Vaccines, Vaccine Hesitancy, and Current Vaccine Practices

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Objectives

- Vaccines as a public health **success**
- Vaccines as a public relations **challenge**
- The five categories of vaccine **hesitancy**
- The origins and impact of **National Childhood Vaccine Injury Act**
- The basis for **current** vaccine practices

WHICH
VACCINE
WOULD YOU IDENTIFY
AS OUR MOST
SUCCESSFUL ONE?

Annual Number of Cases in the US

Disease	Pre-Vaccine Era		Post-Vaccine Era	
Smallpox	1920	110,672	2019	0
Pertussis (Whooping cough)	1934	265,269	2019	15,662
Diphtheria	1938	30,508	2019	2
Tetanus	1948	601	2019	19
Paralytic polio	1952	21,269	2019	0
Measles	1962	763,094	2019	1,287
Mumps	1964	212,932	2019	3,509
Congenital rubella syndrome	1965	20,000	2019	0
Hib (invasive, <5 years of age)	1985	20,000	2019	14
Acute Hepatitis B	1985	74,361	2018	21,600
Varicella (Chickenpox)	1988	5,358,595	2017	102,128
Hepatitis A	1995	117,333	2018	24,900
Pneumococcal (invasive, <5 y.o.a.)	1999	16,069	2016	1700

Routine Vaccination in the Top Ten List

- 1st of public health achievements 1900-1999
- Cost-effective reduction of disease
- Eradication of **smallpox** worldwide in 1980
- Stopped vaccinating against it altogether
- Eradication of polio worldwide nearing
- Control of many other important diseases

The Trouble with Being #1

- Successful suppression, resultant recklessness
- Elimination of measles in US in 2000
  - Elimination means no persisting chain of outbreaks
  - Every outbreak since has been result of travel to US
  - Primarily US residents returning home
  - Primarily unvaccinated, non-immune US residents
- Number of cases in 2019: 1261
- Outbreaks just a **plane-ride away**!

A Public Relations Challenge

- Recent survey of ~1000 **vaccinating** parents
  - 15%: It's better to develop immunity by getting sick
  - 23%: Children get more vaccines than are good for them
  - 34%: Immunity could be weakened by too many vaccines
  - 34%: Unvaccinated children ought to be allowed in school

Five General Categories of Vaccine Hesitancy

- The vaccine won’t **work**
- The vaccine isn’t **safe**
- The vaccine isn’t **needed**
- **Alternatives** are just as good or better
- The **authorities** are rejected

How Vaccines Join the Routine Vaccine Schedule

- An independent science-based authority determines
  - Effectiveness…
  - Safety…
  - Need…
  - Lack of alternatives…

Effective

- Blinding and controls overcome coincidences, prove cause-effect
- Licensure requires randomized controlled, double-blinded trials
  - Tested using lot-to-lot consistent batches
  - Tested with all the constituents to be used when licensed
  - Given (or not) at the age when due
  - Given (or not) with the other vaccines already due at that age
  - Shown to be **effective** in preventing disease
  - Licensed by US Food and Drug Administration (FDA)

Safe

- Randomized controlled trials pre-licensure
    - Shown to have an acceptable low rate of reactions
    - Shown not to cause persisting problems
    - Shown to not interfere with other vaccines
- Monitored after FDA licensure for lot-to-lot consistency
- Mandated surveillance systems for **safety** post-licensure
    - Vaccine Adverse Events Reporting System
    - Vaccine Safety Data Link and Phase IV testing

Needed

- Demonstrated need epidemiologically in this country—when, who
- Not just FDA-licensed safe & effective, but graded as **necessary**
    - US Advisory Committee on Immunization Practices (ACIP)
        - Independent body of experts
    - All four major national medical academies concur
- Not all FDA licensed vaccines get recommended for use
- When no longer necessary, they are no longer recommended

Lacking Alternatives

- FDA demands proposed vaccines work just as well
  - Combinations used in other countries
  - Not licensed in US given lack of equivalence
- ACIP requires vaccinations meet or exceed current **alternatives**
  - BCG licensed vaccine in US against tuberculosis
  - Not recommended for use given successful non-vaccine control
  - PCV13 vaccine previously recommended for all >65 years old
  - No longer as infant PCV13 greatly reduced adult risk

The Independent Authority

- U.S. Advisory Committee on Immunization Practices
  - 14 infectious disease and public health experts
  - 1 lay person
- Meets throughout year
- Receives support from FDA and CDC but **independent**
- Generates only source of civilian federal vaccine recommendations
- Standardizes use, dosing, timing, contraindications, precautions

Evidence Required

	Recommended Vaccines	Prescription Drugs	Over-the-Counter Drugs	Vitamins, Minerals, and Nutritional Supplements
Effective	Yes	Yes	Sometimes	No
Safe	Yes	Yes	Sometimes	No
Needed	Yes	No	No	No
Lacking Alternatives	Yes	No	No	No

Vaccine Safety Datalink

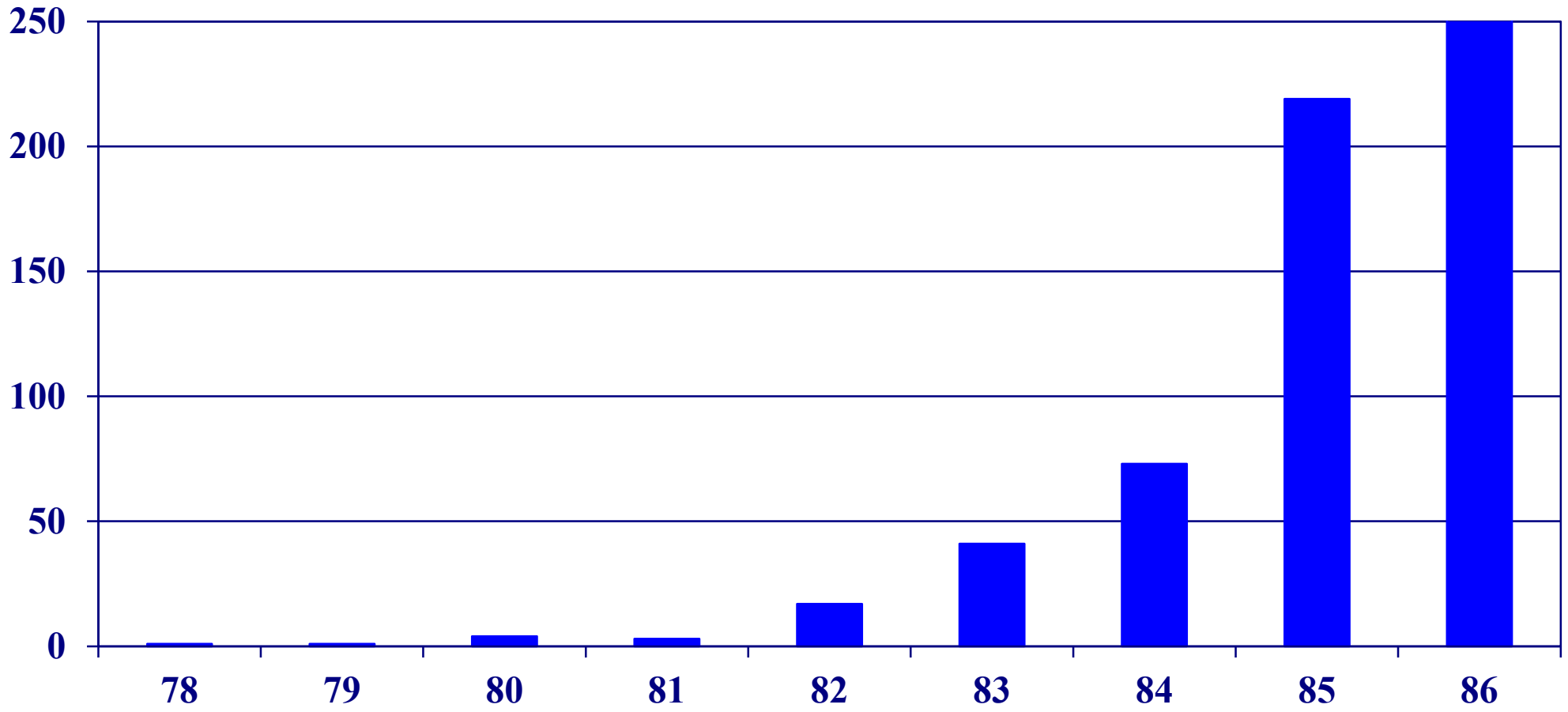
- Links receipt of vaccine with medical records
- Connects 15% of US population to ongoing safety study
- Conducts population-based investigations
- Upholds and extends **safety** post-licensure
  - No sudden infant death syndrome
  - No autism
  - No mercury poisoning
  - No auto-immune phenomena

WHAT'S HAPPENING WITH **LAWSUITS** AND VACCINES? ARE THERE MORE EACH YEAR OR LESS? WHY?

DTwP as Lightening Rod

- Diphtheria-Tetanus-whole cell Pertussis
- Old whole cell pertussis well-known reactivity
- Number of transient local and systemic effects
- Long-held claim of rare but real neurologic harm
- Claim **rejected scientifically** in 1980s
- No increased risk in large population studies

Nonetheless DTwP Lawsuits Increased Exponentially



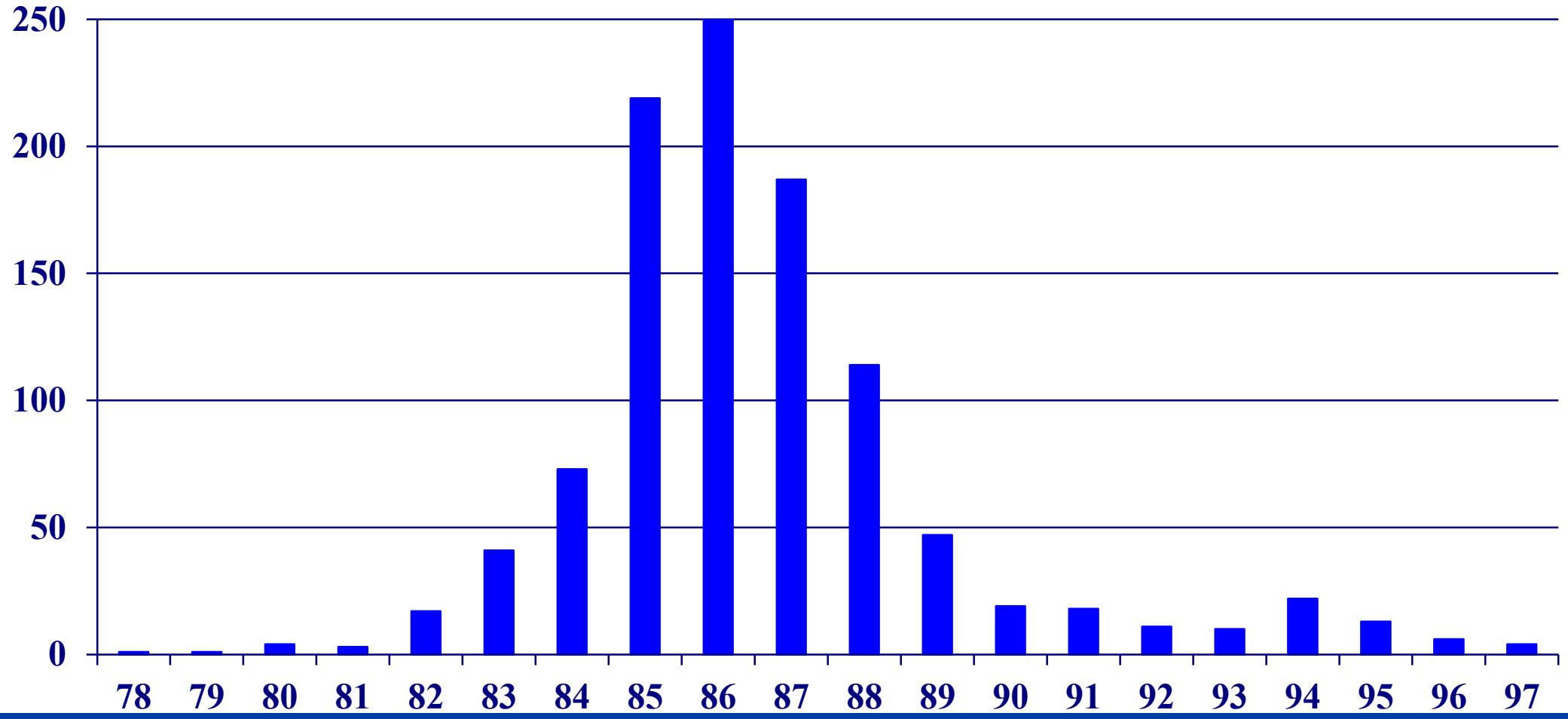
Impact of Litigation

- 7 of 9 DTwP manufacturers left the marketplace
- Prices rose 2100% a dose over 10-year period
- 255 lawsuits filed in 1986 alone
- Congress passed law in 1986
  - **PL 99-660**
  - National Childhood Vaccine Injury Act
  - National Vaccine Injury Compensation Program

National Vaccine Injury Compensation Program

- Funded by excise tax on vaccines
- Helps pay for the care of those seriously injured
- Removes adjudication from civil courts & juries
- Resulted in **renewed vaccine production**
- Resulted in **tremendous innovation**

Reduction in DTwP Lawsuits



National Vaccine Injury Compensation Program

- No fault alternative to traditional legal system
- Provided financial compensation using evidence-based table
- >22,919 claims since it began in Oct 1, 1988
- 4260 for doses given before Oct 1, 1988
- 7,754 compensable; 11,717 claims dismissed
- Claims out of over 3.7 billion doses of covered vaccines
- Complements **two other features** of the Act

Vaccine Adverse Event Reporting System

- VAERS
- Post-marketing safety surveillance program
- Mandatory for providers, manufacturers
- Specific vaccines, reactions, and events
- Other vaccines, events permitted
- Any one however can make report

Vaccine Information Statements

- VISs
- All health care providers
- Must use statement produced by the CDC
- One for each routine childhood vaccine
- Before administration of each dose
- Parent or legal representative of every child

Topics Covered in a VIS

- Why get this vaccine?
- Who should get it?
- Who should not get this vaccine?
- What are the risks from the vaccine?
- What should be done for a reaction?
- What is the injury compensation program?
- How can one learn more?

WHAT IS THE PRIMARY **CHALLENGE** FOR VACCINATION AS A PREVENTIVE HEALTH MEASURE?

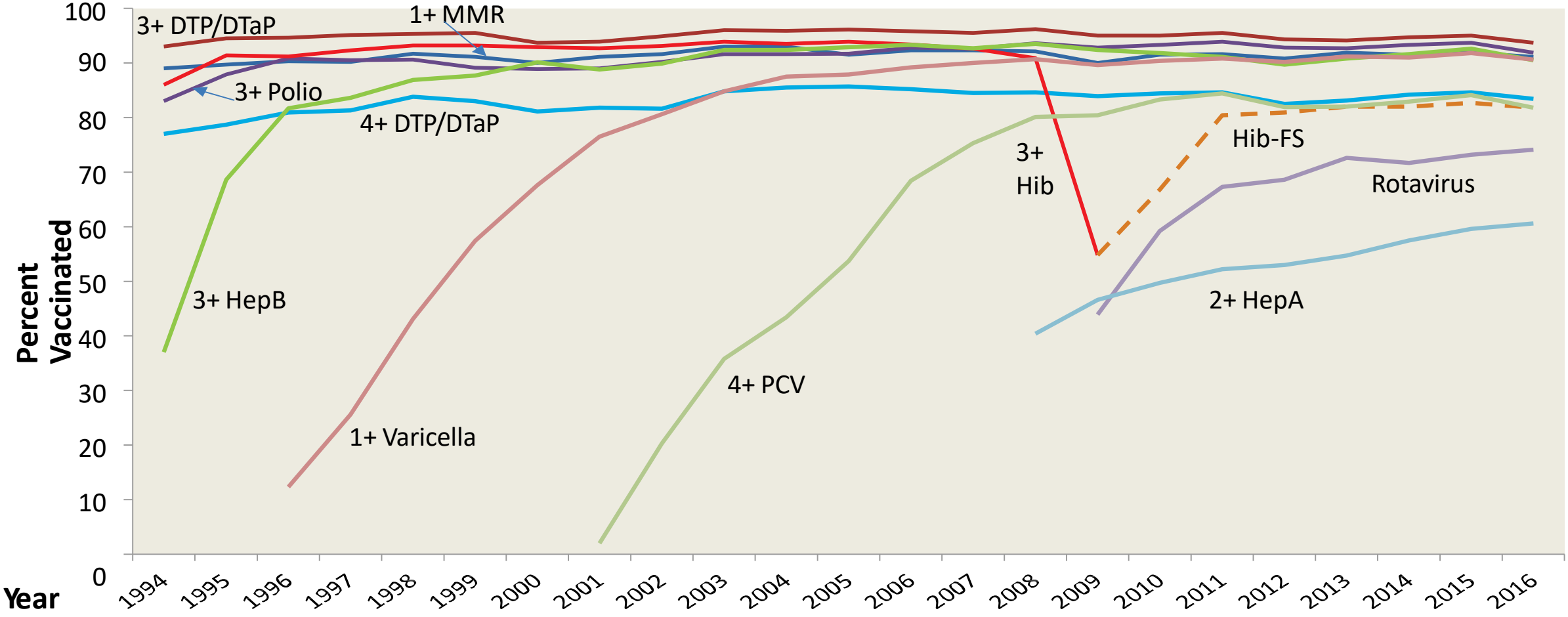
Uptake, Not Outright Refusal

- Only ~1.1% of US children 19-35 months unvaccinated
  - Have had none of the 10 vaccines due
  - Proportion unchanging over years
- Most children get most of the vaccines recommended
  - **School mandates** act primarily as prompts
  - 95.2% have received 2 doses MMR by school

The Challenge is Uptake

- 11,000 births every day in the US
- 13 vaccines due in the first 18 years of life
- 24 injections and 3 oral doses by 2 years of age
- 8 more doses by 6 years of age
- 12 more flu doses for next 12 years
- 3 more vaccines for teens as well, 5 doses in all
- The pandemic this year has really hurt this uptake
- Minnesota saw a **70% drop** with MMR vaccination early on

Vaccine Uptake among Children 19-35 Months Old



Abbreviations: **MMR** = measles, mumps, and rubella vaccine; **DTP/DTaP** = diphtheria and tetanus toxoids and pertussis vaccine / diphtheria and tetanus toxoids and acellular pertussis vaccine; **Hib** = *Haemophilus influenzae* type b vaccine; **FS** = full series; **HepB** = hepatitis B vaccine; **PCV** = pneumococcal conjugate vaccine; **HepA** = hepatitis A vaccine

Issues with Uptake

- Affordability and availability
- Disagreements in routine schedule
- Misunderstandings about contraindications
- Sheer complexity with all those doses and ages
- Opposition from anti-vaccinationists
- Vaccine hesitancy in large plurality of parents

Vaccines for Children (VFC), Affordability, Accessibility

- Free to those who serve eligible children
- Covers recommended routine vaccinations
- CDC contracts with vaccine manufacturers
- CDC buys vaccines at reduced rates
- States enroll providers
- Eligible children receive vaccines for free from their providers
- Complements Affordable Care Act's first $ coverage for vaccines

Vaccines for Children (VFC)

- Created by the federal government in 1993
- Executed by the states
- Serves >40% of US children in **their own medical home**
- Eligible children 0 to 18 years of age
  - Uninsured (and underinsured)
  - Native Americans and Alaskan natives
  - Medicaid recipients
- ACIP determines which vaccines are covered

Harmonized Schedule

- Centers for Disease Control and Prevention
- Advisory Committee on Immunization Practices
- American Academy of Pediatrics
- American Academy of Family Physicians
- Published widely and on-line
- Updated at least annually

Contraindications

- Most ones believed and practiced are false
- **Few true ones exist**
- Reversal of belief re acute illness
- NOT mild illnesses with or without fever
- Multiple vaccines don’t weaken immunity
- Use **every visit** as an opportunity to vaccinate

Current Vaccine Practices

- Rely on the **ACIP** for its independent review and recommendations (Effectiveness, safety, need, and lack of alternatives)
- Use the single, standard vaccine schedule the ACIP publishes
- Catch children up on missed and late vaccines as soon as possible
- Apply only the true contraindications and precautions
- Use every visit to review vaccines due and vaccinate
- Provide the parent the official Vaccine Information Statement
- Report adverse events to central federal authority VAERS

Summary

- Vaccines have been and are a public health success
- Vaccines however have also been a public relations challenge
- Five categories of vaccine hesitancy persist
- The National Childhood Vaccine Injury Act continues to protect
- Current vaccine practices reflect the science that support vaccines