TEACHING IMMUNIZATION for Medical Education

REVISED BY

Richard Kent Zimmerman, MD, MPH
March 2005

•

SPONSORED BY

Association of Teachers of Preventive Medicine
Centers for Disease Control and Prevention

•

DEVELOPED BY

Richard Kent Zimmerman, MD, MPH
Ellen R. Wald, MD
Ellen R. Ahwesh, MA

From the Department of Family Medicine and Clinical Epidemiology (RKZ, ERA), and the Departments of Pediatrics and Otolaryngology (ERW), University of Pittsburgh School of Medicine.

•

DEVELOPING INSTITUTION

Department of Family Medicine and Clinical Epidemiology of the University of Pittsburgh School of Medicine

•

FOR MORE INFORMATION

The Association of Teachers of Preventive Medicine (ATPM) can be contacted at (202)463-0550 for additional information.

•

CHILDHOOD VACCINATION

Facilitator's Guide

ATPM
ASSOCIATION OF TEACHERS OF PREVENTIVE MEDICINE

CDC
SAFER·HEALTHIER·PEOPLE™

DEPARTMENT OF FAMILY MEDICINE
UNIVERSITY OF PITTSBURG

This project was supported by funding from the Centers for Disease Control and Prevention (CDC), National Immunization Program, through Cooperative Agreement U50/CCU300860-10 to the Association of Teachers of Preventive Medicine.

TEACHING IMMUNIZATION for Medical Education

ACKNOWLEDGMENTS

The following people have been invaluable to this project and their work is greatly appreciated.

ASSOCIATION OF TEACHERS OF PREVENTIVE MEDICINE

William H. Barker, MD, Chair, Teaching Immunization for Medical Education Advisory Committee
Donna A. Page, MPH

CENTERS FOR DISEASE CONTROL AND PREVENTION

William L. Atkinson, MD, MPH
Patricia D. Brugliera, RN, MPH
Jennifer E. Hamborsky, MPH
Raymond A. Strikas, MD

UNIVERSITY OF PITTSBURGH

Janine E. Janosky, PhD
Steven L. Kanter, MD
Tammy A. Mieczkowski, MA
Daniel P. Morrison, MPhil

•

TEACHING IMMUNIZATION FOR MEDICAL EDUCATION ADVISORY COMMITTEE

The following people have been invaluable to this project and their work is greatly appreciated.

William H. Barker, MD
Chair, Teaching Immunization for Medical Education Advisory Committee
Associate Professor of Community and
Preventive Medicine and Gerontology
University of Rochester School of Medicine
Association of Teachers of Preventive Medicine

James R. Allen, MD, MPH
Vice President, Science, Technology, and Public Health Standards
American Medical Association

M. Brownell Anderson, MEd
Associate Vice President, Educational Programs
Association of American Medical Colleges

Laurence A. Carr, PhD
Associate Dean for Curriculum
University of Louisville School of Medicine
Association of American Medical Colleges

Richard D. Clover, MD
Professor and Chairman, Family and Community Medicine
University of Louisville School of Medicine
Society of Teachers of Family Medicine

Suzanne E. Dandoy, MD, MPH
Director, Graduate Program in Public Health
Eastern Virginia Medical School
American College of Preventive Medicine

Rene F. Rodriguez, MD
President
Interamerican College of Physicians and Surgeons

J. Martin Kaplan, MD
Professor of Clinical Pediatrics
Hahnemann University
American Academy of Pediatrics

F. Marc LaForce, MD
Physician-in-Chief
The Genesee Hospital
University of Rochester School of Medicine
American College of Physicians

Kristin L. Nichol, MD, MPH
Acting Chief, Medical Services
Minneapolis Veterans Affairs Medical Center
Society of General Internal Medicine

John K. Podgore, DO, FAAP
Acting Chairman, Department of Pediatrics
University of North Texas Health Science Center at Fort Worth
American Osteopathic Association

Richard Schwarz, MD
Professor, Department of Obstetrics and Gynecology
State University of New York Health Science Center at Brooklyn
Past President, American College of Obstetricians and Gynecologists

Jessie L. Sherrod, MD, MPH, FAAP
Director of Infectious Disease Control and Prevention
Assistant Professor, Pediatric Infectious Disease
Charles R. Drew University of Medicine and Science
President, Pediatric Section, National Medical Association

CONSULTANTS

W. Scott Schroth, MD, MPH
Assistant Dean for Student Affairs
George Washington University Medical Center

Gail Povar, MD, MPH
Clinical Professor of Health Care Sciences and Medicine
George Washington University Medical Center

FORMER AMERICAN MEDICAL ASSOCIATION REPRESENTATIVES

Hannah L. Hedrick, PhD
Director, Division of Medical Education Products
American Medical Association

Carlos J.M. Martini, MD, MPH, MSc
Executive Vice President and Chief Medical Officer
Med Scholar

•

CONTENTS

INTRODUCTION

• MODULE ORGANIZATION

Multistation clinical teaching scenarios (MCTS) materials were developed to encourage active learning in a small-group setting with a modest amount of faculty time. The MCTS module consists of two booklets.

Facilitator's Guide

This guide includes all contents of the *Small-Group Booklet*, as well as information about the development and history of the module, instructions for the facilitator, and suggested teaching points for each scenario.

Small-Group Booklet

Each small group of 3 to 5 students or residents should receive one *Small-Group Booklet*. Extra copies are available from the Association of Teachers of Preventive Medicine's website: www.atpm.org. The booklet contains a list of the session's objectives, the module pages (each representing a case scenario), related learning aids (e.g. graphs and abstracts), and questions to answer.

• THE TEACHING IMMUNIZATION FOR MEDICAL EDUCATION (TIME) PROJECT

The Teaching Immunization for Medical Education (TIME) Project is a collaboration of the Association of Teachers of Preventive Medicine (ATPM) and the Centers for Disease Control and Prevention (CDC).[1] An Advisory Committee of representatives from professional and educational organizations* provides guidance on all activities of the project. A survey to assess the current teaching about immunization in medical schools and residency programs was conducted.[2-3] In response to deficiencies revealed by the survey, the Advisory Committee envisioned a resource to assist the educator and to provide information to practicing physicians. From a framework of core curriculum objectives, the *TIME Resource* was created to offer a variety of educational modules for integration into existing curricula or for self-study by practicing physicians.

*The organizations include the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American College of Physicians, the American College of Preventive Medicine, the American Medical Association, the American Osteopathic Association, the Association of American Medical Colleges, the Association of Teachers of Preventive Medicine, the Centers for Disease Control and Prevention (CDC), the Interamerican College of Physicians and Surgeons, the National Medical Association, the Society of General Internal Medicine, and the Society of Teachers of Family Medicine.

The *TIME Resource* includes:

- Traditional didactic modules which present review articles for hepatitis B, influenza, and measles. These modules, the results of the medical school and residency surveys, and core curriculum objectives were published as a supplementary issue to the *American Journal of Preventive Medicine*.[4-7]
- Slide sets to accompany the modules for didactic presentation on influenza, and measles.
- Case-based materials in two formats, developed by a multidisciplinary team and widely field-tested.

Problem-Based Learning (PBL) Approach - intended for medical schools with the time and resources available for PBL and the desire for student-directed learning. PBL approach modules are available for hepatitis B, influenza, measles, and pertussis.[8,9]

Multistation Clinical Teaching Scenarios (MCTS) - encourages active, small-group learning, uses modest amounts of faculty and learner time, and is objective-driven. MCTS uses a more structured approach than classic PBL. MCTS modules are available for adult vaccination, childhood vaccination, *Haemophilus influenzae* type b, hepatitis B, influenza, measles, and pertussis.[9,10]

INFORMATION FOR FACILITATORS

- **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.

  MCTS was developed at Harvard University to teach radiology.[11] Viewboxes were displayed around a room and small groups of students rotated between viewboxes. At each viewbox, a clinical history was given along with questions (e.g., What is the differential diagnosis?). W. Scott Schroth, MD, modified this approach to teach medical students during a primary care clerkship at George Washington University.[12] Students rotated between stations that consisted of microscopes (e.g., Gram stain and urine specimens), x-rays, and brief histories. After all cases were completed, the facilitator led a discussion of the relevant teaching points. This approach was adapted by the authors for use with vaccine-preventable diseases.

  Students and residents are assigned to small groups of 3 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.

• MCTS MODULE DEVELOPMENT AND EVALUATION

A multidisciplinary team at the University of Pittsburgh, with expertise in preventive medicine, public health, family practice, pediatric infectious diseases, adult infectious diseases, and education evaluation, developed the MCTS materials in consultation with a general internist at George Washington University.[9,10]

The curricular goals are to (1) increase learner knowledge about vaccine-preventable diseases, vaccines, indications for vaccinations, and methods to increase vaccine coverage; (2) foster problem-solving abilities; (3) stimulate learning in a clinical context; and (4) help learners gain familiarity with key references such as the recommendations of the Advisory Committee on Immunization Practices (ACIP).

The first step in developing the modules was the creation of specific learning objectives that used the spectrum of Bloom's taxonomy, when possible.[13] After development and revision of the learning objectives, actual clinical cases were sought from hospital and medical office records and modified for teaching purposes. Additional scenarios were written to address objectives not covered by the clinical cases.

Following development, the scenarios were pilot-tested with students or residents from the University of Pittsburgh School of Medicine, George Washington University School of Medicine, and Saint Margaret Memorial Hospital Family Practice Residency (Pittsburgh, Pennsylvania). The materials were subsequently revised. Formative evaluation was used for modification, via pilot-testing, of the assessment tools. Subsequently, summative evaluation was done by field-testing the materials at other medical schools and residencies for an independent evaluation.*

The purposes of the field test were to (1) examine the degree to which the students and residents met the learning objectives, (2) assess their perceptions of the teaching method, and (3) examine the feasibility and acceptability of the curriculum to the institution.[9] Mastery levels were defined using the modified Nedelsky procedure.[14,15] Three experts rated the likelihood that a minimally competent learner would know whether each alternative answer in a multiple choice question was correct. Then, the mastery level was calculated using the Nedelsky formulas and rounded, with the result that third-year medical students and second-year residents needed to achieve scores of 50% and 60%, respectively, to pass the posttest.

Results of the field test revealed that, depending on the subject, 96% to 99% of MCTS learners achieved mastery on the posttest.[9] A mean increases in scores from the 10-item pretest to the posttest were 1.8 items for hepatitis B; 3.8 items for influenza; 3.1 items for measles; 3.9 items for pertussis, 1.9 items for adult vaccination, 1.9 items for childhood vaccination, and 2.6 items for *Haemophilus influenzae* type b ($p < .01$ for each). Virtually all (98%) of the learners rated the MCTS sessions overall as very good or good. Furthermore, they found the sessions interesting (96%), agreed that the MCTS session made a valuable contribution to their learning (95%), rated the information learned in the session as applicable (99%), and liked MCTS as a learning method (93%).

*Field test sites included Albert Einstein College of Medicine of Yeshiva University, George Washington University School of Medicine, Hahnemann University, Kirksville College of Osteopathic Medicine, Mayo Medical School-Mayo Clinic and Foundation, the Medical Center of Delaware, Medical University of South Carolina, Ponce School of Medicine (PR), Shadyside Hospital (Pittsburgh), Sutter Health Family Practice (Sacramento, CA), University of California at Irvine, University of Louisville, University of Maryland School of Medicine, University of Puerto Rico School of Medicine, West Side Family Practice Center (Akron, OH), and West Virginia University School of Medicine.

The facilitators generally rated the materials highly. All (100%) rated the facilitator's guide as sufficiently clear; and most (97%) rated the learner materials as clear. Most (97%) rated the session overall as very good or good. Conference calls were conducted with participants at the field-test sites for further evaluation. Following field-testing, and review by CDC, the materials were revised.

This material was developed using information from the Advisory Committee on Immunization Practices and the American Academy of Family Physicans (General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices [ACIP] http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf and the American Family Physicians [AAFP]. MMWR 2002;51[No. RR-2], and the Centers for Disease Control and Prevention (CDC Recommended Childhood Adolescent Immunization Schedule—United States, 2005 MMWR 2005; 53 (Nos. 51 & 52). http://www.cdc.gov/nip/recs/child-schedule.htm

The facilitator should use the most recent versions available. See http://www.cdc.gov/nip

- **STRATEGIES FOR USING THE MCTS MODULE**

The content of the scenarios fits into the following categories: (1) description of a vaccine-preventable disease (usually the first scenario in a module), (2) missed opportunities to immunize, resulting in vaccine-preventable diseases, (3) outbreak investigation or control, (4) quality assessment and improvement of vaccination rates, and (5) vaccination decisions for a given clinical situation. The most pertinent scenarios can be selected or all can be used, at the discretion of the facilitator. If time is limited, the most important scenarios to cover are scenarios 1, 2, and 3. We recommend that facilitators limit the small group time per scenario to approximately 8 minutes, depending on the complexity of the scenario and the education level of the learners.

- **Here are some possible settings for these materials:**

1) Noon conference or the equivalent — three or four of the scenarios can be covered within 45 to 60 minutes. Residents have enjoyed the change from lecture or seminar to small-group learning experience.
2) Small-group breakout sessions to complement lectures in pre-clinical microbiology, immunology, and epidemiology courses.
3) Curriculum of a primary care clerkship — the materials have been used successfully as part of primary care clerkships, including clerkships in family practice, internal medicine, and pediatrics. Several scenarios can be selected to fit within the allotted period.
4) Workshops for residents, fellows, or providers — a longer block of time can be devoted to covering in depth many or all of the scenarios in one or two modules.
5) Grand Rounds — materials have been used in multidisciplinary Grand Rounds, resulting in intriguing discussions.
6) A "mix and match" option allows representative adult or childhood vaccinations to be covered in any of the above settings within one session. For instance, two of the hepatitis B scenarios and two of the influenza scenarios could be covered in the same session.

• PREPARATION LIST FOR THE FACILITATOR

___1) Obtain a location and date to meet. A comfortable room with tables surrounded by movable chairs is ideal.

___2) For each small group, obtain an electronic copy of the *Small-Group Booklet* from ATPM's website: http://www.atpm.org.

___3) Choose the scenarios to be discussed. Typically, a group can cover three to four scenarios within 1 hour (students are often slower than residents).

___4) Have basic familiarity with the vaccine(s) addressed in this module, prevention strategies, and this MCTS module. Basic familiarity, rather than content expertise, is needed. See the section "Sources of Information on . . ." for suggested resources.

• 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 *Small-Group Booklet* to each group along with a copy of the learning aids listed for the scenarios to be discussed.
3. Review the objectives briefly, focusing on the primary objectives.
4. Instruct the students or residents 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. Instruct them to stay on the same page so everyone is working on the same scenario. To answer the questions, the learners should use their previous knowledge and experience, the resource materials, and the abstracts included in selected scenarios. Instruct them to divide the resource materials since each individual may not have time to read all of the materials.
5. 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 their answers and discuss the teaching points for 5 to 7 minutes.
6. Repeat steps 4 and 5 for the remaining scenarios that you have selected.

• SOURCES OF INFORMATION ON CHILDHOOD VACCINATION

1. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2002;51(RR-2):1-35 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5102a1.htm
2. American Academy of Pediatrics. Pickering LK, ed., Red Book 2003: *Report of the Committee on Infectious Diseases*. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003.
3. Chin J, ed. *Control of Communicable Diseases Manual: An Official Report of the American Public Health Association*. 17th ed. Washington, DC: American Public Health Association; 2000.
4. U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*, 3rd ed. http://wwww.ahrq.gov/clinic/prevnew.htm
5. Plotkin SA, Orenstein WA, eds. *Vaccines*. 4th ed. Philadelphia PA: Saunders 2004.
6. Centers for Disease Control and Prevention. National Immunization Program. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 8th ed., 2nd printing. Atlanta, GA: Centers for Disease Control and Prevention; 2005. This book may be viewed at http://www.cdc.gov/nip/publications/pink/def_pink_full.htm and may be purchased from the Public Health Foundation by calling 1-800-418-7246. http://www.phf.org
7. Shots PDA software. Available free at www.immunizatioined.org.

• REFERENCES

1. Barker WH. Overview: The ATPM-CDC Immunization in Medical Education Project. Am J Prev Med. 1994;10(suppl):1-3.
2. Falter KH, Strikas RA, Barker WH, et al. Curriculum content on vaccine-preventable diseases in U.S. medical schools. Am J Prev Med. 1994;10(suppl):4-10.
3. Strikas RA, Falter KH, Barker WH, et al. Curriculum content on vaccine-preventable diseases in primary care and preventive medicine residency programs in the United States. Am J Prev Med. 1994;10(suppl):11-17.
4. The Immunization in Medical Education Advisory Committee. Vaccine-preventable diseases core curriculum objectives. Am J Prev Med. 1994;10(suppl):18-21.
5. Atkinson WL, Kaplan JM, Clover R. Measles: virology, epidemiology, disease, and prevention. Am J Prev Med. 1994;10(suppl):22-30.
6. LaForce FM, Nichol KL, Cox NJ. Influenza: virology, epidemiology, disease, and prevention. Am J Prev Med. 1994;10(suppl):31-44.
7. Moyer LA, Mast EE. Hepatitis B: virology, epidemiology, disease, and prevention, and an overview of viral hepatitis. Am J Prev Med. 1994;10(suppl):45-55.
8. Zimmerman RK, Ahwesh ER. Using problem-based learning to target public health problems. Acad Med. 1996;71:543.
9. Zimmerman RK, Barker WH, Strikas RA, et al. Developing curricula to promote preventive medicine skills: the Teaching Immunization for Medical Education (TIME) project. JAMA. 1997;278:705-711.
10. Zimmerman RK, Janosky JE, Wald ER, et al. Development and multicenter evaluation of Multistation Clinical Teaching Scenarios on immunization: the ATPM-CDC Teaching Immunization for Medical Education (TIME) Project. Am J Prev Med. 1997;13(2):78-83.
11. Wetzel M, Reid L. The Multistation Exercise: Accessible, Adaptable, Active-Learning. Washington, DC: Association of American Medical Colleges National Meeting; 1991.
12. Schroth WS, Carlson LG. Multistation office simulations [Abstract]. In: Schultz HJ, Thane MW, eds. The Educational Clearing House for Internal Medicine. 3rd ed. October 1994:2.
13. Bloom BS, Engelhart MD, Furst EJ, et al. Taxonomy of Educational Objectives: The Classification of Educational Goals. Handbook 1: Cognitive Domain. New York, NY: David McKay Co; 1956.
14. Gross LJ. Setting cutoff scores on credentialing examinations: a refinement of the Nedelsky procedure. Eval Health Prof. 1985;8(4):469-493.
15. Maguire T, Skakun E, Harley C. Setting standards for multiple-choice items in clinical reasoning. Eval Health Prof. 1992;15(4):434-453.

OBJECTIVES

Primary Objectives

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

1. Given a child, 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, procedures for undocumented vaccination histories, and vaccine contraindications.
3. Explain that severely immunocompromised persons should not receive live viral vaccines, except that HIV-infected persons who are not severely immunosuppressed can receive MMR when indicated.

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. Family history: Her mother's hepatitis B surface antigen status was negative. Her father has allergic rhinitis and skin tests show that he is allergic to ragweed, cat dander, and chicken dander; otherwise, her parents are healthy. Parent questions: 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/nip/recs/child-schedule.htm
2. Abstract 1
3. Vaccine Information Statement on DTaP. http://www.cdc.gov/nip/publications/vis/ and to get the DTaP VIS: http://www.cdc.gov/nip/publications/VIS/vis-dtp.pdf
4. Table 1 and Abstract 2
5. Shots PDA software (optional www.immunizationed.org)

- **Questions for Learners**

1. What vaccination(s) are indicated?
2. How would you answer the parents' question, "Are they really needed?"
3. Why is pneumococcal conjugate vaccine recommended for all infants?
4. Does Joan have any contraindications to vaccination?
5. When should Vaccine Information Statements be used?

- **Abstract 1**

Vaccine Information Statements (VIS).

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 B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), influenza, or pneumococcal conjugate 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 Centers for Disease Control and Prevention (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.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate. If there is not a single VIS for a combination vaccine (e.g., hepatitis A/hepatitis B), use the VISs for both component vaccines.

Adapted from Centers for Disease Control and Prevention (CDC): Instructions for the Use of Vaccine Information Statements. http://www.cdc.gov/nip/publications/vis/vis-Instructions.pdf

This page corresponds to page 7 in the Small-Group Booklet.

DIPHTHERIA TETANUS & PERTUSSIS VACCINES

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

DIPHTHERIA causes a thick covering in the back of the throat.
- It can lead to breathing problems, paralysis, heart failure, and even death.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.
- It can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in about 1 out of 10 cases.

PERTUSSIS (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.
- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can help prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2 Who should get DTaP vaccine and when?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

✓ 2 months ✓ 4 months ✓ 6 months
✓15-18 months ✓ 4-6 years

DTaP may be given at the same time as other vaccines.

3 Some children should not get DTaP vaccine or should wait

- Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.
- Any child who had a life-threatening allergic reaction after a dose of DTaP should not get another dose.
- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get another dose.
- Talk with your doctor if your child:
  - had a seizure or collapsed after a dose of DTaP,
  - cried non-stop for 3 hours or more after a dose of DTaP,
  - had a fever over 105°F after a dose of DTaP.

Ask your health care provider for more information. Some of these children should not get another dose of pertussis vaccine, but may get a vaccine without pertussis, called **DT**.

4 Older children and adults

DTaP should not be given to anyone 7 years of age or older because pertussis vaccine is only licensed for children under 7.

But older children, adolescents, and adults still need protection from tetanus and diphtheria. A booster shot called **Td** is recommended at 11-12 years of age, and then every 10 years. There is a separate Vaccine Information Statement for Td vaccine.

Diphtheria/Tetanus/Pertussis 7/30/2001

5 What are the risks from DTaP vaccine?

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses. Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, lasting 1-7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1-3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105°F (about 1 child out of 16,000)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage.

  These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures. You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual conditions, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If a high fever or seizure were to occur, it would usually be within a week after the shot.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

  Or you can file this report through the VAERS web site at www.vaers.org, or by calling 1-800-822-7967.
  VAERS does not provide medical advice

7 The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at **www.hrsa.gov/osp/vicp**

8 How can I learn more?

- Ask your health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit the National Immunization Program's website at **www.cdc.gov/nip**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
National Immunization Program

Vaccine Information Statement
DTaP (7/30/01) 42 U.S.C. § 300aa-26

Table 1

Impact of Vaccines in the 20th Century

Disease	20th Century Annual Morbidity	2003 Total	% Decrease
Smallpox	448,164	0	100
Diptheria	175,885	1	>99.9
Pertussis	147,271	11,647	92.1
Tetanus	1,314	20	98.5
Polio (paralytic)	16,316	0	100
Measles	503,282	56	>99.9
Mumps	152,209	231	99.9
Rubella	47,745	7	>99.9
Congenital rubella	823	1	99.8
Haemophilus influenzae (<5yrs)	20,000 (est.)	259 (serotype B or unknown serotype)	98.8

http://www.cdc.gov/nip/publications/pink/appendices/A/impact_vaccs.pdf

Sources:

1. CDC. Impact of vaccines universally recommended for children—United States, 1900 - 1998. MMWR 1999;48 (12):243 - 8.

2. CDC. Notice to Readers: Final 2003 Reports of Notifiable Diseases. MMWR 2004;53(30):687.

- **Abstract 3**

Pneumococcal Conjugate Vaccine for Young Children

Before the introduction of pneumococcal conjugate vaccine, *Streptococcus pneumoniae* caused approximately 6000 cases of meningitis, 61,000 cases of bacteremia, 100,000-135,000 cases of pneumonia requiring hospitalization, and 7 million cases of otitis media annually.

Risk factors for invasive pneumococcal disease include age, race, attendance at daycare, and chronic medical conditions. The incidence rates are highest in infancy, decline with age, and then increase in the elderly. African Americans have rates about two- to three-fold higher than whites and Alaska Natives and Native Americans have rates about three- to seven-fold higher than whites. Children with sickle cell disease have quite high rates of disease, penicillin prophylaxis reduces the risk for pneumococcal disease in sickle cell disease, but the rates are still elevated. Other predisposing risk factors include other asplenia, infection with HIV, recent antibiotic treatment, and passive smoking. Out-of-home day care increases the risk for invasive pneumococcal disease by two- to three-fold.

A 7-valent pneumococcal conjugate vaccine, (PCV), was licensed in 2000. PCV was designed to cover the seven serotypes most common in children; in fact, these serotypes account for about 80% of

invasive infections in children less than 6 years of age. Obviously, PCV covers fewer serotypes than the 23-valent polysaccharide vaccine. However, among the serotypes in PCV, it is more immunogenic than the polysaccharide vaccine. PCV elicits a T-dependent immune response that leads to anamnestic response on challenge and is effective in infants. The efficacy was 100% against invasive pneumococcal disease in the primary analyses of a large randomized, double-blind controlled trial conducted in California. In the follow-up analysis done 8 months later, the efficacy against invasive disease was 94 percent for serotypes included. No serious adverse reactions associated with PCV were reported. When given with DTaP but at another site, fever $\geq$38°C occurred in 15% to 24% of those vaccinated with PCV compared to 9% to 17% of those receiving the control vaccine.

PCV is recommended for routine infant immunization.

For infants, the routine vaccine schedule is 2, 4, 6 and 12-15 months. The catch-up schedule varies by age and by presence of high risk medical conditions.

- **Answers to Questions for Learners**

1. *Q: What vaccination(s) are indicated?*

   A: Joan needs the first dose of DTaP, the first dose of Hib, the first dose of inactivated poliomyelitis vaccine, the first dose of PCV, and the second dose of hepatitis B vaccine.

2. *Q: How would you answer the parent's question, "Are they really needed?"*

   A: Historically, larger numbers of cases of vaccine-preventable diseases were greatly reduced by vaccination. Deaths, hospitalizations, and brain damage decreased as well. Since these diseases are contagious, they can return if immunization rates drop, as has happened in other developed countries when immunization rates dropped.

3. *Q: Why is pneumococcal conjugate vaccine recommended for all infants?*

   A: Prior to the introduction of pneumococcal conjugate vaccine, *Streptococcus pneumoniae* caused approximately 6000 cases of meningitis, 61,000 cases of bacteremia, 100,000-135,000 cases of pneumonia requiring hospitalization, and 7 million cases of otitis media annually. The incidence rates are highest in infancy. The vaccine efficacy was 100% against invasive pneumococcal disease in the primary analyses of a large ran domized, double-blind controlled trial conducted in California. In the follow-up analysis done 8 months later, the efficacy against invasive disease was 94 percent for serotypes included. No serious adverse reactions associated with PCV were reported.

4. *Q: Does Joan have any contrandications to vaccination?*

   A: Joan does not have any contraindications to vaccination. Breast-feeding is not a valid contraindication to vaccination. Neither a family history of allergic rhinitis nor a household contact who has allergic rhinitis are valid contraindications.

5. *Q: When should Vaccine Information Statements be used?*

   A: Vaccine Information Statements are currently available for all vaccines that she should received today. They should be given to the legal parent or guardian of any child receiving these vaccinations.

SCENARIO TWO

Rose, a 10-month-old who is new to your practice, is in your office 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, but they know that she has received some vaccines. A vaccination record was faxed to your office showing receipt of the first dose of hepatitis B vaccine at 1 day of age; at 3 months of age, she received the first dose of diphtheria and tetanus toxoid and acellular pertussis vaccine (DTaP), the first dose of *Haemophilus influenzae* type b (Hib) conjugate vaccine, a dose of inactivated poliovirus vaccine (IPV), and a dose of pneumococcal conjugate vaccine.

Rose's mother is pregnant with her second child.

- **Learning Aids**

1. *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*; sections: Table 1, Recommended and Minimum Ages and Intervals Between Vaccine Doses (p. 3), Simultaneous Administration (pp. 4-5), Lapsed Vaccination Schedule (p. 8), and Table 5: Guide to contraindications and precautions to commonly used vaccinations (pp. 9-10). http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf
2. *Recommended Childhood and Adolescent Immunization Schedule—United States* (current year, including footnotes and catch-up schedule) http://www.cdc.gov/nip/recs/child-schedule.htm or shots software for PDA. http://www.immunizationed.org/AnyPage.aspx?PageName=ShotsHome
3. Table 2, Recommended Injection Routes, Needle Gauge and Needle Length, Based on Patient Characteristics on following pages.

- **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. By what route and site should the vaccines be given?
5. 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?
6. If she comes for the second visit at the recommended time and is appropriately vaccinated, when should she next return, and for which vaccines?

This page corresponds to page 12 in the Small-Group Booklet.

Table 2

Recommended Injection Routes, Needle Gauge and Needle Length, Based on Patient Characteristics

Vaccines	Injection Route	Needle Size	Patient Characteristics (Age)	Needle Length (inches)	Administration Site
DTaP DT Hepatitis A Hepatitis B Hib Influenza inactivated Pneumococcal conjugate vaccine Pneumococcal polysaccharide vaccine* Td Rabies vaccine	Intramuscular	22 to 25 gauge	Infants	7/8 to 1	Anterolateral thigh
			Toddlers (≥12 months) and adolescents	1	Anterolateral thigh (if deltoid muscle mass inadequate)
				7/8 to 1.25	Deltoid (if adequate muscle mass)
			Adults	1 to 1.5	Deltoid
IPV* MMR Varicella vaccine Pneumococcal polysaccharide vaccine*	Subcutaneous	23 to 25 gauge	Infants	5/8	Fat of anterolateral thigh or upper arm (triceps)
			Toddlers and adults	5/8	Fat of upper arm (triceps region)

Modified from Middleton DB, Zimmerman RK, Mitchell KB: Vaccine Schedules and Procedures, 2001. *J Fam Pract* 2001; 50:S44. Copyright STFM, used with permission.

*pneumococcal polysaccharide vaccine and IPV can be given either IM or SQ; most authorities recommend the SQ route for IPV.

- **Answers to Questions for Learners**

1. *Q: Which vaccinations are due today?*

   A: Rose is due for the second dose of DTaP, Hib, IPV PCV, inactivated influenza vaccine, and hepatitis B vaccine.

2. *Q: Are any of these vaccines contraindicated today? If so, why and which ones? If not, why not?*

   A: None of these vaccines are contraindicated today. A mild upper respiratory tract infection is not a valid contraindication to vaccination. She could have been vaccinated at 5 months of age when she had a cold and should be vaccinated today. The presence of a pregnant household contact is not a valid contraindication to vaccination. She does not need to restart any of the vaccination series.

3. *Q. 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?*

   A. Rose needs two more doses of hepatitis B vaccine. The schedule should be continued from where they lapsed; they should not be started over again.

4. *Q: By what route and site should the vaccines be given?*

   A: DTaP, Hib, PCV, inactivated influenza vaccine, and hepatitis B vaccine should be administered intramuscularly in the anterolateral thigh of infants. IPV is administered subcutaneously.

5. *Q: 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?*

   A: Rose's next (second) appointment should be scheduled in 1 month when she is 11 months of age. At that time, she should receive the third dose of DTaP, Hib, PCV, IPV, and the second dose of inactivated influenza vaccine. One month is the minimum interval between doses for all of these vaccines. The third dose of hepatitis B vaccine should be administered at least 4 months after the first dose and at least 2 months after the second dose. Two doses of inactivated influenza vaccine are recommended in the first year that a child less than nine years of age receives influenza vaccine; one dose is recommended in subsequent years.

6. *Q: If she comes for the second visit at the recommended time and is appropriately vaccinated, when should she next return, and for which vaccines?*

   A: Rose's third visit to the office should be scheduled at 12 months of age. At that time she should receive the third dose of hepatitis B vaccine, MMR, and varicella vaccine. The minimum interval between the third and fourth doses of DTaP is 6 months; hence, it cannot be given until she is 17 months of age. The booster dose of Hib vaccine should be given at least 2 months after the previous dose, so it should be given at 13 to 15 months of age.

SCENARIO THREE

Rhonda is a 25-month-old who comes into the Health Center in November for a routine follow-up visit for reactive airways disease. She receives cromolyn three times per day; albuterol is added when she has symptoms. She has a history of four hospitalizations for reactive airways disease and bronchopulmonary dysplesia. 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 the third dose of DTaP, the second dose of IPV, and the third dose of hepatitis B vaccine were given at 11 months of age; Measles-mumps-rubella vaccine (MMR) and the last dose of Hib were 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.

- **Learning Aids**

1. *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*; sections: Table 1: Recommended and minimum ages and intervals between vaccine doses (p.3), Table 5: Guide to contraindications and precautions to vaccinations (pp. 9-10) Altered Immunocompetence (p. 22), and Corticosteroids (p. 23). http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf
2. *Recommended Childhood and Adolescent Immunization Schedule—United States* (current year). http://www.cdc.gov/nip/recs/child-schedule.htm
3. Abstract 4

- **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?
3. Are any vaccines contraindicated? What is the impact of the history of oral steroids?
4. What dosage of influenza vaccine should be given?

This page corresponds to page 14 in the Small-Group Booklet.

- **Abstract 4**

Influenza and pneumococcal vaccines.
Zimmerman, RK.

Inactivated influenza and pneumococcal vaccines are recommended for persons who are at risk for complications from these diseases. Both vaccines are recommended for persons with chronic pulmonary or cardiovascular diseases. Inactivated influenza vaccine is recommended for persons with asthma. Both are also recommended for persons with chronic metabolic disease (including diabetes mellitus), renal dysfunction, or immunosuppressive diseases (including HIV). Pneumococcal vaccines are recommended for persons with anatomic or functional (e.g., sickle cell disease) asplenia. Inactivated influenza vaccine is recommended for persons with hemoglobinopathies and children <19 years of age who are on long-term aspirin therapy (due to the possibility of Reye syndrome should they contract influenza). Persons who are household contacts of chronically ill persons should receive influenza vaccine yearly to reduce the likelihood that they will transmit influenza to the ill person.

The dose of inactivated influenza vaccine is 0.5 mL IM except for children 6 months through 35 months old who should receive 0.25 mL IM. Previously unvaccinated children <9 years of age should receive two doses, at least 1 month apart, in the first year that they receive influenza vaccine.

Pneumococcal conjugate vaccine is recommended for all infants and for catch-up of high risk children who were not previously vaccinated. In addition, children with a high risk condition may also need pneumococcal polysaccharide vaccine at age $\geq$ 2 years (see Table to right).

Schedule for follow-up vaccination using 23-valent polysaccharide vaccine (PPV) for children ≥2-years-old who previously received the 7-valent conjugate vaccine (PCV).

Population	Schedule for follow-up with PPV for children ≥ 2 years of age	Revaccinate with PPV?
• 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 PPV at age > 2 years and ≥2 months after last dose of PCV	Yes‡
•Chronic illness (e.g., diabetes mellitus, cerebrospinal fluid leaks, chronic bronchupulmonary dysplasia, or cyanotic congenital heart disease)	1 dose PPV at age ≥2 years and ≥2 months after last dose of PCV	Not Recommended

Adapted from: Preventing Pneumococcal Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2000;49(No. RR-9):25.

§ Health care providers of Alaska Natives and American Indians may wish to consider whether Native American children would benefit by the additional coverage provided by the expanded serotypes in 23-valent PPV.

‡ Regardless of when administered, a second dose of PPV should not be given earlier than 3 years following the previous PPV dose. If patient is aged > 10 years: single revaccination ≥ 5 years after previous dose. If patient is age ≤ 10 years: one revaccination 3-5 years after previous dose should be considered.

- **Answers to Questions for Learners**

1. *Q: What vaccinations does Rhonda need?*

   A: Rhonda needs the fourth dose of DTaP, the third and final dose of PCV, the third dose of IPV, varicella vaccine, and two doses of influenza vaccine (1 month apart). Inactivated influenza is indicated due to her chronic lung disease.

2. *Q: 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?*

   A: Since the incidence of wild poliomyelitis in the United States is thought to be zero, IPV is the best choice to defer since Rhonda's mother will not permit more than three injections. If the third and final dose of PCV, varicella vaccine, and the first dose of influenza vaccine are given now, at 25 months of age, Rhonda should return at 26 months of age for the second dose of influenza vaccine, the third dose of IPV, and the fourth dose of DTaP. PPV is also recommended 2 months after the last dose of PCV since it covers more serotypes than does PCV. The reason for administering pneumococcal vaccine is her chronic lung disease. Pneumococcal polysaccharide vaccine should not be given prior to 24 months of age because children <24 months old do not respond to polysaccharide vaccines.

   Routine hepatitis A vaccination is recommended for children who live in states, counties, or communities having an annual rate of hepatitis A infection during 1987-1997 of at least 20 per 100,000 e.g., Arizona, Alaska, Oregon, New Mexico, Utah, Washington, Oklahoma, South Dakota, Idaho, Nevada, and California. Routine vaccination can be considered for states, counties, or communities where the average rate was at least 10 per 100,000. The age for implementing this recommendation may vary by state.

3. *Q: Are any vaccines contraindicated? What is the impact of the history of oral steroids?*

   A: Neither reactive airways disease, the convalescent stage following otitis media, nor antibiotic therapy is a valid contraindication to routine childhood vaccinations. Due to the immunosuppressive effects of corticosteroids when given in high doses, providers should wait at least 1 month after completion of corticosteroid therapy before administering live-virus vaccines to persons who have received high systemic doses of corticosteroids for $\geq$2 weeks. Since Rhonda last had corticosteroids 5 months ago, she can receive MMR and varicella, which are live-virus vaccines. (However, live, attenuated influenza is not recommended for her, due to reactive airway disease and due to age less than 5 years).

4. *Q: What dosage of influenza vaccine should be given?*

   A: The dosage of inactivated influenza vaccine for children <3 years of age is 0.25mL IM.

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 series. 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 $5,000 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
  2. Abstract 5

- **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

This page corresponds to page 17 in the *Small-Group Booklet*.

Abstract 5

Office procedures to improve vaccination compliance.
Zimmerman, RK.

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 it may 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 routinely evaluate the vaccination status of patients prior to the physician's encounter with the patient. This can be done at the time of registration (perhaps with the aid of a computer) or by nursing personnel while obtaining vital signs. Colored stickers, checklists, or inked rubber stamps are practical ways to communicate the need for vaccinations. (b) Send reminder postcards 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) Post 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.

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.

- **Answers to Questions for Learners**

1. *Q: What are possible causes for low vaccination rates?*

   A: Vaccination rates may be low for one or more of the following reasons:

   a. Lack of simultaneous vaccine administration

   b. Failure to note and address vaccination status at acute-care visits, hospital discharge, and chronic-care visits

   c. Incorrect interpretation of vaccine contraindications

   d. Economic issues, such as lack of insurance or transportation difficulties may occur but are less likely now due to the VFC program and CHIP.

   e. Parental concerns about vaccine safety

   f. Parental lack of awareness of the vaccine schedule

   g. Provider apathy

2. *Q: 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?*

   A: a. Ways to improve parental compliance with vaccination include the following:

   1) Postcard reminders or auto dialing machine sending telephone messages to patients. The office computer can be used to assess vaccination status and results used for generating postcards or phone calls to those who are not up-to-date with vaccinations.

   2) Provision of personal vaccination cards for patients that list both the schedule and the date for the child's next vaccination.

   b. Ways to improve office vaccination rates include the following:

   1) After evaluation of the practice's current vaccination rates, problem solving and goal setting should occur. Subsequently, vaccination rates should be monitored with ongoing feedback to providers about vaccination rates.

   2) Having office staff ask vaccination status at patient registration or during vital signs. Colored stickers, checklists or inked rubber stamps can be used to communicate the information. Alternatively, the office computer can generate "tickler" reminders about vaccinations at patient registration.

   3) Administering vaccines simultaneously if more than one is indicated.

   4) Having a dedicated spot in the medical record for vaccination information.

   5) Training on valid and invalid contraindications.

   6) Write standing orders to allow the nurse to administer routine vaccinations.

   7) Post updated copies of schedules, and contraindication checklists.

SCENARIO FIVE

Shasta, a 4-month-old infant, came to Dr. Johnson's office today at 11:30 am for a complete physical examination and vaccinations. The examination was entirely normal. The second doses of DTaP, Hib, PCV, 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. *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)* sections: Contraindications and Precautions (pp. 8-11), Reporting of Adverse Events After Vaccination (p. 24), and Vaccine Injury Compensation Program (p. 25) http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf
2. Abstracts 6 and 7

- **Questions for Learners**

1. Which vaccine is most likely to have been responsible for the adverse events?
2. Should Shasta receive another dose of DTaP?
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?

This page corresponds to page 19 in the Small-Group Booklet.

- **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.

Incidence rates of HHE vary widely, from 3.5 to 291 per 100,000 whole-cell pertussis vaccinations. Two of the three controlled studies comparing children immunized with DTP or DT found no association between HHE and DTP compared with that between HHE and DT vaccine, and the other study found a significantly increased risk that the authors ascribed to the voluntary reporting system. A clinical presentation that could be classified as HHE has been widely observed and reported. Thus, the evidence for causality rests here on the typical clinical presentation that occurs within a few hours after administration of the vaccine.

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, PCV and IPV.
Centers for Disease Control and Prevention (CDC). National Immunization Program.

Adverse events to each of the four 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 PCV7 occur in 10%-20% of recipients. Fewer than 3% of local reactions are considered to be severe (e.g, tenderness that interferes with limb movement). Local reactions are more common with the fourth dose than with the first 3 doses. In one study, acellular pertussis vaccine (DTaP) was given at the same visit as the booster dose of PCV7. In this study, 11% of recipients had a temperature < 39°C. No serious adverse reactions attributable to PCV 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, National Immunization Program. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 8th ed. 2nd printing. Atlanta, GA; Centers for Disease Control and Prevention; 2005. http://www.cdc.gov/nip/publications/pink/default.htm

- **Answers to Questions for Learners**

1. *Q: Which vaccine is most likely to have been responsible for the adverse events?*

   A: The vaccine most likely to have been responsible for the hypotonic-hyporesponsive episode (HHE) and fever is DTaP. Whole-cell DTP is the only vaccine of those reviewed by the Institute of Medicine (IOM) for which the IOM found the evidence consistent with a causal relation between a vaccine and HHE. HHE has been reported following DTaP, but appears to occur less frequently than after whole-cell DTP.

2. *Q: Should Shasta receive another dose of DTaP?*

   A: No; HHE is considered a precaution to further DTaP vaccination. Providers may elect to administer additional doses of pertussis vaccine if they believe that the benefits outweigh the risks for this particular patient. Alternatively, the provider may choose to withhold further pertussis vaccination, and complete the series with DT.

3. *Q: Do these adverse events need to be reported?*

   A: HHE should be reported to the Vaccine Adverse Event Reporting System (VAERS). Forms are available in the *Physicians' Desk Reference* or from VAERS at 1-800-822-7967. http://www.vaers.org

4. *Q: If Shasta's parents allege that vaccination caused a permanent injury, what could be done?*

   A: If Shasta's parents allege that vaccination caused a permanent injury, they can apply for compensation from the Vaccine Injury Compensation Program (VICP). The VICP is a system under which no-fault compensation can be awarded for specified injuries that are temporally related to administration of immunizations against measles, mumps, rubella, diphtheria, tetanus, pertussis, pneumococcal conjugate vaccine (PCV), polio, hepatitis B, *Haemophilus influenzae* type b, influenza, or varicella. The VICP has reduced the risk of litigation for both providers and vaccine manufacturers. The VICP can be reached at 1-800-338-2382.

CHILDHOOD VACCINATION SAMPLE TEST

This test was developed using expert knowledge and psychometric methods for the construction of criterion-referenced tests. It may be used as a sample examination.

1. Which administration route is incorrect?

a. DTaP intramuscularly in the anterolateral thigh of an infant.

b. Varicella vaccine subcutaneously in the deltoid region of a child.

c. Hib intramuscularly in the anterolateral thigh of an infant.

d. Hepatitis B intramuscularly in the upper outer quadrant of the buttock of a child.

e. IPV administered subcutaneously.

2. Which statement about the routine schedule is false?

a. The first dose of hepatitis B vaccine is recommended from birth to 2 months of age.

b. The first dose of MMR is ideally given from 15 to 19 months of age.

c. The first dose of varicella vaccine is ideally given from 12 to 18 months of age.

d. The second dose of Hib vaccine is ideally given at 4 months of age.

e. The fourth dose of DTaP is ideally given at 15 to 18 months of age.

3. Which of the following is incorrect?

a. MMR is an attenuated, live viral vaccine.

b. Pertussis vaccine is an inactivated bacterial vaccine.

c. OPV is an attenuated, live viral vaccine.

d. Hepatitis B is an attenuated, live viral vaccine.

e. Pneumococcal vaccine is an inactivated, bacterial vaccine.

4. Which is not a valid contraindication?

a. For varicella vaccine, pregnancy in the vaccine recipient.

b. For DTP/DTaP, encephalopathy within 7 days of a previous DTP/DTaP dose.

c. For MMR, current, prolonged use of high-dose systemic steroids.

d. For MMR, asymptomatic infection with HIV.

e. All are valid contraindications.

5. Which of the following is false?

a. Missed vaccination opportunities occur when the first dose of MMR is needed but only the fourth dose of DTP/DTaP is given.

b. Missed vaccination opportunities occur when vaccinations are not administered during visits for mild acute illnesses.

c. Missed vaccination opportunities occur when providers limit the number of injections.

d. Missed vaccination opportunities could occur when the last dose of Hib vaccine is needed but only varicella vaccine is given.

e. Missed vaccination opportunities are a minor contributor to low vaccination rates in many practices.

6. Regarding DTP and hypotonic-hyporesponsive episodes (HHE), all of the following are correct <u>except:</u>

a. HHE is uncommon following DTP.

b. HHE should be reported to the Vaccine Adverse Event Reporting System.

c. The relationship between DTP and HHE is based on randomized, controlled studies showing that HHE occurs 1 to 12 hours after DTP.

d. According to the Advisory Committee on Immunization Practices (ACIP), HHE is a valid precaution to future doses of DTP.

e. The evidence for causality rests on the typical clinical presentation that occurs within hours after DTP.

7. Which of the following is false?

a. The Vaccine Injury Compensation Program provides compensation for permanent and non-permanent injuries temporally associated with any recommended vaccination.

b. The Vaccine Injury Compensation Program differs from civil litigation in that negligence does not need to be proven.

c. Professionals who administer vaccines are required to keep a permanent record of information including vaccine manufacturer, lot number, and date of administration.

d. Systemic adverse events following Hib vaccination are infrequent.

e. Possible adverse events (reactions) to vaccines which are severe enough for the recipient to seek medical attention should be reported to the Vaccine Adverse Event Reporting System.

8. Which of the following procedures is <u>least</u> likely to improve vaccination rates over several years?

a. Evaluation of the practice's vaccination rates and causes of low rates in the practice.

b. Set numerical goals for raising vaccination rates.

c. Posters in the waiting room about vaccinations in general.

d. Phone call reminders about needed vaccinations.

e. Evaluation by nursing staff of vaccination status when vitals are taken, and recording of missing vaccinations on colored stickers.

9. Which of the following DTaP immunization records, although late at times, is otherwise entirely within the recommended guidelines?

a. 4, 6, 8, and 13 months.

b. 3, 4, 6, and 15 months.

c. 1, 2, 4, 7, and 17 months.

d. 2 weeks, 3 months, 7 months, and 15 months.

e. None of the above.

10. Which of the following is a contraindication to further doses of DTaP vaccine?

a. Hypotonic-hyporesponsive episode within 48 hours of DTaP.

b. Seizures within 3 days of DTaP.

c. Persistent, inconsolable crying lasting ≥3 hours within 48 hours of DTaP.

d. Temperature of ≥40.5°C (105°F) within 48 hours of DTaP.

e. Anaphylaxis after DTaP.

CHILDHOOD VACCINATION TEST ANSWER KEY

1. D
2. B
3. D
4. D
5. E
6. C
7. A
8. C
9. B
10. E