



General Recommendations on Immunization

Part Two and Vaccination Safety

General Best Practice Guidelines

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General Recommendations

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General Best Practice Guidelines for Immunization

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Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)

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[Printer friendly version](#)  [1.16 MB, 194 pages]

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General Best Practice Guidelines for Immunization

- ACIP MMWR Table of Contents

- Timing and spacing

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General Best Practice Guidelines for Immunization

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

General Best Practice Guidelines for 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 which vaccines your child may be given today. If you answer "yes" to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

| | Yes | No | Don't Know |
|--|--------------------------|--------------------------|--------------------------|
| 1. Is the child sick today? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Does the child have allergies to medications, food, a vaccine component, or latex? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Has the child had a serious reaction to a vaccine in the past? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Does the child have cancer, leukemia, AIDS, or any other immune system problem? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. In the past 3 months, has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Has the child received vaccinations in the past 4 weeks? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Form completed by: _____ Date: _____
 Form reviewed by: _____ Date: _____

Did you bring your child's immunization record card with you? yes no

It is important to have a personal record of your child's vaccinations. If you don't have a personal record, ask the child's healthcare provider to give you one with all your child's vaccinations on it. Keep this record in a safe place and bring it with you every time you seek medical care for your child. Your child will need this important document for the rest of his or her life to enter day care or school, for employment, or for international travel.

Revised and updated by the Centers for Disease Control and Prevention, October 2010. www.immunize.org/askg-6y-10-02.pdf Item #7462 (10/10)

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 colds, 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 reaction 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 influenza vaccine, or if a person has anaphylaxis after eating gelatin, do not administer measles-mumps-rubella (MMR), MMR-4-varicella (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/ocma/pubs/printbook/downloads/appendices/false-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/DTaP is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTaP (not Tdap) include the following: (a) seizure within 3 days of a dose, (b) pale or limp episode or collapse within 48 hours of a dose, (c) 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, MMR, IV, IAV, MMRV, DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP 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 (exceptions: 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 consideration 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? [IAV, MMR, MMRV, IV, 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 3–49 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 antitoxin drugs, 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, at www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a.htm.
2. ACP. Red Book Report of the Committee on Infectious Diseases at www.uptodate.com.
3. Table of Vaccine Components. www.cdc.gov/ocma/pubs/printbook/downloads/appendices/false-table.pdf.
4. CDC. Measles, mumps, and rubella vaccine use and strategies for elimination of measles, mumps, and congenital rubella syndrome and control of scarlet fever. [MMWR 50\(17\):47-50 \(5\)](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a.htm).
5. CDC. Prevention of varicella. Recommendations of the Advisory Committee on Immunization Practices. [MMWR 50\(17\):48-54 \(5\)](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a.htm).
6. CDC. Prevention and Control of Influenza—Recommendations of ACP at www.cdc.gov/flu/pandemic/resources/.
7. CDC. Current Good Clinical Practice: recommendations for preventing opportunistic infections among hematopoietic stem cell transplant recipients. [MMWR 50\(17\):45-51 \(5\)](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a.htm).
8. CDC. Notice to readers: Revised ACP recommendations for avoiding pregnancy after receiving a rubella-containing vaccine. [MMWR 50\(17\):50 \(5\)](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a.htm).
9. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants. Recommendations of the ACP. [MMWR 50\(17\):48-54 \(5\)](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5017a.htm).

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)

Family History of Adverse Events

- Family history of adverse events generally NOT a contraindication
- Family history can be a precaution:
 - Example: family history of seizures is a precaution to MMRV
- Family history of a condition can also be a contraindication/precaution
 - Example: family history of immunosuppression requires screening to assure the condition is not inherited in the vaccine recipient prior to administering MMR and varicella vaccine

What Do You Think?

- A pregnant woman living in the household is a contraindication for measles-mumps-rubella (MMR) and varicella (VAR) vaccines to a healthy child in the same household.
- True
- False

Vaccine Safety

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

| Disease | 20th Century Annual Morbidity [†] | 2017 Reported Cases ^{† †} | Percent Decrease |
|-------------------------------|--|------------------------------------|------------------|
| Diphtheria | 21,053 | 0 | 100% |
| Measles | 530,217 | 122 | > 99% |
| Mumps | 162,344 | 5,629 | 97% |
| Pertussis | 200,752 | 15,808 | >92% |
| Polio (paralytic) | 16,316 | 0 | 100% |
| Rubella | 47,745 | 9 | > 99% |
| Congenital Rubella Syndrome | 152 | 2 | 99% |
| Tetanus | 580 | 32 | 95% |
| <i>Haemophilus influenzae</i> | 20,000 | 22 | > 99% |
| Total | 999,159 | 24,493 | 97% |
| <i>Vaccine Adverse Events</i> | Not available | ~30,000 | Not available |

[†] JAMA. 2007;298(18):2155-2163

^{† †} CDC. *National Notifiable Diseases Surveillance System, Week 52, 2017 Weekly Tables of Infectious Disease Data*. Atlanta, GA. CDC Division of Health Informatics and Surveillance, 2018. Available at: www.cdc.gov/nndss/infectious-tables.html. Accessed on January 4, 2018.

**Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 11 cases of Hib are estimated to have occurred among the 237 notifications of Hib (< 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
- Receives ~30,000 reports per year
- Passive - depends on healthcare providers and others to report

The screenshot shows the VAERS website homepage. At the top, there is a search bar and navigation tabs for 'Report an Adverse Event', 'About VAERS', 'VAERS Data', 'Vaccine Resources', 'Information for Healthcare Professionals', 'Information for U.S. States and Territories', and 'Information for Vaccine Manufacturers'. The main content area features a purple sidebar with the question 'Have you or your child had a reaction following vaccination?' and a list of steps: 1. Contact your health care provider, 2. Report the reaction, 3. Submit Follow-Up Information, and 4. Visit the National Vaccine Injury Compensation. Below this is a Spanish version of the same content. The right sidebar includes 'VAERS Data last updated: 06/08/2017', a photo of a young girl with a dog, and a 'Featured Resources' section with links to 'Seasonal Flu Update', 'Summary of 2016-2017 Influenza Vaccine Information', 'Government Agencies' (including Immunization Safety Office, National Center for Immunization and Respiratory Diseases, National Vaccine Injury Compensation Program, National Vaccine Program Office, and Center for Biologics Evaluation and Research), and 'Health Topics' (including Vaccine Safety, Immunization Schedules, Preventing Flu with Vaccination, Traveler's Health: Vaccinations, Vaccine-Preventable Diseases, and CDC en Español: Inmunización). At the bottom, there are two video thumbnails: 'VIDEO: An Overview of VAERS' and 'VIDEO: Searching the VAERS Database'.

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-1)

Vaccine Adverse Event Reporting System (VAERS) and VAERS reporting form

■ VAERS

- National spontaneous reporting system for monitoring the safety of U.S.-licensed vaccines
- Co-managed by CDC and FDA
- Accepts reports from anyone (providers, patients, etc.)

■ VAERS Reporting Methods

- Option 1: online reporting tool (preferred)
- Option 2: writable PDF form combined with electronic document upload capability

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed.)

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: () _____ Email: _____

2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: Male Female Unknown

4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm _____ AM PM

5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm _____ AM PM

6. Age at vaccination: _____ Years _____ Months 7. Today's date: (mm/dd/yyyy) _____

8. Is the report about a pregnant woman? No Unknown Yes (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18).

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination: _____

10. Allergies to medications, food, or other products: _____

11. Other illnesses at the time of vaccination and up to one month prior: _____

12. Chronic or long-standing health conditions: _____

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____
Relation to patient: Healthcare professional/staff Patient (yourself) Parent/guardian/caregiver Other: _____
Street address: _____ Check if same as item 1.
City: _____ State: _____ ZIP code: _____
Phone: () _____ Email: _____

14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: () _____ Ext: _____

15. Facility/clinic name: _____
Fax: () _____
Street address: _____ Check if same as item 13.
City: _____ State: _____ ZIP code: _____
Phone: () _____

16. Type of facility: (Check one).
 Doctor's office or hospital
 Pharmacy or drug store
 Workplace clinic
 Public health clinic
 Nursing home or senior living facility
 School/student health clinic
 Other: _____
 Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given). Use Continuation Page if needed.

| Vaccine (type and brand name) | Manufacturer | Lot number | Route | Body site | Dose no. in series |
|-------------------------------|--------------|------------|--------|-----------|--------------------|
| select | select | select | select | select | select |
| select | select | select | select | select | select |
| select | select | select | select | select | select |

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) _____

19. Medical tests and laboratory results related to the adverse event(s): (include dates) _____

20. Has the patient recovered from the adverse event(s)? Yes No Unknown

21. Result or outcome of adverse event(s): (Check all that apply).
 Doctor or other healthcare professional office/clinic visit
 Emergency room or emergency department visit
 Hospitalization: Number of days (if known) _____
Hospital name: _____ City: _____ State: _____
 Prolongation of existing hospitalization (vaccine received during existing hospitalization)
 Life threatening illness (immediate risk of death from the event)
 Disability or permanent damage
 Patient died: Date of death _____ (mm/dd/yyyy)
 Congenital anomaly or birth defect
 None of the above

22. Any other vaccines received within one month prior to the date listed in item 4:
Vaccine (type and brand name) _____ Manufacturer _____ Lot number _____ Route _____ Body site _____ Dose no. in series _____

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name).
 No Unknown Yes

24. Patient's race: American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander
(Check all that apply). White Unknown Other: _____

25. Patient's ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown

26. Immuniz. proj. report no.: (Health Dept use only) _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: Active duty Reserve National Guard Beneficiary Other: _____

28. Vaccinated at Military/DoD site: Yes No

FORM FDA VAERS-2.0 (01/17)

VAERS (additional information)

- Instructions for reporting to VAERS at <https://vaers.hhs.gov/reportevent.html>
- Additional assistance
 - Email at info@vaers.org
 - Phone at 1-800-822-7967

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 |

$$\frac{\text{Rate in "vaccine" group}}{\text{Rate in "no vaccine" group}} = \frac{a / a + b}{c / c + d}$$

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 |
| $\frac{\text{Risk in "vaccine" group}}{\text{Risk in "no vaccine" group}} =$ | | $\frac{7.83/10,000}{7.96/10,000}$ |

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% (~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



- 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

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-7)

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

Vaccine Information Statements

By Federal Law, You Must Provide Current VISs

VACCINE INDEX

- English
- Amharic
- Arabic
- Armenian
- Bengali
- Bosnian
- Burmese
- Cambodian (Khmer)
- Chinese
- Chuukese
- Croatian
- Farsi
- French
- German
- Haitian Creole

LANGUAGE INDEX

- Hindi
- Hmong
- Ilokano
- Indonesian
- Italian
- Japanese
- Karen
- Khmer (Cambodian)
- Korean
- Laotian
- Marshallese
- Nepali
- Polish
- Portuguese
- Punjabi

A-Z

- Romanian
- Russian
- Samoan
- Serbian
- Somali
- Spanish
- Swahili
- Tagalog
- Thai
- Tigrigna
- Turkish
- Urdu
- Vietnamese
- Yiddish



New and Revised VISs

Check here for weekly updates

Current VIS Dates

Check your stock of VISs against this list. If you have outdated VISs, get current versions.

| | | | |
|-------------|---------|---------------|---------|
| Adenovirus | 6/11/14 | MMRV | 5/21/10 |
| Anthrax | 3/10/10 | Multi-vaccine | 11/5/15 |
| Chickenpox | 3/13/08 | PCV13 | 11/5/15 |
| DTaP | 5/17/07 | PPSV | 4/24/15 |
| Hib | 4/2/15 | Polio | 7/20/16 |
| Hepatitis A | 7/20/16 | Rabies | 10/6/09 |
| Hepatitis B | 7/20/16 | Rotavirus | 4/15/15 |
| HPV | 12/2/16 | Shingles | 10/6/09 |
| Influenza | 8/7/15 | Td | 4/11/17 |
| J. enceph. | 1/24/14 | Tdap | 2/24/15 |
| MCV4/MPSV4 | 3/31/16 | Typhoid | 5/29/12 |
| MenB | 8/9/16 | Y. fever | 3/30/11 |
| MMR | 4/20/12 | | |

PRINT VERSION

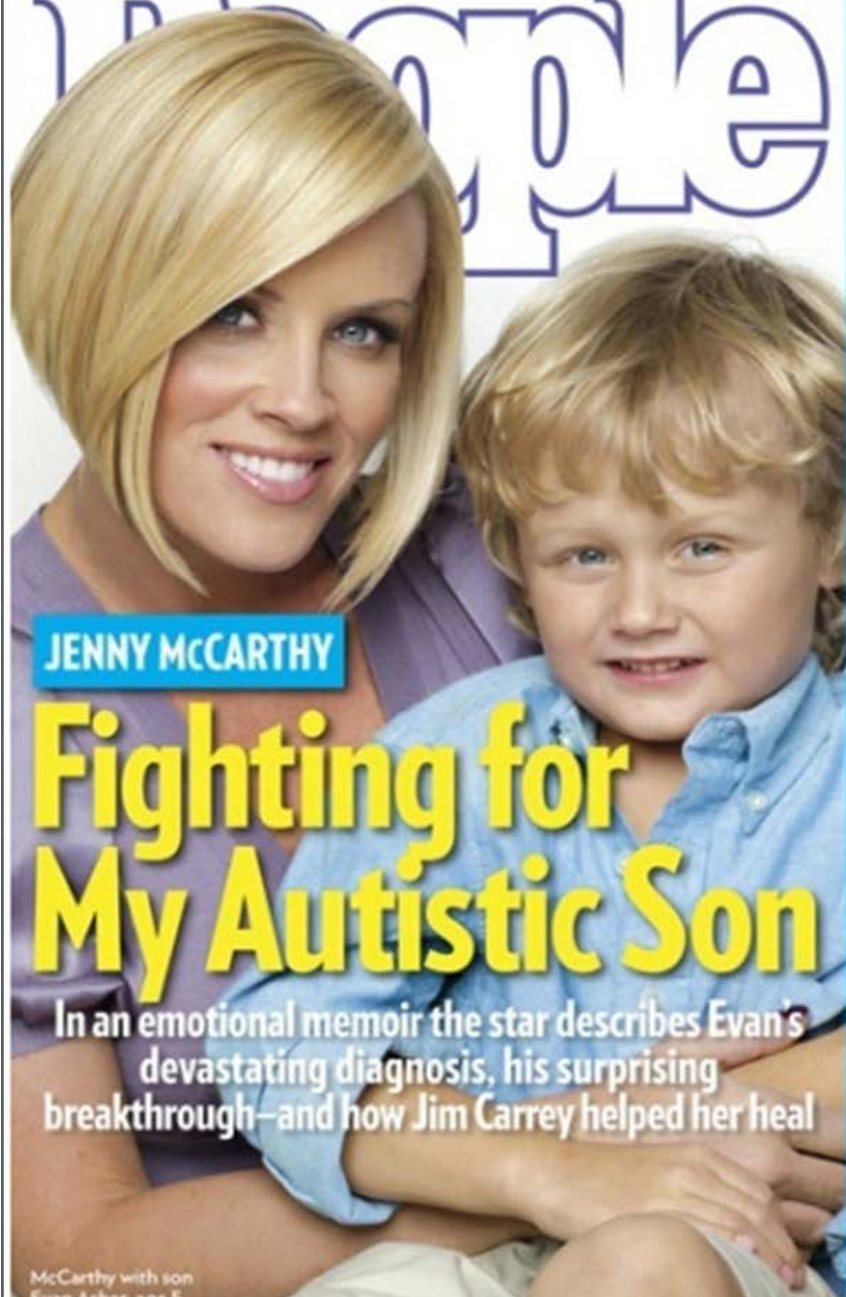


Feedback: VIS Translations

Let us know what you think

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 Asher, age 5



THE MCCANN'S
WHAT'S NEXT



EMMY
GLAMOUR!
• All the Dresses
• All the Drama



O.J. SIMPSON
| ALL TIME?



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

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

[Overview](#)[Science News](#)[Research & Grants](#)

An Interview with Dr. Geri Dawson, Chief Science Officer, Autism Speaks, about the Organization's Research Funding and Position on Vaccines 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



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