General Best Practice Guidelines
Part Two

June 19, 2019

Chapter 2, Page 9
General Best Practice Guidelines for Immunization

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  - Timing and spacing
  - Contraindications and precautions
    - Preventing and managing adverse reactions to immunization
    - Vaccine administration
    - Storage and handling
    - Altered immunocompetence
    - Special situations
    - Vaccination records
    - Vaccination programs
    - Vaccine information sources
General Best Practice Guidelines for Immunization

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

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

1. Is the child sick today? [ ] Yes [ ] No [ ] Know
2. Does the child have allergies to medications, food, a vaccine component, or latex? [ ] Yes [ ] No [ ] Know
3. Has the child had a serious reaction to a vaccine in the past? [ ] Yes [ ] No [ ] Know
4. Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder is listed on long-term aspirin therapy? [ ] Yes [ ] No [ ] Know
5. If the child is 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? [ ] Yes [ ] No [ ] Know
6. Has the child, a sibling, or a parent have a history of or been diagnosed with any known nerve or nervous system problems? [ ] Yes [ ] No [ ] Know
7. Does the child have cancer, leukemia, AIDS, or any other immune system problem? [ ] Yes [ ] No [ ] Know
8. In the past 3 months, has the child taken cortisone, prednisone, other steroids, or an antibiotic drug, or had radiation treatment? [ ] Yes [ ] No [ ] Know
9. In the past year, the child has received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antibiotic drug? [ ] Yes [ ] No [ ] Know
10. Is the child pregnant or is there a chance she could become pregnant during the next month? [ ] Yes [ ] No [ ] Know
11. Has the child received vaccinations in the past 4 weeks? [ ] Yes [ ] No [ ] Know

Form completed by: [ ]
Form reviewed by: [ ]

Did you bring your child’s immunization record card with you? [ ] Yes [ ] No [ ]

It is important to have a personal copy of your child’s vaccinations. If you do not have a private 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 the important information for the rest of his or her life to enter day care or school, for employment, or for international travel.

Immunization Action Coalition • 1575 Sibley Ave. • St. Paul, MN 55104 • (651) 647-0000 • www.immunize.org • www.vaccineinformation.org
Invalid Contraindications

- Mild illness
- Antimicrobial therapy
- Disease exposure or convalescence
- Pregnant or immunosuppressed person in the household
- Breastfeeding
- Preterm birth
- Allergy to products not present in vaccine or allergy that is not severe (e.g., anaphylactic)
- Family history of adverse events
- Tuberculin skin testing
- Multiple vaccines
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 nonlive influenza vaccine 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 prior to receipt of MMR and varicella vaccine
A pregnant woman living in the household is a contraindication to measles-mumps-rubella (MMR) and varicella (VAR) vaccines for a healthy child in the same household.

a. True

b. False
Resources
Appendix A24: Interval Between Antibody-Containing Products and Measles- and Varicella-Containing Vaccines
<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age at the time of the dose</th>
<th>Minimum age before next dose</th>
<th>Maximum age before next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>2 months</td>
<td>8 months</td>
<td>12 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>4 months</td>
<td>12 months</td>
<td>16 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>6 months</td>
<td>16 months</td>
<td>20 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>8 months</td>
<td>20 months</td>
<td>24 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>10 months</td>
<td>24 months</td>
<td>28 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>12 months</td>
<td>28 months</td>
<td>32 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>14 months</td>
<td>32 months</td>
<td>36 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>16 months</td>
<td>36 months</td>
<td>40 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>18 months</td>
<td>40 months</td>
<td>44 months</td>
</tr>
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<td>HBV, DTP, HIB, PCV13</td>
<td>20 months</td>
<td>44 months</td>
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<td>22 months</td>
<td>48 months</td>
<td>52 months</td>
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<td>HBV, DTP, HIB, PCV13</td>
<td>24 months</td>
<td>52 months</td>
<td>56 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>26 months</td>
<td>56 months</td>
<td>60 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>28 months</td>
<td>60 months</td>
<td>64 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>30 months</td>
<td>64 months</td>
<td>68 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>32 months</td>
<td>68 months</td>
<td>72 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>34 months</td>
<td>72 months</td>
<td>76 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>36 months</td>
<td>76 months</td>
<td>80 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>38 months</td>
<td>80 months</td>
<td>84 months</td>
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<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>40 months</td>
<td>84 months</td>
<td>88 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>42 months</td>
<td>88 months</td>
<td>92 months</td>
</tr>
<tr>
<td>HBV, DTP, HIB, PCV13</td>
<td>44 months</td>
<td>92 months</td>
<td>96 months</td>
</tr>
</tbody>
</table>

Included in Pink Book Appendix A-13
<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria-tetanus-acellular pertussis (DTaP)-1</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>DTaP-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>DTaP-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6-12 months</td>
<td>6 months</td>
</tr>
<tr>
<td>DTaP-4</td>
<td>15-18 months</td>
<td>12 months</td>
<td>3 years</td>
<td>—</td>
</tr>
<tr>
<td>DTaP-5</td>
<td>4-6 years</td>
<td>4 years</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><em>Haemophilus influenzae type b (Hib)-1</em></td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hib-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hib-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6-9 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Hib-4</td>
<td>12-15 months</td>
<td>12 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hepatitis A (HepA)-1</td>
<td>12-23 months</td>
<td>12 months</td>
<td>6-18 months</td>
<td>6 months</td>
</tr>
<tr>
<td>HepA-2</td>
<td>≥18 months</td>
<td>18 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><em>Hepatitis B (HepB)-1</em></td>
<td>Birth</td>
<td>Birth</td>
<td>4 weeks-4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HepB-2</td>
<td>1-2 months</td>
<td>4 weeks</td>
<td>8 weeks-17 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-3</td>
<td>6-18 months</td>
<td>24 weeks</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Included in Pink Book Appendix A-13
<table>
<thead>
<tr>
<th>Disease</th>
<th>20th Century Annual Morbidity†</th>
<th>2017 Reported Cases † †</th>
<th>Percent Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>29,005</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>21,053</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Measles</td>
<td>530,217</td>
<td>122</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Mumps</td>
<td>162,344</td>
<td>5,629</td>
<td>97%</td>
</tr>
<tr>
<td>Pertussis</td>
<td>200,752</td>
<td>15,808</td>
<td>92%</td>
</tr>
<tr>
<td>Polio (paralytic)</td>
<td>16,316</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>9</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>152</td>
<td>2</td>
<td>99%</td>
</tr>
<tr>
<td>Tetanus</td>
<td>580</td>
<td>31</td>
<td>95%</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em></td>
<td>20,000</td>
<td>22*</td>
<td>&gt; 99%</td>
</tr>
</tbody>
</table>

† JAMA. 2007;298(18):2155-2163


* *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

- 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
Prelicensure Vaccine Safety Studies

- Laboratory
- Animals
- Humans
Prelicensure Human Studies

- Phase I, II, III trials
- Phase III trials usually include a control group that receives 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
Postlicensure 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
2

Federal Vaccine Safety Monitoring
Vaccine Adverse Event Reporting System (VAERS)

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

https://vaers.hhs.gov/index
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 (Pink Book Appendix D-2)
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 (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

- Causation requires knowledge of
  - Correct diagnosis of event
  - Clinical and/or laboratory evidence
  - Known causal association between event and vaccine
  - Any evidence against a causal association?
  - Specific laboratory test supporting vaccine role
Elements Needed To Assess Correlation of Vaccine Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Disease</th>
<th>No disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>No vaccine</td>
<td>c</td>
<td>d</td>
</tr>
</tbody>
</table>

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.


<table>
<thead>
<tr>
<th></th>
<th>ASD</th>
<th>No ASD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>345</td>
<td>440,310</td>
</tr>
<tr>
<td>No vaccine</td>
<td>77</td>
<td>96,571</td>
</tr>
</tbody>
</table>

Risk in “vaccine” group = 7.83/10,000
Risk in “no vaccine” group = 7.96/10,000

Relative Risk = 0.98
Postlicensure Vaccine Safety Activities

- Phase IV trials
  - ~10,000 participants
  - Better but still limited

- Vaccine Safety Data Link

- Clinical Immunization Safety Assessment Project (CISA)
Vaccine Safety Datalink

- Large linked databases
- Connects vaccination and health records
- Partnership with large health plans: population under “active surveillance”
  - 9 HMOs
  - >3% (~12 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)
- “No fault” program
- Covers all routinely recommended childhood vaccines
- Vaccine Injury Table (Appendix D-5, D-6)

Vaccine Injury Compensation Program website: www.hrsa.gov/vaccinecompensation/index.html
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
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
Your Source for VISs
www.immunize.org
Common Concerns
National Academy 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
- 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
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
Multiple Vaccines

- Early vaccination is important to prevent diseases

- Vaccines are given at a young age because infants and children are at highest risk of getting sick or dying if they get these diseases

- Newborn babies have antibodies to some diseases from their mothers. BUT
  - Maternal antibodies lasts a few months—passive immunity
  - Most babies do not get protective antibodies against diphtheria, pertussis polio, tetanus, hepatitis B, or Hib from their mothers.
  - Therefore should vaccinate a child before she or he is exposed to a disease.
## Antigens in Vaccines for Children, 1960-2019

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>1960</th>
<th>1980</th>
<th>2000</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>~200</td>
<td>Not recommended</td>
<td></td>
<td></td>
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<tr>
<td>Diphtheria</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Tetanus</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>W cell pertussis</td>
<td>~3,000</td>
<td>~3,000</td>
<td>Acellular pertussis 2-5</td>
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<tr>
<td>Polio</td>
<td>15</td>
<td>15</td>
<td>15</td>
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<td>Measles</td>
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<td>10</td>
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<tr>
<td>Mumps</td>
<td>9</td>
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<td>Rubella</td>
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<td>Hib</td>
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<tr>
<td>Varicella</td>
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<td></td>
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<tr>
<td>Pneumococcal</td>
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<td></td>
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<tr>
<td>Hep B</td>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>Hep A</td>
<td></td>
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<td></td>
<td>4</td>
</tr>
<tr>
<td>Rotavirus</td>
<td></td>
<td></td>
<td></td>
<td>11-16</td>
</tr>
<tr>
<td>Influenza</td>
<td></td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>~3,217</td>
<td>~3,041</td>
<td>134-137</td>
<td>149-157</td>
</tr>
</tbody>
</table>

Multiple Vaccines

- Babies are exposed to thousands of germs and other antigens in the environment from the time they are born
  - When a baby is born, his or her immune system is ready to respond to the many antigens in the environment and the selected antigens in vaccines
  - Vaccines contain weakened or killed versions of the germs that cause a disease

- Getting multiple vaccines at the same time has been shown to be safe
  - The recommended vaccines have been shown to be as effective in combination as they are individually

- ACIP childhood vaccination schedule ensures children get the best protection
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*


*Partial listing of representative studies
... 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
What Do You Think?

The Vaccine Adverse Event Reporting System (VAERS) detects new or rare events, increases in rates of known events, and patient risk factors associated with vaccination. VAERS cannot establish causality.

a. True

b. False