

# Teaching Immunization

*for Medical Education (TIME)*



MULTISTATION CLINICAL TEACHING SCENARIOS

## Childhood Vaccination: Small Group Booklet

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## **Childhood Vaccination: Small Group Booklet**

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## **BACKGROUND ON THE MULTISTATION CLINICAL TEACHING SCENARIOS (MCTS) METHOD**

The multistation clinical teaching scenarios were developed to encourage active small-group learning in a clinically relevant context with a modest amount of faculty time. The time commitment of both the facilitator and the student is typically 50 to 90 minutes, depending on the setting and goals. The MCTS teaching method may be readily used in medical pre-clinical and clinical years when students' or residents' time is limited. MCTS is well-suited to objective-driven curricula. In the MCTS session, one facilitator can interact with groups ranging from 10 to 30 residents or students. The facilitator needs basic knowledge about the disease and immunization covered but does not need to be a content expert.

Students and residents are assigned to small groups of 2 to 5 for an MCTS session. All of the small groups simultaneously address the first scenario. Each small group spends approximately 5 to 10 minutes attempting to solve the problem addressed in the scenario. The scenario is then discussed in a large group. The facilitator calls on one of the small groups to present their answers, then the facilitator and the large group discuss each small group's response to the scenario and summarize the teaching points. The facilitator should correct wrong answers and discuss the teaching points. Generally, the large-group discussion should not last more than 7 minutes per scenario. After the first scenario is discussed, each small group works on the second scenario.

A large-group discussion follows. The process is repeated until all scenarios are completed or the allotted time expires.

### Suggested Schedule for MCTS Session

1. Arrange chairs in groups of 3 to 5, and separate students or residents into small groups.
2. Distribute one copy of the Childhood Vaccination MCTS *Small-Group Booklet* to each group along with a copy of the learning aids listed for the scenarios to be discussed. A major learning aid is needed: appropriate chapter from the CDC's Pink Book, [www.cdc.gov/vaccines/pubs/pinkbook/pink-chapters.htm](http://www.cdc.gov/vaccines/pubs/pinkbook/pink-chapters.htm) and/or slide set [www.cdc.gov/vaccines/pubs/pinkbook/pink-slides.htm](http://www.cdc.gov/vaccines/pubs/pinkbook/pink-slides.htm), *Shots* by STFM smartphone app from [www.immunizationed.org](http://www.immunizationed.org), and/or internet access to CDC's website [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines). Review the objectives briefly, focusing on the primary objectives.
3. The students or residents are to start the first scenario by having one member of each small group read the scenario aloud. Subsequently, each small group should work on answering the questions for that scenario. To answer the questions, the learners should use their previous knowledge and experience, the resource materials/internet, and the abstracts included in selected scenarios. They should divide the resource materials since each individual may not have time to read all of the materials.
4. Convene as a large group after 5 to 10 minutes, depending upon the complexity of the scenario. Select one group to present their answers to the questions. Critique answers and discuss the teaching points for 5 to 7 minutes.
5. Repeat steps 3 and 4 for the remaining scenarios that have been selected.

## OBJECTIVES

**At the end of this session, every learner should be able to accomplish the following core set of objectives.**

### **Primary Objectives:**

1. Given a patient scenario, recommend vaccination appropriately, according to the recommended childhood immunization schedule, and state the administration routes and injection sites for these vaccinations.
2. Given a child who is behind schedule, explain the principles of accelerated and catch-up vaccination, and determine needed vaccinations for current and subsequent visits.
3. Explain the rationale for simultaneous vaccine administration and the potential consequences of nonsimultaneous administration.
4. Given a patient scenario, identify valid contraindications and precautions to vaccination without missing vaccination opportunities that are appropriate.
5. Explain general vaccine safety and adverse event information, including the Vaccine Injury Compensation Program (VICP), the Vaccine Adverse Event Reporting System (VAERS), and use of the Vaccine Information Statements (VISs).
6. Suggest three procedures that a physician can implement in a practice or clinic to improve childhood vaccination rates.

### **Secondary Objectives:**

1. Given a patient scenario, recommend vaccination, if indicated, during both acute-care and well-child care visits to providers, thereby reducing missed opportunities.
2. State sources of current information on childhood vaccinations, including information about the schedule, minimal interval between doses, and vaccine contraindications.

## SCENARIO ONE

Joan is a healthy 2-month-old in Dr. Stevenson's office for her first well-child visit. She is breast-fed. Immunization history: She received the first dose of hepatitis B vaccine at 24 hours of age, just prior to being discharged from the hospital. Her mother's hepatitis B surface antigen status was negative. Parent question: Her parents wonder if so many shots are really needed.

### Learning Aids

1. *Recommended Childhood and Adolescent Immunization Schedule—United States* (use latest version) <http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm> or *Shots* by STFM smartphone app (optional [www.ImmunizationEd.org](http://www.ImmunizationEd.org))
2. Abstract 1 and 2, pages 6 & 7
3. Tables 1 and 2, pages 8 & 9
4. Combination Vaccines:
  - Pentacel® = DTaP + IPV/Hib
  - Pediarix® = DTaP + IPV + Hepatitis B
  - Comvax® = Hepatitis B + Hib

### Questions for Learners

1. What vaccination(s) are indicated?
2. By what route and site should the vaccines be given?
3. How would you answer the parents' question, "Are so many shots really needed?"
4. What information about vaccines should be given prior to vaccination?

**Abstract 1****Provide Vaccine Information Statements (VIS) when vaccine is given.**

As required under the National Childhood Vaccine Injury Act, all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV) or varicella (chickenpox) vaccine shall, **prior to administration of each dose of the vaccine**, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the CDC:

- to the parent or legal representative of any child to whom the provider intends to administer such vaccine, or
- to any adult to whom the provider intends to administer such vaccine.

A multi-vaccine statement that covers DTaP, hep B, polio, Hib, pneumococcal, and rotavirus is available at: [www.cdc.gov/vaccines/pubs/vis/downloads/vis-multi.pdf](http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-multi.pdf)

Adapted from CDC: Instructions for the Use of Vaccine Information Statements.  
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-Instructions.pdf>

## Abstract 2

### Vaccine Safety

Offit PA, Davis RL, Gust D (Centers for Disease Control and Prevention)

A practical way to determine capacity of the immune system to respond to vaccines would be to consider the number of B and T cells required to generate adequate levels of binding antibodies:

1. Approximately 10 ng/mL is likely to be an effective concentration of antibody against a specific epitope.
2. Approximately  $10^3$  B cells/mL are required to generate 10 ng of antibody/mL.
3. Given a doubling time of about 0.75 days for B cells, it would take about 7 days to generate  $10^3$  B cells/mL from a single B-cell clone.
4. Because vaccine-specific humoral immune responses are first detected about 7 days after immunization, those responses could initially be generated from a single B-cell clone per milliliter.
5. One vaccine contains about 10 immunogenic proteins or polysaccharides.
6. Each immunogenic protein or polysaccharide contains about 10 epitopes (i.e.,  $10^2$  epitopes per vaccine).
7. Approximately  $10^7$  B cells are present per milliliter of blood.

Given these assumptions, the number of vaccines to which an individual could respond would be determined by dividing the number of circulating B cells ( $\sim 10^7$ ) by the average number of epitopes per vaccine ( $10^2$ ). Therefore, an individual could theoretically respond to about  $10^5$  vaccines at one time.

Adapted from Chapter 74, Vaccine Safety. In: Plotkin, S.A., Orenstein, W.A., Offit, P.A. (eds), *Vaccines. Fifth Edition*. Elsevier Inc., 2008, p 1636.

Supplemental resource to guide discussion with parents: Too Many Vaccines? What you should know. <http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/too-many-vaccines.pdf>



**Table 1**

**Recommended Injection Routes and Sites, Based on Patient Characteristics**

Vaccines	Injection Route	Patient Characteristics (Age)	Administration Site
DTaP DT Hepatitis A Hepatitis B Hib Influenza inactivated Pneumococcal conjugate vaccine Meningococcal conjugate vaccine	Intramuscular	Infants	Anterolateral thigh
		Toddlers (≥12 months) and adolescents	Anterolateral thigh (if deltoid muscle mass inadequate)
			Deltoid (if adequate muscle mass)
IPV* MMR Varicella vaccine	Subcutaneous	Infants	Fat of anterolateral thigh or upper arm (triceps)
		Toddlers and adults	Fat of upper arm (triceps region)

Modified from MiddletonDB, Zimmerman RK, Mitchell KB: Vaccine Schedules and Procedures, 2001.

J Fam Pract 2001;50:S44. Copyright STFM, used with permission.

\*IPV can be given either IM or SQ; most authorities recommend the SQ route for IPV.

**Table 2**

**International Experience with Recurrence of Vaccine-Preventable Diseases when Vaccination Rates Dropped**

Country	Vaccine	Disease Recurrence
Former Soviet States	DTP	Diphtheria
Japan, Wales, England, Sweden	DTP	Pertussis
United Kingdom	MMR	Measles
USA	MMR	Measles

References:

1. Centers for Disease Control and Prevention. Update: Diphtheria Epidemic in New Independent States of the Former Soviet Union, January 1995 – March 1996. *MMWR* 1996;45:693-697.
2. Centers for Disease Control and Prevention. Update: Measles – United States, January – July 2008. *MMWR* 2008;57:893-896.
3. Gangarosa EJ, et al. Impact of anti-vaccine movements on pertussis control: the untold story. *Lancet* 1998;351:356-361.

## SCENARIO TWO

Rose, a 10-month-old who is new to your practice, is in your office for the first time in November for a cold. She is afebrile and you diagnose an upper respiratory tract infection. Her last visit to her previous physician was at 5 months of age for a cold.

Immunization history: Her parents are not sure which vaccines she received previously. A vaccination record was obtained from the state's immunization information system showing receipt of the first dose of hepatitis B vaccine at 1 day of age; at 3 months of age she received DTaP#1, Hib #1, IPV#1, PCV13#1, and RV #1.

Family history: Her father has allergic rhinitis and skin tests show that he is allergic to ragweed and chicken dander; otherwise, her parents are healthy. Rose's mother is pregnant with her second child.

### Learning Aids

1. Guide to contraindications and precautions to commonly used vaccinations  
<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm>
2. *Recommended Childhood Immunization Schedule –United States* (current year, particularly catch-up schedule) [www.cdc.gov/vaccines/recs/schedules/child-schedule.htm](http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm) or *Shots* by STFM smartphone app ([www.ImmunizationEd.org](http://www.ImmunizationEd.org))
3. Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines  
<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf>

### Questions for Learners

1. Which vaccinations are due today?
2. Are any of these vaccines contraindicated today? If so, why and which ones? If not, why not?
3. Rose had a 10-month lapse since her first hepatitis B vaccination. How many doses does she need now? Does Rose need to restart this or any of the vaccination series?

4. When should her next (second) appointment be scheduled? What vaccines should be administered at that visit? What is the minimal interval between doses of these vaccines?
5. If she comes for the second visit at the recommended time and is appropriately vaccinated, when should she next return, and for which vaccines?

### SCENARIO THREE

Rhonda is a 25-month-old who comes into the Health Center in November for a routine follow-up visit for asthma. She receives cromolyn three times per day; albuterol is added when she has symptoms. She has a history of four hospitalizations for asthma and bronchopulmonary dysplasia. She received a 16-day course of daily oral corticosteroids 5 months ago during an exacerbation of her lung disease. Her vaccination record reveals that DTaP #3, Hib #2, IPV #2, hepatitis B #3 and PCV13 #3 were given at 11 months of age; MMR was given at 15 months of age. She does not have a history of varicella. She currently is on day 8 of a 10-day course of antibiotics for otitis media and is no longer symptomatic. She lives with her mother and a brother who has hemophilia and developed HIV infection from a transfusion. Combination vaccines are available.

#### Learning Aids

1. Guide to contraindications and precautions to vaccinations  
<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm>
2. *Recommended Childhood and Adolescent Immunization Schedule –United States* (current year, particularly catch-up schedule)  
<http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm> or *Shots* by STFM smartphone *app* or *Shots* On-line (optional [www.ImmunizationEd.org](http://www.ImmunizationEd.org))
3. Abstract 3, page 13
4. Table 3, page 13

#### Questions for Learners

1. What vaccinations does Rhonda need?
2. Rhonda's mother refuses to let her have more than three injections at one time. Which vaccination(s) would you defer until the next visit? When should she return for that visit and for which vaccines? Are additional visits needed?
3. Are any vaccines contraindicated? What is the impact of the history of oral steroids?
4. What dosage and type of influenza vaccine should be given?

**Abstract 3**

**Combination Vaccines**

1. Pentacel® = DTaP + IPV/Hib
2. Pediarix® = DTaP + IPV + Hepatitis B
3. Comvax® = Hepatitis B + Hib

**Table 3**

**Schedule for follow-up vaccination using 23-valent polysaccharide vaccine (PPSV23) for children >2-years-old who previously received the conjugate vaccine (PCV13).**

Population	Schedule for follow-up with PPSV23 for children ≥ 2 years of age	Revaccinate with PPSV23?
Healthy children	None	No
Children with sickle cell disease or anatomic or functional asplenia  Immunocompromised (e.g. renal failure or leukemia)  HIV-infected	1 dose of PPSV23 at age > 2 and ≥ 8 weeks after last indicated dose of PCV13	Yes, one dose 5 years after first PPSV23
Chronic illness (e.g. chronic heart or lung disease, diabetes mellitus, cerebrospinal fluid leaks, or cochlear implant)	1 dose PPSV23 at age ≥ 2 years and ≥ 8 weeks after last indicated dose of PCV13	Not Recommended

Adapted from: Prevention of Pneumococcal Disease Among Infants and Young Children: Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2010;59 (RR11):15.

## SCENARIO FOUR

Okmulgee Medical Center is a primary care office of a health maintenance organization. Dr. Kent, the medical center director, received a disturbing report indicating that the Center's vaccination rates are low: 62% overall for the 4:3:1:3:3:1:4 series (4 DTaP, 3 polio, 1 MMR, 3 Hib, 3 hepatitis B, 1 varicella, and 4 pneumococcal conjugated doses). Physician-specific rates are 70% for Dr. Kent, 60% for Dr. Diamond, and 57% for Dr. Bloom. Furthermore, because the rates are lower than the HMO's average, the physicians in the Center will lose the \$10,000 quality bonus that they received last year. To clarify the problem, Dr. Kent conducted 75 chart audits, 25 from each physician. Infants were seen in the Center an average of five times in the first year of life. Two of these were for well-child care and three were for acute-care visits.

### Learning Aids

1. Figure 1, page 15
2. Abstract 4, page 16

### Questions for Learners

1. What are possible causes for low vaccination rates?
2. What can be done to raise the vaccination rates, i.e., what can be done to encourage parents to bring their children to the office according to schedule, and once children are at the office, what can be done to ensure that they receive the needed vaccinations?

Figure 1. Okmulgee Medical Center Chart Audit

Barrier	Number of Charts			
	Dr. Kent	Dr. Diamond	Dr. Bloom	Overall
Lack of simultaneous vaccination	2	3	3	8
Failure of vaccine during mild illnesses such as upper respiratory tract infections	13	17	16	46
Invalid contraindications such as family history of seizures	10	7	8	25
Number of charts with one or more of the previous barriers	17	18	18	53
Missed appointments for well-child care	15	17	18	50
Parental refusals	1	0	4	5



**Abstract 4****Office procedures to improve vaccination compliance.**

Zimmerman, R.K.

The procedures that are most important to improving vaccination rates are (1) evaluation of the practice's current vaccination rates, (2) problem solving, (3) goal setting, and (4) monitoring vaccination rates and provision of ongoing feedback to providers about vaccination rates.

The first step in developing a plan is evaluation of the practice's current vaccination rates. An evaluation is important since providers may overestimate vaccination rates and the evaluation may also suggest particular barriers within the clinic. In one clinic audit, the vaccination barriers, in descending order, were gaps in patient attendance due to missed appointments, missed opportunities by physicians to immunize, and overly cautious interpretation of contraindications (*J Am Board Fam Pract* 1994;7:100-104).

The second step is problem solving. Physicians and staff can choose from the following strategies to custom design interventions that are suited for them and their patients: (a) during office visits, ask the office staff to use computer algorithms to routinely evaluate the vaccination status of patients prior to the physician's encounter with the patient. (b) Send reminder letters or autodialer messages to inform parents about needed vaccinations. Reminders have been shown to increase vaccination rates in a number of studies. (c) Write standing orders to allow nurses to administer routine vaccines without needing to get a new order for each patient. (d) Have updated copies of the schedules, vaccinations for high-risk persons, and checklists of valid contraindications in places readily accessible to office and medical staff. The Task Force on Community Preventive Services published a systematic review on ways to increase immunization rates. See their website at [www.thecommunityguide.org](http://www.thecommunityguide.org).

The third step is setting a numerical goal. For instance, a goal could be that at least 90% of 2-year-olds would be fully vaccinated.

The final step is monitoring vaccination rates and giving feedback to providers. For instance, the percentage of 2-year-olds that are fully vaccinated can be graphed and displayed, allowing providers to compare their records with others. The physician/team that has the highest immunization rate can be awarded a prize. The impact of evaluation, competition, and feedback should not be underestimated – they are among the most important changes a practice can make to improve vaccination rates.

**SCENARIO FIVE**

Shasta, a 4-month-old infant, came to Dr. Johnson's office today for a complete physical examination and vaccinations. The examination was entirely normal. The second doses of DTaP, Hib, PCV13, and IPV were given. His mother called at 2:30 pm saying he had a temperature of 101.7°F (38.7°C) and was not eating well. She was instructed to administer acetaminophen and observe him. She called back at 4:45 pm indicating that he was limp and inactive. He was referred to the emergency department and found to be pale and listless. Physical examination showed a pale, inactive 4-month-old with a temperature of 102.6°F (39.2°C), decreased reaction to painful stimuli, and hypotonicity. Laboratory studies were normal. After 2 hours in the emergency department, he began to improve and started drinking from his bottle. He was sent home. The next day, the office nurse called his mother and found that he was active and playing.

**Learning Aids**

1. Guide to contraindications and precautions to commonly used vaccinations  
<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm>
2. Possible side-effects from vaccines, <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm>
3. Abstracts 5-7, pages 18-19

**Questions for Learners**

1. Which vaccine is most likely to have been responsible for the adverse events?
2. Should Shasta receive another dose of this vaccine?
3. Do these adverse events need to be reported?
4. If Shasta's parents allege that vaccination caused a permanent injury, what could be done?

**Abstract 5****Vaccine Adverse Event Reporting System**

The Vaccine Adverse Event Reporting System (VAERS), <https://vaers.hhs.gov/esub/step1> is a national vaccine safety surveillance program co-sponsored by the CDC and FDA. VAERS collects and analyzes information from reports of adverse events following immunization. Some of these events may occur coincidentally following vaccination, while others may truly be caused by vaccination. VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination.
- VAERS online reporting, <https://vaers.hhs.gov/esub/step1> or 800-822-7967

The National Childhood Vaccine Injury Act created the Vaccine Injury Compensation Program (VICP) to compensate individuals whose injuries may have been caused by vaccines recommended by the CDC for routine use.

**Abstract 6****Hypotonic, hyporesponsive episodes. Institute of Medicine (IOM) and the Centers for Disease Control and Prevention (CDC).**

Shock or shock-like state, collapse, and hypotonic, hyporesponsive episodes (HHE) are terms that are used interchangeably in the literature to refer to an unusual reaction consisting of an acute diminution in sensory awareness or loss of consciousness accompanied by pallor and muscle hypotonicity. As described, the syndrome has its onset between 1 and 12 hours after immunization. Most children are initially irritable and febrile. They then become pale, limp, and unresponsive or hyporesponsive. Respirations are shallow and cyanosis is frequently noted. The duration can be as short as a few minutes and as long as 36 hours.

The ACIP reports that HHE appears to be without sequelae. HHE has been reported following DTaP but appears to occur less frequently than after whole-cell DTP.

Modified from Howson CP, Howe CJ, Fineberg HV, eds. *Adverse Effects of Pertussis and Rubella Vaccines*. Washington, DC; National Academy Press; 1991: 171-177, and Update: vaccine side effects, adverse reactions, contraindications, and precautions—recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1996;45(RR-12):1-35.

**Abstract 7****Adverse events from Hib, PCV13 and IPV. Centers for Disease Control and Prevention (CDC). National Center for Immunization and Respiratory Diseases**

Adverse events to the five Hib conjugate vaccines are uncommon. Swelling, redness, and/or pain have been reported in 5% to 30% of recipients and usually resolve within 12 to 24 hours. Systemic reactions such as fever and irritability are infrequent. Local reactions following PCV13 occur in half of recipients. Eight percent of local reactions interfere with limb movement. No serious adverse reactions attributable to PCV13 have been reported.

Minor local reactions (injection site pain and redness) may occur after IPV. No serious adverse reactions to IPV have been documented.

Modified from Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Atkinson W, Wolfe S, Hamborsky J, McIntyre L, eds. 12th ed, Washington DC: Public Health Foundation, 2011.

**SCENARIO SIX**

Micaïla, a 2 month old, comes to Dr. Davis' office for a health supervision visit. Her parents are hesitant about vaccinations due to concerns about autism and vaccine reactions. They have searched web sites critical of vaccines and are concerned about inadequate safety testing. They have read tear-jerking testimonials about autism being caused by vaccines.

**Learning Aids**

1. Abstracts 8-10, pages 21-23
2. Mercury and Vaccines:  
<http://www.cdc.gov/vaccinesafety/Concerns/thimerosal/index.html>
3. MMR Vaccine:
4. <http://www.cdc.gov/vaccinesafety/Vaccines/MMR/MMR.html>
4. Supplemental resource to guide discussion with parents: Too Many Vaccines? What you should know. <http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/too-many-vaccines.pdf>

**Questions for Learners**

1. How could Dr. Davis respond to the parents concerns?
2. The parents read a report about a scientific article written by Drs. Geier and Geier that linked vaccines with autism; how would you respond?

**Abstract 8****Immunization Safety Review: Vaccines and Autism**

The Immunization Safety Review Committee, Institute of Medicine, reviewed the extant published and unpublished epidemiological studies regarding causality and studies of potential biologic mechanisms by which these immunizations might cause autism. The committee concludes that the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism and favors rejection of a causal relationship between thimerosal-containing vaccines and autism.

Epidemiological studies examining thimerosal containing vaccines (TCVs) and autism, including three controlled observational studies (Hviid et al., 2003; Miller, 2004; Verstraeten et al., 2003) and two uncontrolled observational studies (Madsen et al., 2003; Stehr-Green et al., 2003), consistently provided evidence of no association between TCVs and autism, despite the fact that these studies utilized different methods and examined different populations. Other studies reported findings of an association. These include two ecological studies (Geier and Geier, 2003a, 2004a), three studies using passive reporting data (Geier and Geier, 2003a,b,d) one unpublished study using Vaccine Safety Datalink (VSD) data (Geier and Geier, 2004b,c), and one unpublished uncontrolled study (Blaxill, 2001). However, the studies by Geier and Geier cited above have serious methodological flaws and their analytic methods were nontransparent, making their results uninterpretable, and therefore noncontributory with respect to causality (see text for full discussion). The study by Blaxill is uninformative with respect to causality because of its methodological limitations. Thus, based on this body of evidence, **the committee concludes that the evidence favors rejection of a causal relationship between thimerosal containing vaccines and autism.**

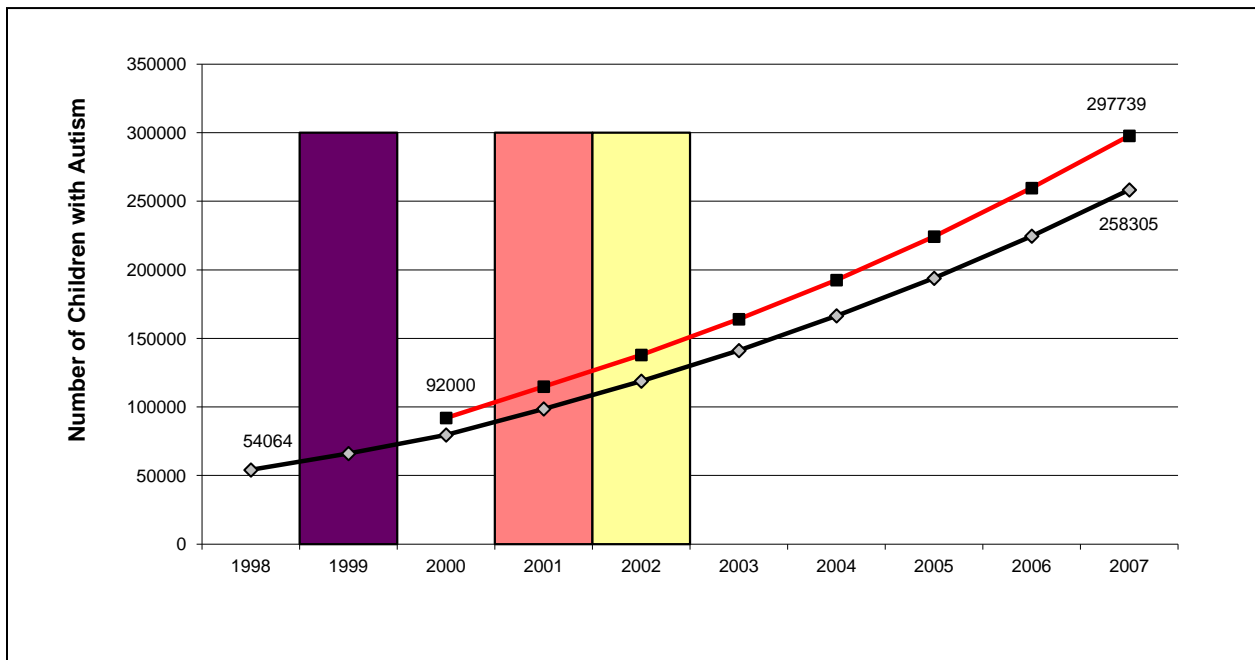
Adapted from Immunization Safety Review Committee, Institute of Medicine of the National Academies, The National Academies Press, Washington, D.C. 2004  
<http://www.nap.edu/openbook.php?isbn=030909237X>

Note: Members do not have any conflicts of interest.

**Abstract 9**

- A measles resurgence occurred in the United Kingdom when MMR vaccination decreased due to autism fears
- Rates of autism are increasing despite removal of thimerosal from infant vaccines

**Increase in Autism Rates 1998 – 2007 Despite Removal of Thimerosal from Infant Vaccines**



- 1999: Joint AAP-USPHS recommendation that thimerosal be removed as soon as possible from childhood vaccines
- 2001: All new lots of routine childhood vaccines (other than influenza vaccine) contain no more than traces of thimerosal
- 2002: Expiration dates for residual lots of routine childhood vaccines (other than influenza vaccine) that contain more than traces of thimerosal
- U.S. And Outlying Areas, Autism, Ages 3-22 <https://www.ideadata.org/PartBChildCount.asp>
- ◆ U.S. And Outlying Areas, Autism, Ages 6-22 <https://www.ideadata.org/PartBChildCount.asp>

Supplemental resource to guide discussion with parents: “Vaccines and Autism: What you should know” <http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/autism.pdf>

**Abstract 10****Importance of Childhood Immunizations**

- Young children do not have maternal immunity against some vaccine-preventable diseases, such as whooping cough.
- Some diseases (like polio and diphtheria) are becoming very rare in the U.S. Of course, they are becoming rare largely because we have been vaccinating against them. It's much like bailing out a boat with a slow leak. When we started bailing, the boat was filled with water. But we have been bailing fast and hard, and now it is almost dry. We could say, "Good. The boat is dry now, so we can throw away the bucket and relax." But the leak hasn't stopped. Before long we'd notice a little water seeping in, and soon it might be back up to the same level as when we started.
- In 1974, Japan had a successful pertussis (whooping cough) vaccination program, with nearly 80% of Japanese children vaccinated. That year only 393 cases of pertussis were reported in the entire country, and there were no deaths from pertussis. But then rumors began to spread that pertussis vaccination was no longer needed and that the vaccine was not safe, and by 1976 only 10% of infants were getting vaccinated. In 1979 Japan suffered a major pertussis epidemic, with more than 13,000 cases of whooping cough and 41 deaths. In 1981 the government began vaccinating with acellular pertussis vaccine, and the number of pertussis cases dropped again.

Modified from CDC Vaccines & Immunizations website, "What Would Happen if We Stopped Vaccinations?" <http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm>