

General Recommendations on Immunization Part Two and Vaccination Safety

National Center for Immunization and Respiratory Diseases
Immunization Services Division



Centers for Disease Control and Prevention

MMWR

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General Recommendations on Immunization

Recommendations of the Advisory Committee
on Immunization Practices (ACIP)



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/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?

Patient name: _____ Date of birth: ____/____/____
(mo.) (day) (yr.)

Screening Questionnaire for Child and Teen Immunization

For parents/guardians: The following questions will help us determine who to be given today. If you answer "yes" to any question, it does not necessarily mean you should be vaccinated. It just means additional questions must be asked. If a question healthcare provider to explain it.

1. Is the child sick today?
2. Does the child have allergies to medications, food, a vaccine component, or latex?
3. Has the child had a serious reaction to a vaccine in the past?
4. Has the child had a health problem with lung, heart, kidney or metabolic diseases (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy?
5. If the child to be vaccinated is between the ages of 2 and 4 years, has a health provider told you that the child had wheezing or asthma in the past 12 months?
6. Has the child, a sibling, or a parent had a seizure; has the child had brain or of nervous system problems?
7. Does the child have cancer, leukemia, AIDS, or any other immune system problem?
8. In the past 3 months, has the child taken cortisone, prednisone, other steroid or anticancer drugs, or had radiation treatments?
9. In the past year, has the child received a transfusion of blood or blood product or been given immune (gamma) globulin or an antiviral drug?
10. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?
11. Has the child received vaccinations in the past 4 weeks?

Form completed by: _____

Form reviewed by: _____

Did you bring your child's immunization record card with you?

It is important to have a personal record of your child's vaccinations. If you don't have healthcare provider to give you one with all your child's vaccinations on it. Keep this record every time you seek medical care for your child. Your child will need this important information to enter day care or school, for employment, or for international travel.

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010

MMW 2010

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.imz.org

Information for Health Professionals about the Screening Questionnaire for Child & Teen Immunization

Are you interested in knowing why we included a certain question on the Screening Questionnaire? If so, read the information below. If you want to find out even more, consult the references listed at the bottom of this page.

1. Is the child sick today? (all vaccines)

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1, 2). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Does the child have allergies to medications, food, a vaccine component, or latex? (all vaccines)

History of anaphylactic reactions such as hives (urticaria), wheezing or difficulty breathing, or circulatory collapse or shock (not fainting) to a vaccine component or latex is a contraindication to some vaccines. For example, if a person experiences anaphylaxis after eating eggs, do not administer measles-mumps-rubella (MMR), MMR-2 vaccine (MMRV), or varicella (VAR) vaccine. A local reaction is not a contraindication. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendixB/latex-table.pdf. For an extensive table of vaccine components, see reference 3.

3. Has the child had a serious reaction to a vaccine in the past? (all vaccines)

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). History of encephalopathy within 7 days following DTP/DTPa is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTPa (not Tdap) include the following: (x) seizure within 7 days of a dose, (y) pale or limp episode or collapse within 48 hours of a dose, (z) continuous crying for 3 or more hours within 48 hours of a dose, and (d) fever of 105°F (40°C) within 48 hours of a previous dose. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Has the child had a health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? (IAV)

Children with any of the health conditions listed above should not be given the intranasal, live attenuated influenza vaccine (IAV). These children should be vaccinated with the injectable influenza vaccine.

5. If the child to be vaccinated is between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? (IAV)

Children who have had a wheezing episode within the past 12 months should not be given the live attenuated influenza vaccine. Instead, these children should be given the inactivated influenza vaccine.

6. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? (DTP, M, Mop, M, MMR, MMR2, DTPa and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTPa. An unstable progressive neurologic problem is a precaution to the use of DTPa and Tdap, and a progressive neurologic disorder in a twin is a precaution to the use of Td. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures, vaccine as usual (except for children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a contraindication with the following:

1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give age-appropriate Tdap instead of Td if no history of prior Tdap; 2) influenza vaccine (IV or IAV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with IV if at high risk for severe influenza complications.

7. Does the child have cancer, leukemia, AIDS, or any other immune system problem? (IV, MMR, MMRV, VAR, IAV)

Live virus vaccines (e.g., MMR, MMRV, varicella, rotavirus, and the intranasal live, attenuated influenza vaccine [IAV]) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Likewise, varicella vaccine should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage at 15% or greater and may be considered for children age 8 years and older with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. Immunosuppressed children should not receive IAV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including rotavirus (RV) vaccine. For details, consult the ACP recommendations (4, 5, 6).

8. In the past 3 months, has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? (IAV, MMR, MMRV, IAV)

Live virus vaccines (e.g., MMR, MMRV, varicella, IAV) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACP statement (1). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 7. IAV can be given only to healthy non-pregnant individuals age 2–49 years.

9. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? (IAV, MMR, MMRV, IAV)

Certain live virus vaccines (e.g., IAV, MMR, MMRV, varicella) may need to be deferred, depending on several variables. Consult the most current ACP recommendations or the current Red Book for the most current information on intervals between antiviral drug, immune globulin or blood product administration and live virus vaccines (1, 2).

10. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? (IAV, MMR, MMRV, IAV)

Live virus vaccines (e.g., MMR, MMRV, varicella, IAV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus (1, 6). Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine (5, 8). On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent (e.g., travel to endemic areas) and immediate protection is needed. Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester (9).

11. Has the child received vaccinations in the past 4 weeks? (IAV, MMR, MMRV, IAV, yellow fever)

If the child was given either live, attenuated influenza vaccine (IAV) or an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) in the past 4 weeks, they should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at the same time or at any spacing interval.

References:

1. CDC. General recommendations on immunization. www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a.htm.
2. AAP. Red Book: Report of the Committee on Infectious Diseases. www.aapublications.org.
3. Table of Vaccine Components. www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendixB/immune-table-2.pdf.
4. CDC. Precautions, contraindications, and strategies for administration of measles, mumps, and varicella vaccine and control of mumps. MMWR 2006; 55 (RR-10).
5. CDC. Prevention of varicella. Recommendations of the Advisory Committee on Immunization Practices. MMWR 2007; 56 (RR-4).
6. CDC. Prevention and Control of Influenza—Recommendations of ACP. www.cdc.gov/flu/pdf/summary/summary.pdf.
7. CDC. General Best Practices for preventing opportunistic infections among immunosuppressed stem cell transplant recipients. MMWR 2009; 58 (RR-12). www.cdc.gov/mmwr/preview/mmwrhtml/rr5812a.htm.
8. CDC. Update to measles. Revised ACP recommendations for avoiding pregnancy after receiving a rubella-containing vaccine. MMWR 2001; 50 (RR).
9. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants. Recommendations of the ACP. MMWR 2008; 57 (RR-4).

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	644	> 99%
Mumps	162,344	1,151	99%
Pertussis	200,752	28,660	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	30,512	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 Hib (< 5 years of age) with unknown serotype.



National Center for Immunization & Respiratory Diseases

Historical Comparisons of Vaccine-Preventable Disease Morbidity in the U.S.

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 = $\frac{a}{a + b}$

Rate in “no vaccine” group = $\frac{c}{c + d}$

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		<hr/> 7.83/10,000
Risk in "no vaccine" group		<hr/> 7.96/10,000

Relative Risk = 0.98

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% (9 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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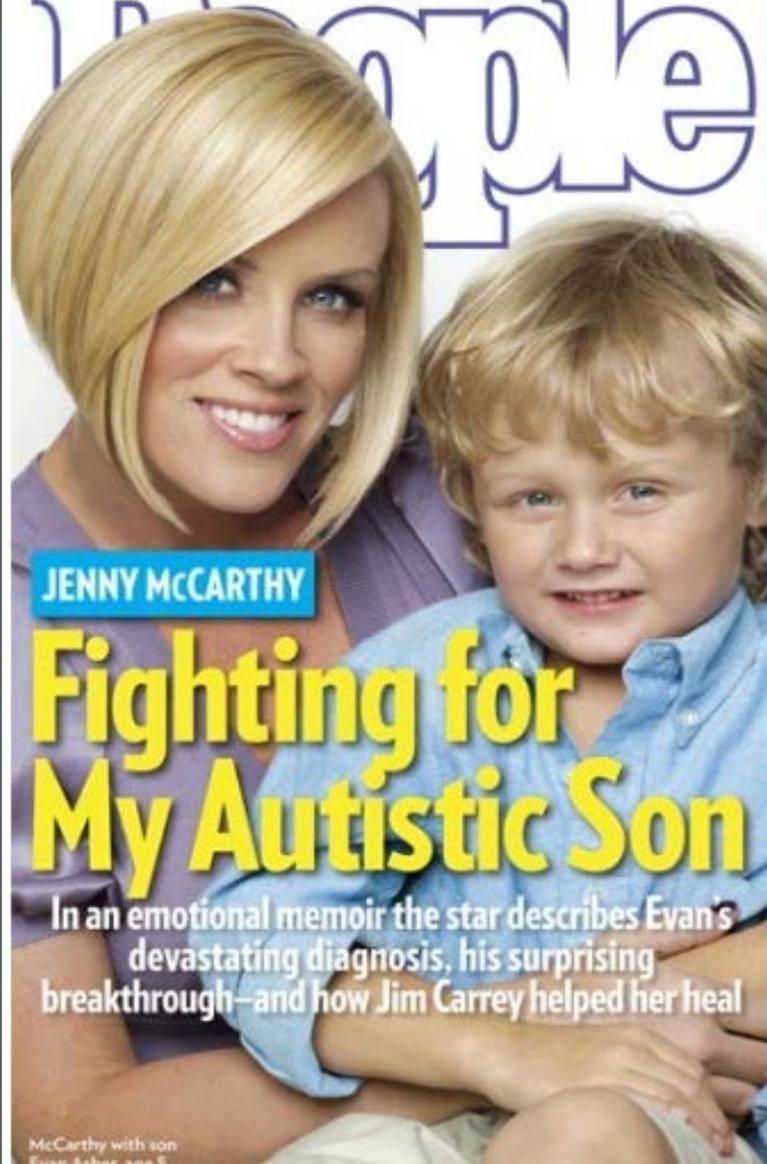
Vaccine Information Statements

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. Photo: [unreadable]



THE MCCANNNS
WHAT'S NEXT



EMMY
GLAMOUR!
• All the Dresses
• All the Drama



O.J. SIMPSON
[A]ll TIME?



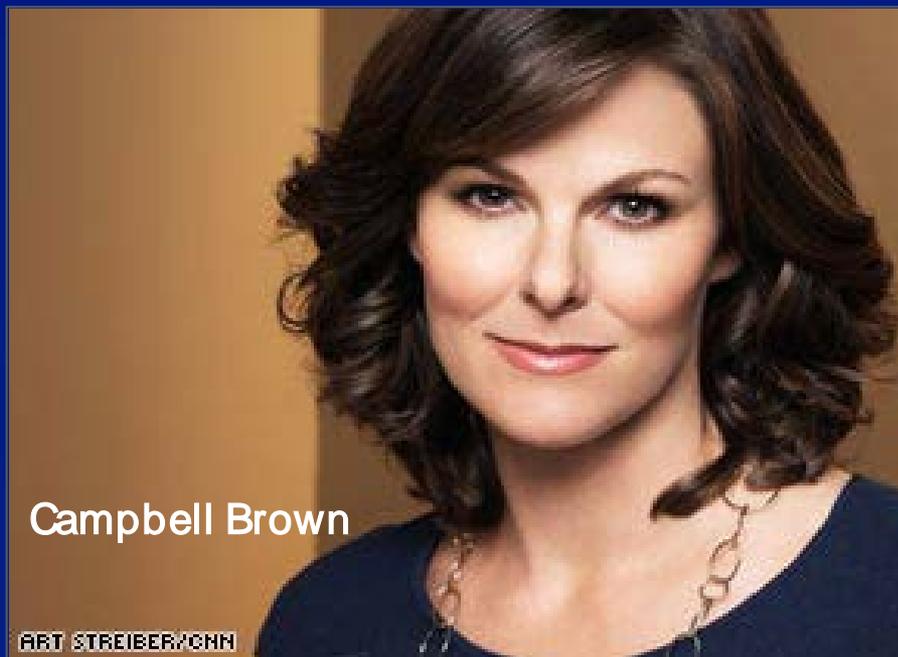
ARE YOU READY FOR ANOTHER KID?
TAKE OUR QUIZ AT COOVIO.ME.COM

AMANDA PEET
speaks out for vaccinations
P. 110



WHOOPIING COUGH

Jennifer Lopez



Campbell Brown

ART STREIBER/OMN

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*

Taylor B, et al. Autism and measles, mumps, and rubella vaccine: no epidemiologic evidence for a causal association. *Lancet* 351:2026-2029, 1999.

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.

Fombonne 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.

*Partial listing of representative studies

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An Interview with Dr. Geri Dawson, Chief

Science Officer, about the
autism epidemic and
autism

“... 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



Gerri Dawson
Chief Science Officer
Autism Speaks

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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