

General Recommendations on Immunization Part Two and Vaccination Safety

National Center for Immunization and Respiratory Diseases
Immunization Services Division



General Recommendations on Immunization

Recommendations of the Advisory Committee on Immunization Practices (ACIP)



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cma/conted.html>



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

General Recommendations on Immunization

- ❑ **A chapter in the Pink Book**
 - Timing and spacing
 - **Contraindications and precautions**

General Recommendations on Immunization

□ A chapter in the Pink Book

- Timing and spacing
- **Contraindications and precautions**
 - Screening

Screening

- ❑ **Specific questions intended to identify contraindications or precautions to vaccination**
- ❑ **Screening must occur at every immunization encounter (not just before the first dose)**
- ❑ **Use of a standardized form will facilitate effective screening**
- ❑ **Following questions written from the perspective of the pediatric patient, but can be adjusted for the adult patient**

Screening Questions

- Is the child sick today?**
- Does the child have an allergy to any medications, food, or any vaccine?**
- Has the child had a serious reaction to a vaccine in the past?**

Screening Questions

- ❑ Has the child had a seizure, brain, or nerve problem?**
- ❑ Has the child had a health problem with asthma, lung disease, heart disease, kidney disease, metabolic disease (such as diabetes), or a blood disorder?**

Screening Questions

- ❑ Does the child have cancer, leukemia, AIDS, or any other immune system problem?**
- ❑ Has the child taken cortisone, prednisone, other steroids, or anticancer medications, or had x-ray treatments in the past 3 months?**

Screening Questions

- Has the child received a transfusion of blood or blood products, or been given a medicine called immune (gamma) globulin in the past year?**
- Is the child/teen pregnant or is there a chance she could become pregnant during the next month?**
- Has the child received vaccinations in the past 4 weeks?**

Invalid Contraindications

Mild Illness

❑ Vaccinate with:

- Low grade fever
- Upper respiratory infection
- Otitis media
- Mild diarrhea

Household Contacts and Pregnancy

❑ Susceptible household contacts of pregnant women

- SHOULD receive MMR and varicella vaccines
- SHOULD receive either non-live influenza or LAIV
- SHOULD receive zoster and rotavirus vaccines if eligible

Invalid Contraindications

Preterm Birth (less than 37 weeks)

- ❑ Generally, infants and children should be vaccinated according to chronologic age (not gestational age)**
- ❑ Use full recommended dose**
- ❑ Birth weight and size not factors but, as with all rules, there are exceptions (HepB)**

Vaccine Safety

National Center for Immunization & Respiratory Diseases
Immunization Services Division



Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases

Disease	20th Century Annual Morbidity [†]	2014 Reported Cases ^{††}	Percent Decrease
Diphtheria	21,053	1	> 99%
Measles	530,217	628	> 99%
Mumps	162,344	1,151	99%
Pertussis	200,752	32,971	86%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	8	> 99%
Congenital Rubella Syndrome	152	0	100%
Tetanus	580	21	96%
<i>Haemophilus influenzae</i>	20,000	27*	> 99%
Total	999,159	34,807	97%
<i>Vaccine Adverse Events</i>	Not available	~30,000	Not available

[†] JAMA. 2007;298(18):2155-2163

^{††} CDC. MMWR January 9, 2015 / 63(53);ND-733-ND-746. (MMWR 2014 provisional week 53 data)

* *Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 12 cases of Hib are estimated to have occurred among the 226 reports of Hi (< 5 years of age) with unknown serotype.



Importance of Vaccine Safety

- ❑ **Vaccinations universally recommended or mandated**
- ❑ **Ongoing safety monitoring needed for the development of sound policies and recommendations**

Importance of Vaccine Safety

- ❑ **Decreases in disease risks and increased attention on vaccine risks**
- ❑ **Public confidence in vaccine safety is critical**
 - Higher standard of safety is expected of vaccines
 - Vaccinees generally healthy (vs. ill for medications)
 - Lower risk tolerance = need to search for rare reactions
 - vaccination universally recommended and mandated

What is “Safe”?

- ❑ **SAFE = No harm from the vaccine?**
No vaccine is 100% safe
- ❑ **SAFE = No harm from the disease?**
No vaccine is 100% effective
- ❑ **Remind parents that to do nothing is to take a risk**

Pre-licensure Vaccine Safety Studies

❑ **Laboratory**

❑ **Animals**

❑ **Humans**



Pre-licensure Human Studies

- ❑ Phase I, II, III trials
- ❑ Phase III trials usually include a control group which receive a placebo
- ❑ Common reactions are identified
- ❑ Most Phase III trials include 2,000 to 5,000 participants
- ❑ Largest recent Phase III trial was REST (rotavirus) – around 70,000 infants

Post-licensure Surveillance

- ❑ **Identify rare reactions**
- ❑ **Monitor increases in known reactions -
Identify risk factors for reactions**
- ❑ **Identify vaccine lots with increased rates
of reactions**
- ❑ **Identify “signals” – reports of adverse
events more numerous than would be
expected**

Vaccine Adverse Event Reporting System (VAERS)



- ❑ **Jointly administered by CDC and FDA**
- ❑ **National reporting system**
- ❑ **Passive - depends on healthcare providers and others to report**
- ❑ **Receives ~30,000 reports per year**

<http://vaers.hhs.gov/>

Vaccine Adverse Event Reporting System (VAERS)

- ❑ **Detects:**
 - New or rare events
 - Increases in rates of known events
 - Patient risk factors
- ❑ **VAERS cannot establish causality**
 - Additional studies required to confirm VAERS signals and causality
- ❑ **Not all reports of adverse events are causally related to vaccine**
- ❑ **Reportable Events Table (PinkBook Appendix D-2)**

Post hoc ergo propter hoc

“After this therefore because of this”

- ❑ Temporal association does not prove causation**
- ❑ Just because one event follows another does not mean that the first caused the second**

Elements Needed To Assess Correlation of Vaccine Adverse Events

	<u>Disease</u>	<u>No disease</u>
<u>Vaccine</u>	a	b
<u>No vaccine</u>	c	d

Rate in "vaccine" group

=

$a / a + b$

Rate in "no vaccine" group

$c / c + d$

If the rate in "vaccine" group is higher than the rate in the "no vaccine" group, then vaccines may be the cause

Risk of Autism Spectrum Disorder (ASD) Among Children in Denmark, 1991-1998

	<u>ASD</u>	<u>No ASD</u>
<u>Vaccine</u>	345	440,310
<u>No vaccine</u>	77	96,571
<hr/> Risk in "vaccine" group		7.83/10,000
Risk in "no vaccine" group		<hr/> 7.96/10,000

Relative Risk = 0.98

Madsen et al. *N Eng J Med* 2002;347:1477-82

Post-licensure Vaccine Safety Activities

❑ Phase IV Trials

- ~10,000 participants
- Better but still limited

❑ Vaccine Safety Data Link (Large Linked Databases)

❑ Clinical Immunization Safety Assessment Project

Vaccine Safety Datalink

□ Vaccine Safety Datalink (Large linked database):

- Links vaccination and health records
- Partnership with large health plans: population under “active surveillance”
 - 9 HMOs
 - 3% (~10 million) of U.S. population
- Plans, executes immunization safety studies
- Investigates hypotheses from medical literature, VAERS reports, changes in schedules, introduction of new vaccines

CISA

Clinical
Immunization
Safety
Assessment
Network



Safer Healthier People

- ❑ **Improve understanding of vaccine safety issues at individual level**
- ❑ **Evaluate individual cases with adverse health events**
- ❑ **Develop strategies to assess individuals**
- ❑ **Conduct studies to identify risk factors**

<http://www.vaccinesafety.org/CISA>

Vaccine Injury Compensation Program

- ❑ **Established by National Childhood Vaccine Injury Act (1986)**

<http://www.hrsa.gov/vaccinecompensation/index.html>

- ❑ **“No fault” program**
- ❑ **Covers all routinely recommended childhood vaccines**
- ❑ **Vaccine Injury Table (Appendix D-5,D-6)**

The Provider's Role

- ❑ **Immunization providers can help ensure the safety and efficacy of vaccines through proper:**
 - **vaccine storage and administration**
 - **timing and spacing of vaccine doses**
 - **screening of contraindications and precautions**
 - **management of adverse reactions**
 - **reporting to VAERS**
 - **benefit and risk communication**

Benefit and Risk Communication

- ❑ **Opportunities for questions should be provided before each vaccination**
- ❑ **Vaccine Information Statements (VISs)**
 - Must be provided before each dose of vaccine
 - Public and private providers
 - Available in multiple languages

Your Source for VISs

www.immunize.org

immunize.org | vaccineinformation.org | hepprograms.org | izcoalitions.org

Immunization Action Coalition

Vaccination Information for Healthcare Professionals

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VISs

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- ▶ [VISs by Language](#)
- ▶ [VISs Alphabetical](#)
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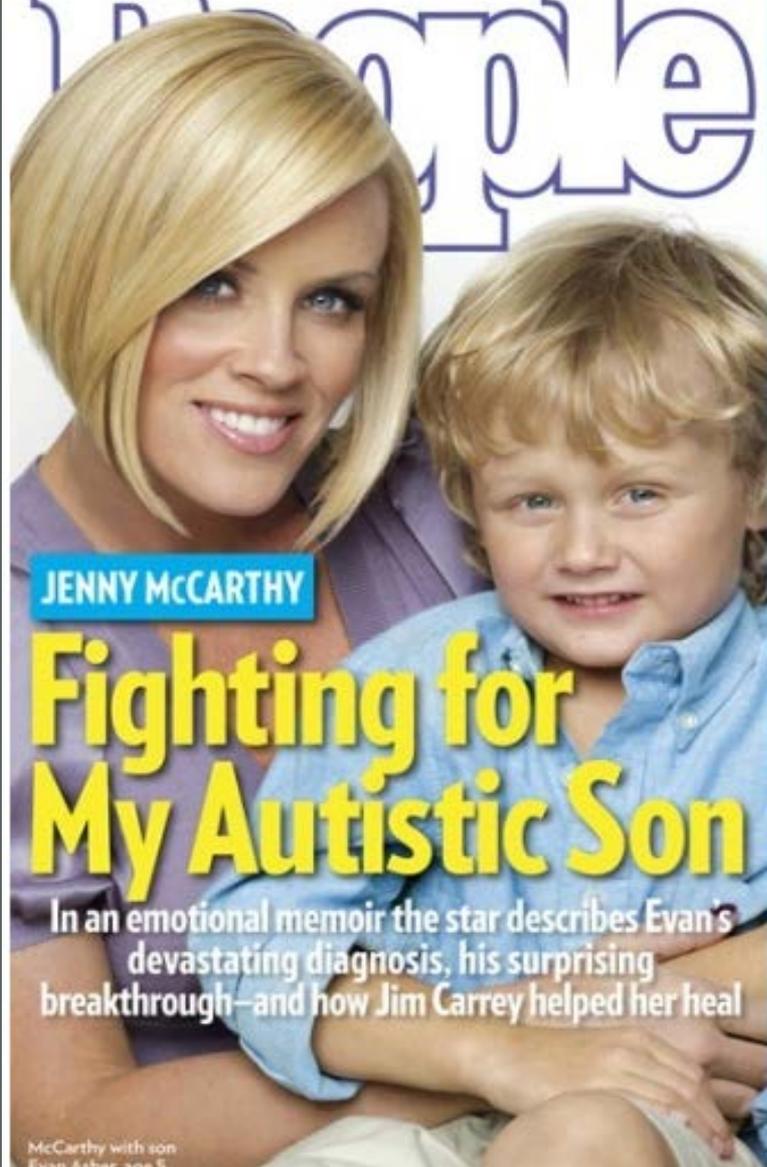
Vaccine Information Statements

VISs by language

English	Chinese	Ilokano	Polish	Somali
Amharic	Croatian	Italian	Portuguese	Spanish
Arabic	Farsi	Japanese	Punjabi	Tagalog
Armenian	French	Karen	Romanian	Thai
Bengali	German	Korean	Russian	Turkish
Bosnian	Haitian Creole	Laotian	Samoan	Urdu
Burmese	Hindi	Marshallese	Serbo-Croatian	Vietnamese
Cambodian	Hmong			

OCTOBER 1, 2007

People



JENNY MCCARTHY

Fighting for My Autistic Son

In an emotional memoir the star describes Evan's devastating diagnosis, his surprising breakthrough—and how Jim Carrey helped her heal

McCarthy with son Evan. Above: age 5



THE MCCANNNS
WHAT'S NEXT



EMMY
GLAMOUR!
• All the Dresses
• All the Drama



O.J. SIMPSON
| ALL TIME?



ARE YOU READY FOR ANOTHER KID?
TAKE OUR QUIZ AT COOVIO.ME.COM

AMANDA PEET
speaks out for vaccinations
P. 110



WHOOPIING COUGH

Jennifer Lopez



Campbell Brown

ART STREIBER/CNN

Communicating with Parents

□ For providers:

- If provider recommends it, parents more likely to follow
- Ask, acknowledge, and advise
- Start at prenatal visit, develop trust
- Offer reliable resources
- Know the science
- Do not get defensive

Autism and Vaccines

- ❑ **Multiple population-based studies have examined the rate of autism among vaccinated and unvaccinated children**
- ❑ **Available evidence does not indicate that autism is more common among children who receive MMR or thimerosal-containing vaccines than among children who do not receive vaccines**

<http://www.cdc.gov/vaccinesafety/Concerns/Autism/Index.html>

Studies of Autism and Vaccines*

Kaye JA, et al. Measles, mumps, and rubella vaccine and incidence of autism recorded by general practitioners: a time-trend analysis. *Brit Med J* 322:460-463, 2001.

Madsen KM, et al. A population-based study of measles, mumps, and rubella vaccination and autism. *N Engl J Med*. 2002;347:1477-1482.

Frambonne E, et al. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. *Pediatrics* 118:e139-50, 2006.

Thompson WW, et al. Early thimerosal exposure and neuro-psychological outcomes at 7 to 10 years. *N Engl J Med* 2007; 357(13):1281-92.

Schechter R, Grether JK. Continuing increases in autism reported to California's developmental services system: mercury in retrograde. *Arch Gen Psychiatry* 2008;65(1):19-24.

Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies. *Vaccine*. 2014 June;32(29):3623-3629

*Partial listing of representative studies



Autism Speaks™

Be Informed

Get Involved

Walk Events

Community

Science

Autism Speaks™

Science News

News Archive

CAN News Archive

SEARCH

Overview

An Interview with Dr. Geri Dawson, Chief

"... given what the scientific literature tells us today, there is no evidence that thimerosal or the MMR vaccine cause autism. Evidence does not support the theory that vaccines are causing an autism epidemic."

- Dr. Geri Dawson, July 30, 2009

discovered some of the risk genes for autism, but we still know little about the

ks, about the
ding and
tism



Gerri Dawson
Chief Science Officer
Autism Speaks

Donate

Store

Resources

Institute of Medicine Studies, August 2011

❑ **Committee findings:**

- CAUSAL RELATIONSHIP between some vaccines and adverse events
 - MMR, VZV, Influenza, etc., and anaphylaxis
- REJECTION OF 5 RELATIONSHIPS
 - Including MMR and autism, TIV and asthma

❑ **Overall, the committee concluded that few health problems are caused by, or clearly associated with, vaccines**

Communicating with Parents

□ **What parents want:**

- Delayed vs. alternate schedules
- Facts and statistics
- Trust good websites
- Do not want to be talked down to
- Unbiased, non-coercive, credible, non-judgmental information

Childhood Immunization Schedule and Safety

❑ Institute of Medicine - Mission

- Review scientific findings and stakeholder concerns related to the safety of the recommended childhood immunization schedule
- Identify potential research approaches, methodologies, and study designs that could inform this question
- Issue a summary report

❑ Findings

- IOM committee finds no evidence that the schedule is unsafe
- Following the complete childhood immunization schedule is strongly associated with reducing vaccine-preventable diseases
- Committee calls for continued study of the immunization schedule using existing data systems

www.iom.edu/childimmunizationschedule