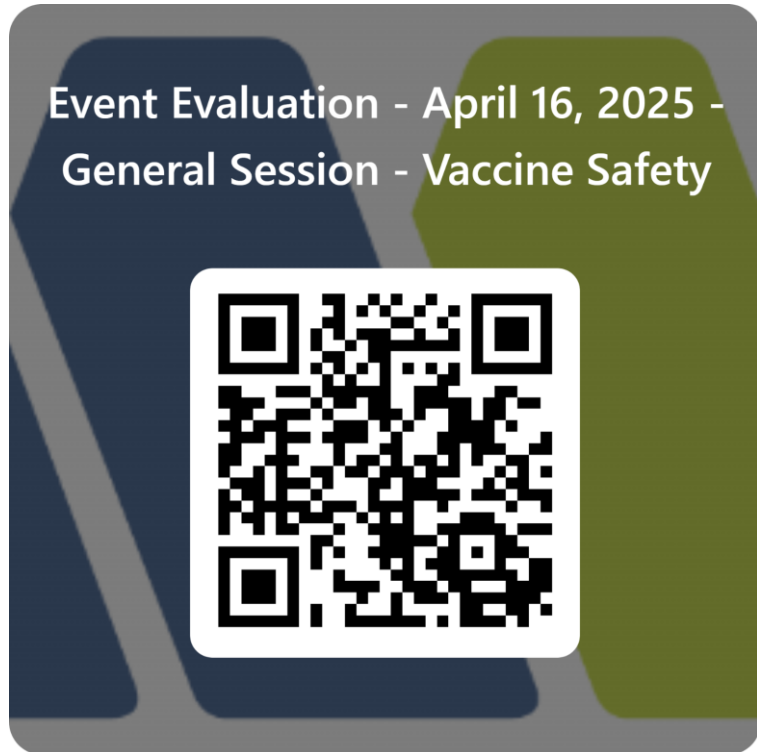
- We have a history of imperfect vaccine development and administration
- Robust systems in place to prevent and detect safety related problems
 - Concerns are welcome: lead to investigation and mitigation of risk
 - Need to combat misinformation and fear
- We've never had better protection from infectious disease than now
- The future is open wide with new discoveries on the horizon

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